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IMMUNOMEDICS INC Form 10-Q November 05, 2014 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, 2014

or

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-12104

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

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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 " 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 4, 2014 was 93,133,094.

# IMMUNOMEDICS, INC.

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# IMMUNOMEDICS, INC. AND SUBSIDIARIES

# CONDENSED CONSOLIDATED BALANCE SHEETS

# (UNAUDITED)

	Se	eptember 30, 2014	June 30, 2014
ASSETS			
Current Assets:			
Cash and cash equivalents	\$	5,445,475	\$ 6,961,494
Marketable securities		26,541,857	34,871,120
Accounts receivable, net of allowance for doubtful accounts of \$86,537 at			
September 30, 2014 and \$88,609 at June 30, 2014		555,474	674,617
Inventory		732,409	778,989
Other receivables		300,647	303,102
Prepaid expenses		1,842,922	1,614,897
Other current assets		104,603	180,678
		ĺ	·
Total current assets		35,523,387	45,384,897
D		, ,	
Property and equipment, net of accumulated depreciation of \$27,453,741		2.007.400	1 005 475
and \$27,312,924 at September 30, 2014 and June 30, 2014, respectively		2,086,408	1,895,475
Value of life insurance policies		176,110	176,110
Other long-term assets		30,000	30,000
Total Assets	\$	37,815,905	\$ 47,486,482
LIABILITIES AND STOCKHOLDERS EQUITY			
Current Liabilities:			
Accounts payable and accrued expenses	\$	9,338,884	\$ 6,886,682
Deferred revenues		243,305	240,158
		,	,
Total current liabilities		9,582,189	7,126,840
Other liabilities		1,525,123	1,500,244
Commitments and Contingencies		, , ,	, ,
Stockholders Equity:			
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares			
issued and outstanding at September 30, 2014 and June 30, 2014			
Common stock, \$0.01 par value; authorized 135,000,000 shares; issued			
93,157,819 shares and outstanding 93,123,094 shares at September 30,			
2014; and issued 93,113,480 shares and outstanding 93,078,755 shares at			
June 30, 2014		931,577	931,134
Capital contributed in excess of par		300,554,900	300,080,804
r		(458,370)	(458,370)
		(100,070)	(150,570)

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Treasury stock, at cost, 34,725 shares at September 30, 2014 and at June 30, 2014

2014		
Accumulated deficit	(273,876,058)	(261,465,638)
Accumulated other comprehensive income	79,255	261,837
Total Immunomedics, Inc. stockholders equity	27,231,304	39,349,767
Noncontrolling interest in subsidiary	(522,711)	(490,369)
Total stockholders equity	26,708,593	38,859,398
Total Liabilities and Stockholders Equity	\$ 37,815,905	\$ 47,486,482

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,		,	
	2014	ļ	2	013
Revenues:	Φ 505	. (22	Φ	550.022
Product sales	\$ 727	7,633		559,023
License fee and other revenues	244	1 265		623,333
Research and development	344	1,365	•	315,465
Total revenues	1,071	,998	5,4	497,821
Costs and Expenses:				
Costs of goods sold	76	5,286		77,199
Cost of license fee and other revenues			1,	189,170
Research and development	9,392	,017	7,:	514,094
Sales and marketing	228	3,637	,	218,032
General and administrative	3,819	,192	1,	732,671
Total costs and expenses	13,516	,132	10,	731,166
Operating loss	(12,444		(5, 1)	233,345)
Interest and other income, net		5,072		6,211
Foreign currency transaction (loss) gain	(11	l <b>,737</b> )		5,452
Loss before income tax expense	(12,430	,799)	(5,	221,682)
Income tax expense	(11	<b>1,963</b> )		(4,501)
Net loss	(12,442	2.762)	(5 '	226,183)
Less: Net loss attributable to noncontrolling interest		2,342)		(25,220)
2000 Tee 1000 and 10 and 10 fine on 10 fine	(02	·,c ·=/		(25,225)
Net loss attributable to Immunomedics, Inc. stockholders	\$ (12,410	),420)	\$ (5,	200,963)
Loss per common share attributable to Immunomedics, Inc. stockholders, (basic and diluted)	\$	(0.13)	\$	(0.06)
Weighted average shares used to calculate loss per common share, (basic and diluted)	93,098	3,202	82,9	947,124

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Other comprehensive (loss) income, net of tax:		
Foreign currency translation adjustments	(178,130)	72,367
Unrealized losses on available-for-sale securities	(4,452)	(4,960)
Other comprehensive (loss) income	(182,582)	67,407
Comprehensive loss	(12,625,344)	(5,158,776)
Less comprehensive loss attributed to noncontrolling interest	(32,342)	(25,220)
Net comprehensive loss attributable to Immunomedics, Inc.	\$ (12,593,002)	\$ (5,133,556)

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, 2014 2013	
Cash flows used in operating activities:		
Net loss	\$ (12,442,762)	\$ (5,226,183)
Adjustments to reconcile net loss to net cash used in operating activities:	. ( , , , ,	. ( )
Depreciation	140,817	157,188
Amortization of deferred revenue	3,147	(2,515,766)
(Decrease) increase in allowance for doubtful accounts	(2,072)	21,153
Non-cash expense related to stock compensation	561,110	418,548
Gain from the sales of marketable securities	(7,215)	, i
Non-cash increase in value of life insurance policy	` ,	(4,250)
Amortization of deferred rent	24,879	24,879
Changes in other operating assets and liabilities	2,475,308	(139,274)
	, ,	
Net cash used in operating activities	(9,246,788)	(7,263,705)
Cash flows provided by (used in) investing activities:		
Proceeds from sales/maturities of marketable securities	8,336,478	
Purchase of marketable securities		(20,082,913)
Purchases of property and equipment	(331,750)	(144,764)
Net cash provided by (used in) investing activities	8,004,728	(20,227,677)
Cash flows (used in) provided by financing activities:	(a.c. == 1)	W <b>20</b> 12 0
Tax withholding payments for stock compensation	(86,571)	(159,436)
Exercise of stock options, net		910,677
Net cash (used in) provided by financing activities	(86,571)	751,241
Effect of changes in exchange rates on cash and cash equivalents	(187,388)	57,191
Net decrease in cash and cash equivalents	(1,516,019)	(26,682,950)
Cash and cash equivalents, beginning of period	6,961,494	41,326,000
Cash and cash equivalents, end of period	\$ 5,445,475	\$ 14,643,050

See accompanying notes to unaudited condensed consolidated financial statements.

## 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, 2014, 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, 2014 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2015, 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 may be unable to secure regulatory approval of and market its drug candidates; the Company s dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under the Company s collaborative agreements, if any; uncertainties about the Company s ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development or regulatory approval of competing products; the Company s ability to protect its proprietary technologies; patent-infringement claims; and risks of new, changing and competitive technologies and regulations in the United States and internationally.

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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 possibilities. The Company s ability to raise capital through public and private debt or equity financings may be negatively impacted by the economy. There can be no assurances that financings will be available when

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needed with acceptable terms to it, if at all. If the Company were unable to raise capital on acceptable terms, its ability to continue its business would be materially and adversely affected. Furthermore, the terms of any such debt or equity financing may include covenants which may limit the Company s future ability to manage the business. At the present time, the Company is unable to determine whether any of these future activities will be successful and, if so, the terms and timing of any definitive agreements.

The Company s budgeted cash requirements in fiscal year 2015 are expected to be approximately \$41.0 million, which 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 (IMMU-132 and IMMU 130). The Company has the ability to reduce its cash flow spending requirements if necessary, after considering certain planned discretionary spending, including the funding of the Company s clinical trial programs. For the three-month period ended September 30, 2014, the Company utilized cash aggregating \$9.8 million. As of September 30, 2014, the Company has \$32.0 million of cash, cash equivalents and marketable securities. The Company will require additional funding in order to fund its planned Phase 3 and Phase 2 clinical trials in fiscal 2015 and beyond.

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

The Company expects research and development activities to continue to expand over time, and it does not believe it will have adequate cash to continue to complete development of product candidates in line with its pipeline included in its long term corporate strategy. As a result, the Company will continue to require additional financial resources in order to conduct its research and development programs, clinical trials of product candidates and regulatory filings.

# 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, 2014. 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.

## 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.

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# Estimated Fair Value of Financial Instruments

The Company has categorized its financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. The Company does not have any financial liabilities that are required to be measured at fair value on a recurring basis. 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.

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Financial assets recorded on the condensed consolidated balance sheets as of September 30, 2014 and June 30, 2014 are categorized based on the inputs to the valuation techniques as follows (in thousands):

Level 1 Financial assets whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which the company has the ability to access at the measurement date (examples include active exchange-traded equity securities and most U.S. Government and agency securities).

Level 2 Financial assets 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 assets 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.

		(\$ in tho	ousands)	
September 30, 2014	Level 1	Level 2	Level 3	Total
Money Market Funds	\$ 1,264	\$	\$	\$ 1,264
Marketable Securities:				
U.S. Treasury Bonds	5,530			5,530
U.S. Government Sponsored Agencies	7,453			7,453
Corporate Debt Securities	13,559			13,559
Total	\$ 27,806	\$	\$	\$ 27,806

		(\$ in tho	ousands)	
June 30, 2014	Level 1	Level 2	Level 3	Total
Money Market Funds	\$ 367	\$	\$	\$ 367
Marketable Securities:				
U.S. Treasury Bonds	8,537			8,537
U.S. Government Sponsored Agencies	7,457			7,457
Corporate Debt Securities	18,877			18,877
Total	\$ 35,238	\$	\$	\$ 35,238

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

## Marketable Securities

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Marketable securities, all of which are available-for-sale, consist of corporate debt securities and municipal bonds. Marketable securities are carried at fair value, with unrealized gains and losses, net of related income taxes, reported as accumulated other comprehensive income, 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) income 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 interest and other income (net).

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## **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.

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## 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 has a stock incentive plan, the Immunomedics, Inc. 2006 Stock Incentive Plan, as amended, that includes a discretionary grant program, a stock issuance program and an automatic grant program. The plan was established to promote the interests of the Company, by providing eligible persons with the opportunity to acquire a proprietary interest in the Company as an incentive to remain with the organization and to align the employee s interest with our stockholders. This plan is described more fully in Note 7 the audited financial statements included in our Annual Report on Form 10-K for the year ended June 30, 2014 and Note 5 to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, included elsewhere herein.

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

The expected term of the option is based upon the contractual term and expected employee exercise and expected post-vesting employment termination behavior. The expected volatility of the price of the underlying stock is based upon the historical volatility of the Company s stock computed over a period of 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, 2014 and 2013:

	Inree-Month Period Ended September 3		
	2014	2013	
Expected dividend yield	0%	0%	
Expected option term (years)	5.07	5.20	
Expected stock price volatility	61%	67%	
Risk-free interest rate	1.60%	1.56%-1.74%	

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

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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

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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, 2014.

Income taxes were provided for profitable foreign jurisdictions at the estimated annual tax rate during the three-month periods ended September 30, 2014 and 2013. The Company s U.S. operations reported a net loss for the three-month periods ended September 30, 2014 and 2013, 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, 2014.

## 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, 2014 and 2013. The common stock equivalents excluded from the diluted per share calculation are 7,461,763 and 7,708,560 shares at September 30, 2014 and 2013, respectively.

## Comprehensive Loss

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

# Reclassification

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

## Accounting Pronouncements

In August 2014, the FASB issued Accounting Standard Update (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.

In June 2014, the FASB issued ASU 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period. This guidance clarifies that awards with these provisions should be treated as performance conditions that affect vesting, and do not impact the award s estimated grant-date fair value. The amendments in this update are effective for annual reporting periods beginning after December 31, 2015, including interim periods, and early application is permitted. The Company is assessing ASU 2014-12 s impact and will adopt it when effective.

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In June 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. This ASU was initiated as a joint project by the FASB and the International Accounting Standards Board ( IASB ) to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and IFRS. For a public company, the amendments in this update are effective for annual reporting periods beginning after December 15, 2016, including interim periods, and early application is not permitted for public companies. The Company is assessing ASU 2014-09 s impact and will adopt it when effective.

#### 3. 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 income (loss). Immunomedics considers all of its current investments to be available-for-sale. Marketable securities at September 30, 2014 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
September 30, 2014				
U.S. Treasury Bonds U.S. Government Sponsored Agencies	\$ 5,529 7,453	\$ 1	\$	\$ 5,530 7,453
Corporate Debt Securities	13,564	5	(10)	13,559
	\$ 26,546	\$ 6	\$ (10)	\$ 26,542

Maturities of debt securities classified as available-for-sale were as follows at September 30, 2014 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	\$ 24,943	\$ 25,027
Due after one year through five years	1,599	1,610
	\$ 26,542	\$ 26,637

Marketable securities at June 30, 2014 consist of the following (in thousands):

Amortized	Gross	Gross	Fair Value
Cost	Unrealized	Unrealized	

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		(	Gain	(L	oss)	
June 30, 2014						
U.S. Treasury Bonds	\$ 8,5	37 \$	1	\$	(1)	\$ 8,537
U.S. Government Sponsored Agencies	7,4	58			(1)	7,457
Corporate Debt Securities	18,8	76	12		(11)	18,877
	\$ 34,8	71 \$	13	\$	(13)	\$ 34,871

Maturities of debt securities classified as available-for-sale were as follows at June 30, 2014 (in thousands):

		Net Carrying
	Fair Value	Amount
Due within one year	\$ 25,336	\$ 25,449
Due after one year through five years	9,535	9,603
	\$ 34,871	\$ 35,052

For the three-month period ended September 30, 2014, \$8.3 million of the Company s debt securities and municipal bonds either matured or were sold. There were no such sales or maturities during the three-month period ended September 30, 2013.

# 4. Stockholders Equity Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income were as follows:

				Net		
			Un	realized		
			(L	Losses)		
	C	Currency	G	ains on	Accui	nulated Other
	Tı	ranslation	Availa	ble-for-Sale	Con	nprehensive
	Ad	ljustments	Se	curities		Income
Balance, July 1, 2014	\$	261,924	\$	(87)	\$	261,837
Other comprehensive income (loss)						
before reclassifications		(178, 130)		2,763		(175,367)
Amounts reclassified from						
accumulated other comprehensive						
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
-						
Balance, July 1, 2013	\$	161,830	\$		\$	161,830
Other comprehensive income (loss)						
before reclassifications		72,367		(4,960)		67,407
Amounts reclassified from						
accumulated other comprehensive						
income <sup>(a)</sup>						

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Net current-period other comprehensive income (loss)	72,367	(4,960)	67,407
Balance, September 30, 2013	\$ 234,197	\$ (4,960)	\$ 229,237

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.

(a) For the three month period ended September 30, 2014, \$7,215 was reclassified from accumulated other comprehensive income to interest and other income. There was no such reclassification during the three month period ended September 30, 2013.

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## 5. Stock Incentive Plan

The Company believes that awards under the Immunomedics, Inc. 2006 Stock Incentive Plan (the Plan ) better align the interests of its employees with those of its stockholders. Option awards are generally granted with an exercise price equal to the market price of the Company s common stock at 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 market price of the Company s common stock at the date of grant, are vested immediately and have seven year contractual terms. At September 30, 2014, there were 9,857,606 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (6,461,763 shares) and which were available to be issued for future grants (3,395,843 shares).

The weighted average fair value at the date of grant for options granted during the three-month periods ended September 30, 2014 and 2013 were \$1.75 and \$3.07 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, 2014 is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding, July 1, 2014	5,308,617	\$ 3.41	Liic	value
Granted	488,719	\$ 3.32		
Cancelled or forfeited	(280,500)	\$ 4.40		
Outstanding, September 30, 2014	5,516,836	\$ 3.35	3.67	\$ 3,445,495
Exercisable, September 30, 2014	4,027,480	\$ 3.16	2.76	\$3,142,578

A summary of the Company s non-vested restricted and performance stock units at July 1, 2014, and changes during the three-month period ended September 30, 2014 are presented below:

	Number of
<b>Outstanding Non-Vested Restricted and Performance Stock Units</b>	Awards
Non-vested at July 1, 2014	788,364
Restricted Units Granted	226,657
Vested	(397,364)
Exercised	(70,094)
Non-vested at September 30, 2014	547,563

The Company has 2,036,919 non-vested options, restricted and performance stock units outstanding as of September 30, 2014. As of September 30, 2014, there was \$3.0 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 3.0 years. The Company recorded \$0.6 million and \$0.4 million for total stock-based compensation expense for employees, executive officers and non-employee Board members for the three-month periods ended September 30, 2014 and 2013, respectively.

Each non-employee Board member who continues to serve shall receive on the date of the annual stockholders meeting an annual grant of non-qualified stock options and restricted stock units, each equal in value to \$45 thousand. The Company recorded \$45 thousand and \$55 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for the three-month periods ended September 30, 2014 and 2013, respectively.

On August 14 2014, the Company awarded an additional 226,657 restricted stock units to certain executive officers of the Company at the market price on that date (\$3.32 per share). These restricted stock units will vest over a four year period. As of September 30, 2014, there was \$1.8 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 2.8 years. The Company recorded \$0.2 million and \$0.1 million for stock-based compensation expense for restricted stock units for each of the three-month periods ended September 30, 2014 and 2013, respectively.

On August 16, 2013, the Company also awarded certain executive officers Performance Units 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 exercised based on a percentage basis on the attainment of anniversary dates. As of September 30, 2014, there are 389,864 Performance Units available if all performances are achieved within five years of grant date. The Company recorded \$32 thousand and \$0.2 million for the stock-based compensation for the three-month periods ended September 30, 2014 and 2013, respectively. There is \$0.9 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of September 30, 2014. That cost is being recognized over a weighted-average period of 2.4 years. The unrecognized compensation cost is subject to modification on a quarterly basis based on review of performance probability and requisite achievement periods.

## 6. 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, 2014 and 2013 (\$ in thousands):

As of and for the
<b>Three Months Ended</b>
September 30, 2014

	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 taxes	(12,455)	24	(12,431)

# As of and for the Three Months Ended September 30, 2013

	United			
	States	Europe	Total	
Total assets	\$ 38,547	\$ 2,663	\$ 41,210	
Property and equipment, net	2,074		2,074	
Revenues	4,949	549	5,498	
Loss before taxes	(5,187)	(35)	(5,222)	

## 7. Related Party Transactions

Certain of the Company s affiliates, including members of its senior management and its 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 Chairman of the Board of Directors and Chief Medical Officer and Chief Scientific 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), and the Company s majority-owned subsidiary IBC.

Immunomedics, Inc. leases approximately 1,000 square feet of its Morris Plains, NJ facility to CMMI at a cost of approximately \$30 thousand per year. The Company incurred \$10 thousand and \$5 thousand of legal expenses on behalf of CMMI for patent related matters for each of the three-month periods ended September 30, 2014 and 2013. 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. On occasion, CMMI engages in research contracts on behalf of Immunomedics, Inc. However, for the three-month periods ended September 30, 2014 and 2013 there were no research related activities charged to the Company.

For the three-month periods ended September 30, 2014 and 2013, Dr. Goldenberg received approximately \$21 thousand and \$20 thousand, respectively, in compensation for his services to IBC.

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# 8. License and Collaboration Agreements Takeda Pharmaceutical/Nycomed GmbH

On July 11, 2008, the Company entered into the Nycomed Agreement with Nycomed providing Nycomed a worldwide license to develop, manufacture and commercialize veltuzumab, the Company s humanized anti-CD20 antibody, in the subcutaneous formulation, for the treatment of all non-cancer indications. The Company retained the rights to develop, manufacture and commercialize veltuzumab in the field of oncology. On September 30, 2011, Takeda Pharmaceutical Company Limited completed its acquisition of Nycomed and made Nycomed a wholly owned subsidiary of Takeda ( Takeda-Nycomed ).

Takeda-Nycomed was solely responsible for the development, manufacturing, regulatory approval and commercialization of veltuzumab and the development, manufacturing and regulatory approval of the subcutaneous formulation for all non-cancer indications. The Company s major obligations were to complete the research and development activities as specified in the Nycomed Agreement and to manufacture and supply veltuzumab to Takeda-Nycomed for the quantity of materials for the period of time specified in the Nycomed Agreement. The Company completed all of its obligations under the agreement, namely its manufacturing and supply obligations and its responsibilities in the Phase 1/2 study in immune thrombocytopenic purpura ( ITP ).

On October 3, 2013, the Company received notification from Takeda Pharmaceutical Company Limited/Nycomed GmbH of termination of the Nycomed Agreement. The notification was received subsequent to the Company s filing of arbitration proceedings in an effort to resolve the dispute the Company has with Nycomed and Takeda concerning delays in the development of veltuzumab, which the Company argues is a material breach of the licensing agreement. As a result of the termination, all rights to veltuzumab revert to the Company. All parties have had discussions regarding the transition of veltuzumab back to the Company and certain materials have been returned to the Company. In addition, the Company has continued to pursue the arbitration procedure to address its claim for damages due to, among other things, delays in the development of veltuzumab.

On October 11, 2013, Takeda and Takeda-Nycomed filed their Statement of Defense and Counterclaims alleging, among other things, that the Company wrongfully terminated the licensing agreement and caused Takeda and Takeda-Nycomed to suffer significant damages and delays in developing veltuzumab. The Company responded by filing its own Statement of Defense on November 12, 2013, denying Takeda and Takeda-Nycomed s allegations and contesting Takeda or Takeda-Nycomed s rights to any relief. An arbitrator was appointed later that month. On December 20, 2013 the arbitrator issued a pre-hearing scheduling order and the arbitration proceeded in accordance with that schedule as subsequently amended. The hearing portion of the arbitration process was completed on August 21, 2014. Each party s counsel filed final post-hearing submissions on October 17, 2014. The decision by the arbitrator is expected within two months of the post-hearing submissions.

## 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. Under the terms of the UCB Agreement, the Company received from UCB a non-refundable cash payment totaling \$38.0 million. On December 27, 2011, the Company entered into the Amendment Agreement with UCB referred to herein as the Amendment Agreement. The Amendment Agreement 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. As of September 30, 2014, UCB has not executed a sublicense agreement with a third-party.

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.

Collectively, pursuant to the UCB Agreement and the Amendment Agreement the Company is

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entitled to receive (i) up to \$145.0 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. No development milestone, commercialization milestone or royalty payments were achieved through September 30, 2014. 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.

The Agreement commenced on May 9, 2006 and shall terminate in accordance with the terms thereof or by mutual written consent, unless UCB decides to cease all development and commercialization of epratuzumab pursuant to the Agreement. Either the Company or UCB has the right to terminate the Agreement by notice in writing to the other party upon or after any material breach of the 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 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 Agreement) and Immunomedics Know-How (as defined in the 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 Agreement) and any other documents relating to or necessary to further develop and commercialize the Licensed Compound (as defined in the Agreement) and Licensed Products (as defined in the 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.

## The Bayer Group (formerly Algeta ASA)

In January 2013, the Company entered into a collaboration agreement with Algeta ASA for the development of epratuzumab to be conjugated with Algeta s proprietary thorium-227 alpha-pharmaceutical payload. On August 2, 2013, an amendment to the collaboration agreement was entered into between the two companies modifying certain delivery and supply parameters. Under the terms of this agreement, as amended, the Company is required to manufacture and supply clinical-grade epratuzumab to Algeta, 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, Algeta 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 Algeta s request. The Company and Algeta 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 which have been recognized upon the Company fulfilling its obligations under the collaboration agreement. For the three-month period ended September 30, 2013, the Company recognized \$4.6 million of revenue under this arrangement, which has been included in license fee and other revenues, while the related costs of \$1.2 million is included in cost of license fee and other revenue. As of fiscal year ended June 30, 2014, the Company recognized all of the initial cash payments as revenue as the aspects of delivery for the clinical supply material have been satisfied. On March 6, 2014, The Bayer Group (Bayer) completed its voluntary takeover of 98.2% shares and voting rights in Algeta ASA which made Algeta ASA a majority-owned subsidiary of Bayer. Bayer has subsequently acquired the remaining shares from the minority shareholders and the program with Immunomedics has been formally transferred to Bayer (Algeta).

# 9. Commitments and Contingencies *Employment Contracts*

Effective July 1, 2011, the Company entered into the Third Amended and Restated Employment Agreement with Dr. Goldenberg for his service to the Company as the Chief Scientific Officer and Chief Medical Officer (the Goldenberg Agreement ), which terminates July 1, 2016. This agreement covers aspects of his compensation as well as duties and responsibilities at Immunomedics. Under this agreement Dr. Goldenberg s annual base salary is at a minimum of \$0.5 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee (increased 3.5% to \$0.6 million for the 2015 fiscal year). Dr. Goldenberg will also be eligible to participate in any Company incentive compensation plan in place for its senior level executives and is eligible to receive an annual discretionary bonus based upon certain performance standards to be determined by the Compensation Committee. Dr. Goldenberg s annual bonus target is 50% of his annual base salary, subject to achievement of performance goals, with a potential payout from 0 to 150% of the target amount.

Under the Goldenberg Agreement, Dr. Goldenberg is eligible to receive certain additional incentive compensation during the agreement term, including being eligible to receive royalty payments from royalties received by the Company. For each fiscal year, the Company shall pay Dr. Goldenberg a sum equal to a percentage of the annual royalties the Company receives on each of the products for which Dr. Goldenberg is an inventor, and all products using, related to or derived from products for which Dr. Goldenberg is an inventor. The percentage of royalties that the Company will pay to Dr. Goldenberg on each patented product will be determined based on the percentage of royalties that the Company receives from external third parties.

Under the terms of the Goldenberg Agreement, the Company makes a minimum quarterly payment of \$37.5 thousand to Dr. Goldenberg during each of the fiscal years during the Goldenberg Agreement, as an advance against the amounts due as additional incentive compensation, royalty payments and dispositions of undeveloped assets. For the three-month periods ended September 30, 2014 and 2013, no additional incentive compensation payments were made to Dr. Goldenberg other than the \$37.5 thousand minimum quarterly payments.

On July 1, 2014, the Company and Cynthia L. Sullivan entered into the Fifth Amended and Restated Employment Agreement pertaining to Ms. Sullivan s service as the Company s President and Chief Executive Officer. The Amended Sullivan Agreement shall terminate on July 1, 2017. Ms. Sullivan s annual base salary under the agreement is \$0.6 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee (increased by 3.5% for the 2015 fiscal year). Ms. Sullivan is also eligible to participate in the Company s incentive compensation plan in place for its senior level executives. 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. Ms. Sullivan will also be eligible to receive equity compensation awards under the Company s 2006 Stock Incentive Plan, or any such successor equity compensation plan as may be in place from time to time.

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## Legal Matters

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

## Former Licensing Partner:

On October 3, 2013, the Company received notification from Takeda Pharmaceutical Company Limited/Nycomed GmbH of termination of the License and Collaboration Agreement that it entered into with 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, referred to herein as the Nycomed Agreement. The notification was received subsequent to the Company s filing of arbitration proceedings in an effort to resolve the dispute it has with Nycomed and Takeda concerning delays in the development of veltuzumab, which the Company argues is a material breach of the Nycomed Agreement. As a result of the termination, all rights to veltuzumab revert to the Company. All parties have had discussions regarding the transition of veltuzumab back to the Company and certain materials have been returned to the Company. In addition, the Company has continued to pursue the arbitration procedure to address its claim for damages due to, among other things, delays in the development of veltuzumab.

On October 11, 2013, Takeda and Takeda-Nycomed filed their Statement of Defense and Counterclaims alleging, among other things, that the Company wrongfully terminated the licensing agreement and caused Takeda and Takeda-Nycomed to suffer significant damages and delays in developing veltuzumab. The Company responded by filing its own Statement of Defense on November 12, 2013, denying Takeda and Takeda-Nycomed s allegations and contesting Takeda or Takeda-Nycomed s rights to any relief. An arbitrator was appointed later that month. On December 20, 2013 the arbitrator issued a pre-hearing scheduling order, and the arbitration proceeded in accordance with that schedule as subsequently amended. The hearing portion of the arbitration process was completed on August 21, 2014. Each party s counsel filed a final post-hearing submission on October 17, 2014. The decision by the arbitrator is expected within two months of the post-hearing submissions.

The Company does not believe these matters, even if adversely adjudicated or settled, would have a material adverse effect on its consolidated financial condition, results of operations or cash flows.

## Shareholder complaints:

Two separate shareholder derivative complaints have been 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 allege, 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 allege 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 allege 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 bring 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. Both derivative actions have been stayed pending the outcome of 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 alleges 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 alleges 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 alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On June 24, 2014 the District Court entered an order appointing John Neff as lead plaintiff and The Rosen Law Firm, P.A. as lead counsel. Lead plaintiff and lead counsel thereafter filed an Amended Class Action Complaint on August 8, 2014. The defendants filed a motion to dismiss the Amended Class Action Complaint on September 22, 2014. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of this lawsuit.

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.

## 10. Subsequent Event

On October 1, 2014, the Company s registration statement on Form S-3, as filed with the U.S. Securities and Exchange Commission (the SEC) on September 16, 2014, was deemed effective using a shelf registration process. Under this shelf registration statement, the Company may issue, in one or more offerings, any combination of common stock, preferred stock senior or subordinated debt securities, warrants, or units, up to a total dollar amount of \$130.0 million.

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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, projects, intends, believes and words and term expects, plans, 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: we may be unable to obtain required financing and other sources of funds on acceptable terms, if at all; 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 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 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. We have an ongoing collaboration with UCB, S. A. (UCB), to whom we licensed epratuzumab for the treatment of all non-cancer indications worldwide. UCB expects Phase 3 data in systemic lupus erythematosus in the first half of 2015. The Company will require additional funding in order to continue the planned Phase 2 and Phase 3 Company-directed clinical trial programs discussed in the Clinical

Pipeline Update section below. We are exploring epratuzumab in oncology in collaboration with independent cancer study groups. Our most advanced candidate, to which we retain worldwide rights for all indications, is <sup>90</sup>Y-clivatuzumab tetraxetan. We initiated a Phase 3 registration trial in January 2014 in patients with advanced pancreatic cancer and expect topline data in mid-2016. Our portfolio of wholly-owned product candidates 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 IMMU-132 (anti-TROP-2-SN-38) and IMMU-130 (anti-CEACAM5-SN-38), which are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer, respectively. 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 and infectious diseases 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® protein conjugation technology. We believe that our portfolio of intellectual property protects 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 financial resources available to us during any particular period;

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, or FDA; and

many other factors associated with the commercial development of therapeutic products outside of our control.

See Risk Factors in Item 1A of this Quarterly Report.

## **Research and Development**

As of September 30, 2014, we employed 17 professionals in our research and development departments and 23 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.

## **Epratuzumab**

Our partner, UCB, is currently evaluating epratuzumab in two Phase 3 clinical trials in systemic lupus erythematosus, or SLE. There is currently no cure for lupus and treatment options are limited; belimumab is the only new drug to have gained U.S approval for SLE in the last 50 years. Moderate to severe SLE is chronic and potentially fatal, affecting approximately 300,000 people both in the U.S. and in the EU. This autoimmune disease is characterized by a variable and unpredictable course and has the potential to affect any part of the body including organs, skin, joints, blood vessels and nervous system. In December 2010, UCB launched the two Phase 3 EMBODY studies based on encouraging results from a Phase 2b study, in which patients treated with epratuzumab reported higher response rates than the placebo patients. Some of the differences in response rates were observed as early as eight weeks after treatment, with further improvement at week 12. In addition, results from an open-label extension arm of the trial showed that continued cycles of epratuzumab therapy maintained improvements or further reduced the lupus disease activity of patients. Furthermore, in some patients, there was a reduction in corticosteroid doses, and no new safety concerns were identified. Patients also reported clinically meaningful improvements in health-related quality of life. UCB has indicated they expect top-line data from these Phase 3 trials during the first half of calendar year 2015.

We have retained the rights to epratuzumab in oncology and continue to develop this product candidate in oncology indications, namely in non-Hodgkin lymphoma, or NHL, and acute lymphoblastic leukemia, or ALL, in cooperation with study groups in the United States and Europe.

The IntreALL Inter-European study group is conducting a large, multicenter, international trial combining epratuzumab with chemotherapy in pediatric patients with relapsed ALL. 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.

## 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. This study is evaluating the safety and efficiency, as measured by overall survival, of the radiolabeled antibody plus low-dose gemcitabine and best supportive care compared to placebo plus low-dose gemcitabine and best supportive care. Repeated treatments with this combination have been found to offer a survival benefit in the same late-stage setting in an earlier Phase 1b study. Two patients from that study remain alive 22 and 24 months after receiving their first therapy cycle of <sup>90</sup>Y-clivatuzumab tetraxetan and low-dose gemcitabine.

We expect to complete accruing 440 patients into the PANCRIT-1 study in the second half of calendar year 2015, with first results possible in the middle of calendar year 2016.

Antibody-Drug Conjugates (ADCs)

We have three product candidates from our proprietary ADC program that are in clinical development, two of which focus on the treatment of patients with metastatic solid tumors. The first ADC program, IMMU-132, is an anti-TROP-2-SN-38 ADC currently being evaluated in patients with a variety of solid tumors. IMMU-130 is an anti-CEACAM5-SN-38 ADC currently in development for the treatment of metastatic colorectal cancer, or mCRC. Additionally, milatuzumab conjugated with the chemotherapeutic doxorubicin is in dose-escalation studies in patients with multiple myeloma, NHL or chronic lymphocytic leukemia, or CLL.

#### *IMMU-132*

IMMU-132 has received orphan drug designation from the FDA for the treatment of patients with small cell lung cancer (SCLC) and pancreatic cancer. The ADC has also been designated an orphan drug by the European Medicines Agency for the treatment of pancreatic cancer in the European Union. In addition to SCLC and pancreatic cancer, IMMU-132 is currently in Phase 2 clinical development focusing on select types of solid cancers including triple-negative breast cancer and colorectal cancer. Results from this multicenter study, as well as initial data from the expansion phase of the trial, were presented at the 2014 Annual Meeting of American Society of Clinical Oncology.

Overall, 71% of patients (34 of 48) with diverse metastatic solid cancers had durable disease stabilization after receiving treatments with IMMU-132. These include seven patients (15%) with colorectal, small-cell and non-small-cell lung, esophageal, or triple-negative breast cancers showing partial responses with tumor shrinkage of 30% or more as measured by computed tomography (CT).

Even after failing multiple prior therapies, a median time to progression of at least 12.6 weeks (range 6.0-51.4 weeks) was observed in 48 patients with at least one CT assessment. One patient with hormone-refractive prostate cancer has a long-term, durable stable disease response, which is approaching a year. This patient has received 30 doses of IMMU-132 and treatment is continuing. Despite repeated dosing, no antibodies against the ADC, neither to the antibody nor to SN-38, have been detected in this or any of the other patients in the study.

## IMMU-130

Our second investigational solid-tumor ADC involves our labetuzumab antibody, anti-CEACAM5, 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. IMMU-130 showed therapeutic activity in all three trials, but a more frequent dosing schedule, with administrations of IMMU-130 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.

With every-other-week dosing, of the 12 assessable patients, there was one partial response, while four other patients had stable disease as best response, resulting in a 42% rate of disease control. The partial responder tolerated a total of 18 doses at 16 mg/kg and showed a 40.6% decrease in the liver and lung target lesions measured by CT, with disease shrinkage observed over a period of about nine months.

For the once- or twice-weekly dosing regimen, a total of 21 patients with mCRC have been enrolled. Treatment responses from 14 patients with at least one CT showed that 10 of 14 patients (71%) responded to IMMU-130. These patients had a median of 4.5 prior therapies (range 1 - 11), one of which must have been an irinotecan-containing regimen. Median time to progression for all 14 patients was at least 15.0 weeks (range 5.9 - >41.1 weeks), with one patient showing an 84% tumor shrinkage and an ongoing duration of partial response of more than seven months. This patient continues to receive treatment and has received a total of 42 doses of the ADC thus far. However, to date, retreated patients have not shown an immune response to the ADC.

The frequent dosing of IMMU-130 appears to be well tolerated by patients, with transient and reversible neutropenia, and manageable diarrhea the major side effects, which were mild and irregular.

Milatuzumab-Doxorubicin

Milatuzumab conjugated with doxorubicin is our first clinically-evaluated agent from our ADC program. The scientific rationale for developing this agent is to take advantage of the rapid internalization property of milatuzumab when bound to CD74. We believe the therapeutic efficacy of milatuzumab-doxorubicin may be the combined cytotoxic effects of both the antibody and the drug. The ADC is in a Phase 1/2 study in multiple myeloma, NHL and CLL. Patient enrollment is completed for the multiple myeloma indication and ongoing for NHL and CLL.

## 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 its doxorubicin conjugate. Other programs include IMMU-114, a humanized anti-HLA-DR antibody.

#### Veltuzumab

Veltuzumab is being evaluated in a Phase 2 study in combination with <sup>90</sup>Y-epratuzumab tetraxetan in patients with aggressive NHL, funded by a grant from the Small Business Innovation Research, or SBIR, program of the National Cancer Institute, or NCI. 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 has completed patient accrual and patients are still being followed for up to 5 years.

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

## Milatuzumab

Milatuzumab is a humanized monoclonal antibody targeting tumors that express the CD74 antigen, which is present on a variety of hematological tumors and even on some solid cancers, with restricted expression by normal tissues. It has received orphan drug designation from the FDA for the treatment of patients with multiple myeloma or CLL. 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 CLL.

Milatuzumab is being developed for the treatment of graft-versus-host disease and has also received a Department of Defense grant for a clinical study in patients with lupus.

## Yttrium-90-Labeled Epratuzumab Tetraxetan

<sup>90</sup>Y-epratuzumab tetraxetan is our radiolabeled anti-CD22 investigational product for patients with NHL. 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.

## IMMU-114

IMMU-114 is a novel humanized antibody directed against an immune response target, HLA-DR, 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.

## Critical Accounting Policies

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results

could differ from these estimates. The following discussion highlights what we believe to be the critical accounting policies and judgments made in the preparation of these condensed consolidated financial statements.

## Marketable securities

Marketable securities, all of which are available-for-sale, consist of corporate debt securities and municipal bonds. Marketable securities are carried at fair value, with unrealized gains and losses, net of

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related income taxes, reported as accumulated other comprehensive income, 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) income 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 interest and other income (net).

## Revenue Recognition

We have accounted for revenue arrangements that include multiple deliverables as a separate unit of accounting if both of the following criteria are met: i) the delivered item has value to the customer on a standalone basis, and ii) 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. We allocate 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 our 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 we have continuing involvement in the agreement are recorded as deferred revenue and recognized over the estimated service period. We estimate 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, we evaluate the contingent milestones using the criteria as provided by the FASB guidance on the milestone method of revenue recognition at the inception of a collaboration agreement. The criteria requires that (i) we determine if the milestone is commensurate with either our performance to achieve the milestone or the enhancement of value resulting from our 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 or determinable and 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.

## **Stock-Based Compensation**

We have a stock incentive plan, the Immunomedics, Inc. 2006 Stock Incentive Plan, as amended, that includes a discretionary grant program, a stock issuance program and an automatic grant program. The plan was established to promote the interests of the Company, by providing eligible persons with the opportunity to acquire a proprietary interest in the Company as an incentive to remain with the organization and to align the employee s interest with our stockholders. This plan is described more fully

in Note 7 to our audited financial statements included in our Annual Report on Form 10-K for the year ended June 30, 2014 and Note 5 to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, included elsewhere herein.

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. We use the Black-Scholes-Merton option pricing formula for determining the grant-date fair value of such awards.

The expected term of the option is based upon the contractual term and expected employee exercise and expected post-vesting employment termination behavior. The expected volatility of the price of the underlying stock is based upon the historical volatility of the Company s stock computed over a period of 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, 2014 and 2013:

	Three-Month Period Ended September 30,	
	2014	2013
Expected dividend yield	0%	0%
Expected option term (years)	5.07	5.20
Expected stock price volatility	61%	67%
Risk-free interest rate	1.60%	1.56%-1.74%

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

## 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. We record these reimbursements as a reduction of research and development expenses as our partner in the collaboration agreement has the financial risks and responsibility for conducting these research and development activities.

## **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, 2014 Compared to 2013

## Revenues

Revenues for the three-month period ended September 30, 2014 were \$1.1 million, as compared to \$5.5 million for the three-month period ended September 30, 2013. License and other revenues were \$4.6 million for the three-month period ended September 30, 2013. There were no license and other revenues for the same period in fiscal 2015. This decrease principally resulted from license revenue earned upon fulfilling the Company s obligations under the Algeta ASA Service Agreement, as amended, in the prior period. Product sales for the three-month period ended September 30, 2014 were \$0.7 million, as compared to \$0.6 million for the same period in 2013. Research and development revenues for both the three-month periods ended September 30, 2014 and 2013 were \$0.3 million.

## Costs and Expenses

Total costs and expenses for the three-month period ended September 30, 2014 were \$13.5 million, as compared to \$10.7 million for the same period in 2013, representing an increase of \$2.8 million or 26%. Research and development expenses for the three-month period ended September 30, 2014 were \$9.4 million, as compared to \$7.5 million for the same period in 2013, an increase of \$1.9 million or 25%. 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 the three-month periods ended September 30, 2014 and 2013 were \$0.1 million. Gross profit margins were 90% for the first quarter of fiscal 2015 as compared to 86% for the first quarter of fiscal 2014. Cost of license fees and other revenues resulting from the recognition of \$1.2 million deferred manufacturing costs related to the Algeta service agreement which was completed during the three-month period ended September 30, 2013. There were no license fees and other costs in the three-month period ended September 30, 2014. Sales and marketing expenses for both three-month periods ended September 30, 2014 and 2013 were \$0.2 million. General and administrative expenses were \$3.8 million for the three month period ended September 30, 2014 representing an increase of \$2.1 million or 124% as compared to \$1.7 million for the three month period ended September 30, 2013. This increase is primarily attributable to approximately \$2.1 million of increased legal and professional fees, (principally increased legal fees regarding the arbitration proceedings with Takeda-Nycomed).

## Foreign Currency Transaction (Loss) Gain

Foreign currency transaction loss amounted to \$12 thousand for the three-month period ended September 30, 2014 as compared to a gain of \$5 thousand for the same period in 2013, primarily as a result of currency fluctuations between the U.S. dollar and the euro.

Net Loss Attributable to Immunomedics, Inc.

Net loss attributable to Immunomedics, Inc. common stockholders for the three-month period ended September 30, 2014 was \$12.4 million, or \$0.13 per share, as compared to a net loss of \$5.2 million or \$0.06 per share, in the same period in 2013. The \$7.2 million increase in the net loss this quarter was primarily due to increased research and development cost related to clinical trials, increased legal and professional fees, and the decrease in other revenues received in the prior period that related to the Algeta agreement.

## **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, 2014 was \$9.2 million as compared to \$7.3 million net cash used in operating activities for the three-month period ended September 30, 2013. Cash used in operating activities in fiscal 2015 increased primarily because of \$1.5 million of cash proceeds received under the Algeta ASA Agreement from the prior year.

Cash flows from investing activities. Net cash provided by investing activities for the three-months ended September 30, 2014 was \$8.0 million as compared to \$20.2 million of net cash used in investing activities for the three months ended September 30, 2013. The increase in cash flow provided by investing activities for fiscal 2015 was primarily due to \$8.3 million of marketable securities that either matured or were sold during the current period and the cash used in the prior period of \$20.1 million for purchases of marketable securities, with no purchases in the first quarter of fiscal 2015.

Cash flows from financing activities. Net cash used in financing activities for the three-month period ended September 30, 2014 was \$0.1 million as compared to \$0.8 million of net cash provided by financing activities for the three months ended September 30, 2013. The change resulted principally from \$0.9 million in proceeds received from the exercise of stock options in the 2013 period that did not occur in the current period.

## **Working Capital and Cash Requirements**

At September 30, 2014, we had working capital of \$25.9 million, which was approximately \$12.4 million lower than the working capital of \$38.3 million at June 30, 2014. Our cash, cash equivalents and marketable securities amounted to \$32.0 million at September 30, 2014, representing a decrease of \$9.8 million from \$41.8 million at June 30, 2014. The decreases were primarily a result of our use of \$9.2 million of cash used in operations. Working capital also decreased as a result of a \$2.5 million increase in accounts payable and accrued expenses, primarily for legal and professional fees.

Our budgeted cash requirements in fiscal year 2015 are expected to be approximately \$41.0 million, which 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 (IMMU-132 and IMMU 130). We have the ability to reduce our cash flow spending requirements if necessary, after considering certain planned discretionary spending, including the funding of our clinical trial programs. For the three-month period ended September 30, 2014, we utilized cash aggregating \$9.8 million. As of September 30, 2014, we have \$32.0 million of cash, cash equivalents and marketable securities. We will require additional funding in order to fund our planned Phase 3 and Phase 2 clinical trials in fiscal 2015 and beyond.

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

We expect research and development activities to continue to expand over time, and we do not believe we will have adequate cash to continue to complete development of product candidates in our pipeline according to our long-term corporate strategy. As a result, we will continue to require additional financial resources in the future in order to conduct our research and development programs, clinical trials of product candidates and regulatory filings. Our

ability to raise capital through public and private equity or debt financings are dependent upon economic conditions that may be present at the time of these fund raising events. There can be no assurances that financing will be available when needed with acceptable terms to us, if at all. If we are unable to raise capital on acceptable terms, our ability to continue our business would be materially and adversely affected. Furthermore, the terms of any such debt or equity financing may include covenants which may limit our future ability to manage the business. 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.

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 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.

## Former Licensing Partner:

On October 3, 2013, the Company received notification from Takeda Pharmaceutical Company Limited/Nycomed GmbH of termination of the License and Collaboration Agreement that it entered into with 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, referred to herein as the Nycomed Agreement. The notification was received subsequent to the Company s filing of arbitration proceedings in an effort to resolve the dispute it has with Nycomed and Takeda concerning delays in the development of veltuzumab, which the Company argues is a material breach of the Nycomed Agreement. As a result of the termination, all rights to veltuzumab revert to the Company. All parties have had discussions regarding the transition of veltuzumab back to the Company and certain materials have been returned to the Company. In addition, the Company has continued to pursue the arbitration procedure to address its claim for damages due to, among other things, delays in the development of veltuzumab.

On October 11, 2013, Takeda and Takeda-Nycomed filed their Statement of Defense and Counterclaims alleging, among other things, that the Company wrongfully terminated the Nycomed Agreement and caused Takeda and Takeda-Nycomed to suffer significant damages and delays in developing veltuzumab. The Company responded by filing its own Statement of Defense on November 12, 2013, denying Takeda and Takeda-Nycomed s allegations and contesting Takeda or Takeda-Nycomed s rights to any relief. An arbitrator was appointed later that month. On December 20, 2013 the arbitrator issued a pre-hearing scheduling order and the arbitration proceeded in accordance with that schedule as subsequently amended. The hearing portion of the arbitration process was completed on August 21, 2014. Each party s counsel filed a final post-hearing submission on October 17, 2014. The decision by the arbitrator is expected within two months of the post-hearing submission.

The Company does not believe these matters, even if adversely adjudicated or settled, would have a material adverse effect on its consolidated financial condition, results of operations or cash flows.

## Shareholder complaints:

Two separate shareholder derivative complaints have been 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 allege, 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 allege 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 allege 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 bring the derivative

actions to recover damages against the directors and officers for the benefit of the Company, and to require the

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Company to reform and improve its corporate governance and internal procedures. Both derivative actions have been stayed pending the outcome of 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 alleges 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 alleges 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 alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On June 24, 2014, the District Court entered an order appointing John Neff as lead plaintiff and The Rosen Firm, P.A. as lead counsel. Lead plaintiff and lead counsel thereafter filed an Amended Class Action Complaint on August 8, 2014. The defendants filed a motion to dismiss the Amended Class Action Complaint on September 22, 2014. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of this lawsuit.

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 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, 2014, we had an accumulated deficit of approximately \$273.9 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 (Algeta). 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. 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 do not believe we will have adequate cash at our current expected spending level to fund our clinical development programs through the next twelve months. We will require additional financial resources after we utilize our current liquid assets in order to continue our clinical development programs as is currently budgeted for fiscal year 2015. We are actively pursuing various financing alternatives as market conditions permit through licensing and collaborative agreements or additional potential equity or debt financings, 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. If we are unable to raise additional capital funding in the near term, we can implement certain planned discretionary spending reductions, including the reduced funding of our clinical trial programs in order for us to continue our operations at least through the next twelve months.

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.

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Our most advanced therapeutic product candidates are still in the clinical development stage and will not be available for commercial sale any time soon, if ever. In order to complete the clinical development process for each of our product candidates, it will be necessary to invest significant financial resources, and devote a great deal of time and effort, just to reach the point where an application for final FDA or foreign regulatory approval can be submitted. In addition, we will need to raise additional capital to finance the costly process of obtaining approval for any of our current products should we get to that stage of product development. However, financing may not be available to us when we need it or on terms acceptable to us.

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 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;

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;

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 by the FDA;

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, including the anticipated Phase 3 trial for Y-90-labeled clivatuzumab tetraxetan in pancreatic cancer, we may be forced to cancel or otherwise curtail such trials and other studies.

Any failure or substantial delay in successfully completing clinical trials for our product candidates, particularly the ongoing trials for our most advanced product candidates, epratuzumab, veltuzumab and Y-90-labeled clivatuzumab tetraxetan, could severely harm our business and results of operations.

## Our clinical trials may not adequately show that our drugs are safe or effective.

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 could result in delays in our trials or require the performance of additional unplanned trials. This 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 the 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, the 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 and given the continued weakness of the economy, 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. Our budgeted cash requirements in fiscal year 2015 are expected to be approximately \$41.0 million, which includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, as well as expenses for the ongoing Phase 2 expansion ADC clinical trials (IMMU-132 and IMMU 130). We have the ability to reduce our cash flow spending requirements if necessary, after considering certain planned discretionary spending, including the funding of our clinical trial programs. For the three-month period ended September 30, 2014, we utilized cash aggregating \$9.8 million. As of September 30, 2014, we have \$32.0 million of cash, cash equivalents and marketable securities. We will require additional funding in order to fund our planned Phase 3 and Phase 2 clinical trials in fiscal 2015 and beyond.

We continue to pursue business development and licensing arrangements as a potential source of financing. These activities include potential payments from partners, UCB S.A. ( UCB ) and The Bayer Group ( Bayer ), as well as any new parties who may be interested in clinical programs as well as any licenses to our vast intellectual property estate. 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;

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The success of UCB in meeting the clinical development and commercial milestones for epratuzumab, 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.

Our ability to raise future capital on acceptable terms will depend not only upon our operating performance, but also on conditions in the public and private debt and equity markets, as well as the overall performance of other companies in the biopharmaceutical and biotechnology sectors. Because of the current economic conditions and risk-adverse conditions in the public and private debt and equity markets, financing may not be available to us when we need it on terms we find acceptable, if at all. Furthermore, the terms of any such debt or equity financing may include covenants which limit our future ability to manage the business, contain preferences, privileges and rights superior to those enjoyed by holders of our common stock or cause substantial dilution to our existing stockholders.

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 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 non-cancer indications worldwide, and they may not be successful.

We have licensed the exclusive worldwide rights for the treatment of non-cancer 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 these compounds, obtaining all necessary regulatory approvals, and then commercializing and manufacturing the compounds for sale. If they do not fully perform their responsibilities under our agreements, or if the clinical trials to be conducted are not initiated, are unsuccessful or are

terminated by them for any other

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reason, our ability to commercialize this product candidate in the future, as well as other product candidates we have in development which are closely related to them, would be severely jeopardized. In such event, it is likely we would 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 would 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 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.

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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.

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.

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, Amgen, Bristol-Myers Squibb, Bayer Healthcare Pharmaceuticals, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic autoimmune and oncology products. For example, Human Genome Sciences, a wholly owned subsidiary of GlaxoSmithKline, has received approval from the FDA for belimumab, their human monoclonal antibody against B-lymphocyte stimulator, or BlyS, for the therapy of patients with SLE. 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.

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.

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.

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 Medical Officer, and Ms. 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 Medical 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. Dr. Goldenberg s employment agreement with us permits him to devote more of his time working for CMMI than for us, and other key personnel of our company also have research collaborations with CMMI. 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.

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

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

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

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

During the last few years, we have generated revenues from awards made to us by the National Institutes of Health and the Department of Defense to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government s obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will continue to scale back these programs or terminate them due to their own budgetary constraints, as they have recently been doing. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing awards may be less than those received to date. In those circumstances, we would need to provide funding on our own, obtain other funding, or scale back or terminate the affected program. In particular, we cannot assure you that any currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding.

## 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 (PPACA), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. The new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. 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 new 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.

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.

These governmental and other regulatory risks 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;

The FDA or other regulatory authorities do not approve a clinical trial protocol or place a clinical trial on hold;

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 product candidates; and

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

#### **Risks Related to Our Securities**

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 were 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 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.

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. 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. For example, as described in this Quarterly Report on Form 10-Q, two separate shareholder derivative complaints have been 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 8, 2014, a complaint styled *Breitman v. Sullivan, et al.*, was filed in the United States District Court for the District of New Jersey. In addition, 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. All three complaints are based on the allegation that we and certain of our 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 an agreement between the Company and Nycomed GmbH (Nycomed). There can be no assurance that such litigation will be resolved in our favor, and we might be required to devote significant resources and management time defending the company from these claims, which could adversely affect our business, financial condition and results of operations.

At November 4, 2014, we had 93,133,094 shares of common stock outstanding, 6,451,763 additional shares reserved for the exercise of outstanding options and restricted stock units 3,395,843 shares available for future grant under our stock option plan and 1,000,000 shares of common stock reserved for issuance upon the exercise of outstanding warrants.

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

As of September 30, 2014, Dr. David M. Goldenberg, our Chairman, Chief Scientific Officer and Chief Medical 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 9% 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 director s breach of the duty of care.

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

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

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

The Sarbanes-Oxley Act requires that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Among other things, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act (Section 404). Compliance with Section 404 requires substantial accounting expense and

significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in

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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 products 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 5, 2014 By: /s/ Cynthia L. Sullivan

Cynthia L. Sullivan

President and Chief Executive Officer

(Principal Executive Officer)

November 5, 2014 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
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, 2014, formatted in XBRL (eXtensible Business Reporting Language) filed electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.

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