

IMMUNOMEDICS INC  
Form 10-Q  
November 04, 2013  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2013**

**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**  
**incorporation or organization)**  
**300 The American Road, Morris Plains, New Jersey 07950**  
**(Address of principal executive offices) (Zip Code)**  
**(973) 605-8200**  
**(Registrant's Telephone Number, Including Area Code)**  
**Former Name, Former Address and Former Fiscal Year,**  
**If Changed Since Last Report: Not Applicable**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period the registrant was required to submit and post such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "accelerated filer", "large accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ☐ Accelerated Filer ☒  
Non-Accelerated Filer ☐ Smaller Reporting Company ☐

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

The number of shares of the registrant's common stock outstanding as of November 1, 2013 was 83,134,280.



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**IMMUNOMEDICS, INC.**

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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(UNAUDITED)**

	September 30, 2013	June 30, 2013
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 14,643,050	\$ 41,326,000
Marketable securities	20,082,913	
Accounts receivable, net of allowance for doubtful accounts of \$70,418 at September 30, 2013 and \$49,265 at June 30, 2013	399,889	622,830
Inventory	973,642	1,030,480
Other receivables	938,230	172,468
Prepaid expenses	1,227,265	432,660
Other current assets	241,568	1,631,172
Total current assets	38,506,557	45,215,610
Property and equipment, net of accumulated depreciation of \$26,900,669 and \$26,743,481 at September 30, 2013 and June 30, 2013, respectively	2,074,487	2,086,911
Value of life insurance policies	599,082	594,832
Other long-term assets	30,000	30,000
Total Assets	\$ 41,210,126	\$ 47,927,353
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 6,066,042	\$ 7,164,946
Deferred revenues	264,543	2,780,309
Total current liabilities	6,330,585	9,945,255
Other liabilities	1,425,607	1,400,728
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at September 30, 2013 and June 30, 2013		
Common stock, \$0.01 par value; authorized 135,000,000 shares; issued 83,153,505 shares and outstanding 83,118,780 shares at September 30, 2013; and issued 82,841,123 shares and 82,806,398 shares outstanding at June 30, 2013	831,534	828,411
Capital contributed in excess of par	266,855,074	265,688,408
	(458,370)	(458,370)

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Treasury stock, at cost, 34,725 shares at September 30, 2013 and at June 30, 2013

Accumulated deficit	<b>(233,593,304)</b>	(229,253,892)
Accumulated other comprehensive income	<b>229,237</b>	161,830
Total Immunomedics, Inc. stockholders' equity	<b>33,864,171</b>	36,966,387
Noncontrolling interest in subsidiary	<b>(410,237)</b>	(385,017)
Total stockholders' equity	<b>33,453,934</b>	36,581,370
Total Liabilities and Stockholders' Equity	<b>\$ 41,210,126</b>	\$ 47,927,353

See accompanying notes to unaudited condensed consolidated financial statements

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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF**  
**COMPREHENSIVE LOSS**  
**(UNAUDITED)**

	<b>Three months ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Revenues:</b>		
License fee and other revenues	<b>\$ 4,623,333</b>	<b>\$</b>
Product sales	<b>559,023</b>	<b>733,187</b>
Research and development	<b>315,465</b>	<b>318,231</b>
<b>Total revenues</b>	<b>5,497,821</b>	<b>1,051,418</b>
<b>Costs and Expenses:</b>		
Costs of goods sold	<b>77,199</b>	<b>96,431</b>
Cost of license fee and other revenues	<b>1,189,170</b>	
Research and development	<b>6,652,543</b>	<b>7,035,102</b>
Sales and marketing	<b>218,032</b>	<b>204,392</b>
General and administrative	<b>1,732,671</b>	<b>1,272,705</b>
<b>Total costs and expenses</b>	<b>9,869,615</b>	<b>8,608,630</b>
<b>Operating loss</b>	<b>(4,371,794)</b>	<b>(7,557,212)</b>
Interest and other income, net	<b>6,211</b>	<b>139,179</b>
Foreign currency transaction gain	<b>5,452</b>	<b>29,705</b>
<b>Loss before income tax expense</b>	<b>(4,360,131)</b>	<b>(7,388,328)</b>
<b>Income tax expense</b>	<b>(4,501)</b>	<b>(19,669)</b>
<b>Net loss</b>	<b>(4,364,632)</b>	<b>(7,407,997)</b>
<b>Less net loss attributable to noncontrolling interest</b>	<b>(25,220)</b>	<b>(25,932)</b>
<b>Net loss attributable to Immunomedics, Inc. stockholders</b>	<b>\$ (4,339,412)</b>	<b>\$ (7,382,065)</b>
<b>Loss per common share attributable to Immunomedics, Inc. stockholders, (basic and diluted)</b>	<b>\$ (0.05)</b>	<b>\$ (0.10)</b>
<b>Weighted average shares used to calculate loss per common share, (basic and diluted)</b>	<b>82,947,124</b>	<b>75,610,238</b>

Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments	<b>72,367</b>	60,146
Unrealized losses on available-for-sale securities	<b>(4,960)</b>	
Other comprehensive income	<b>67,407</b>	60,146
Comprehensive loss	<b>(4,297,225)</b>	(7,347,851)
Less comprehensive loss attributed to noncontrolling interest	<b>(25,220)</b>	(25,932)
Net comprehensive loss attributable to Immunomedics, Inc.	<b>\$ (4,272,005)</b>	\$ (7,321,919)

See accompanying notes to unaudited condensed consolidated financial statements



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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(UNAUDITED)**

	<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Cash flows used in operating activities:		
Net loss	\$ (4,364,632)	\$ (7,407,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	157,188	239,285
Amortization of deferred revenue	(2,515,766)	
Gains from insurance claim for equipment		(137,714)
Increase in allowance for doubtful accounts	21,153	14,241
Non-cash expense related to stock compensation	418,548	463,115
Non-cash increase in value of life insurance policy	(4,250)	(4,350)
Amortization of deferred rent	24,879	24,879
Changes in other operating assets and liabilities	(1,000,825)	(579,543)
Net cash used in operating activities	(7,263,705)	(7,388,084)
Cash flows (used in) provided by investing activities:		
Purchase of marketable securities	(20,082,913)	
Purchases of property and equipment	(144,764)	(97,721)
Proceeds from insurance claim for equipment		137,714
Net cash (used in) provided by investing activities	(20,227,677)	39,993
Cash flows provided by (used in) financing activities:		
Exercise of stock options	910,677	59,071
Payments for stock plan activity	(159,436)	(138,029)
Net cash provided by (used in) financing activities	751,241	(78,958)
Effect of changes in exchange rates on cash and cash equivalents	57,191	109,271
Net decrease in cash and cash equivalents	(26,682,950)	(7,317,778)
Cash and cash equivalents, beginning of period	41,326,000	32,838,096
Cash and cash equivalents, end of period	\$ 14,643,050	\$ 25,520,318

See accompanying notes to unaudited condensed consolidated financial statements.



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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED**

**FINANCIAL STATEMENTS**

Reference is made to the Annual Report on Form 10-K of Immunomedics, Inc., a Delaware corporation ( Immunomedics, the Company, we, our or us ), for the fiscal year ended June 30, 2013, which contains our audited consolidated financial statements and the notes thereto.

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

Immunomedics is a New Jersey-based biopharmaceutical company primarily focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has developed a number of advanced proprietary technologies that allows it to create humanized antibodies that can be used either alone in unlabeled or naked form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins, in each case to create highly targeted agents. Using these technologies, the Company has built a pipeline of therapeutic product candidates that utilize several different mechanisms of action. The Company also manufactures and commercializes its LeukoScan® product in territories where regulatory approvals have previously been granted. The Company has two foreign subsidiaries, Immunomedics B.V. in The Netherlands and Immunomedics GmbH in Darmstadt, Germany, to 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 subsidiary, IBC Pharmaceuticals, Inc. ( IBC ), which has been working since 1999 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. The Company has reclassified prior period amounts to conform to the current period presentation. Operating results for the three-month period ended September 30, 2013 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2014, 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 our drug candidates; the Company's dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under our 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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As of September 30, 2013, the Company has \$34.7 million of cash, cash equivalents and marketable securities. Based on the Company's expected cash utilization rate, the Company

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believes it will have sufficient funds to continue its operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2014 are expected to be in the \$24.0 - \$26.0 million range, which includes expenses related to the Company's ongoing Antibody Drug Conjugate (ADC) programs and certain expenses to initiate the Company's anticipated clivatuzumab tetraxetan Phase III clinical trial for the treatment of patients with pancreatic cancer. The Phase Ib clinical trial of clivatuzumab tetraxetan in patients with advanced pancreatic cancer was completed during the 2013 fiscal year. Based on the results of such trial, the Company decided to proceed with a Phase III clinical trial. The Company will provide further guidance regarding cash flow requirements once the full Phase III Trial estimated expenses have been determined. The Company recognizes that this trial will require additional funding. There can be no assurances that financing will be available when needed on terms acceptable 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 expects research and development activities to continue to expand over time and it does not believe it will have adequate cash to continue to conduct development of product candidates in its pipeline according to its long-term corporate strategy. As a result, the Company, in the future, will continue to require additional financial resources in order to conduct its research and development programs, clinical trials of product candidates and regulatory filings.

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 current weak economy. There can be no assurances that financings will be available when 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.

**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, 2013. The Company adheres to the same accounting policies in preparation of its interim financial statements.

***Principles of Consolidation and Presentation***

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



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**Table of Contents*****Revenue Recognition***

The Company has accounted for revenue arrangements that include multiple deliverables as a separate unit of accounting if: a) the delivered item has value to the customer on a standalone basis, and b) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered items is considered probable and substantially in the control of the vendor, in accordance with the accounting standard for multiple-element arrangements. 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 or the product is delivered. Upfront nonrefundable fees associated with license and development agreements where the Company has continuing obligations in the agreement are recorded as deferred revenue and recognized over the estimated service 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 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 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.

***Research and Development Costs***

Research and development costs are expensed as incurred. During the three-month period ended September 30, 2013, the Company recognized a reversal of clinical trial related accruals of \$1.2 million.

***Manufacturing Costs***

Manufacturing costs incurred in relation to the development of materials produced in order to fulfill contractual obligations are capitalized and are recorded in other current assets until the product is delivered in accordance with the terms of the agreement. These manufacturing costs are classified as cost of license fee and other revenues when the research contractual obligations have been completed.





**Table of Contents*****Financial Instruments***

The carrying amounts of cash and cash equivalents, other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Investments in marketable securities are available-for-sale to fund operations. The portfolio at September 30, 2013 primarily consists of corporate debt securities and municipal bonds.

***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.

Financial assets recorded on the condensed consolidated balance sheets as of September 30, 2013 and June 30, 2013 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 thousands)			
<b>September 30, 2013</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money Market Funds	\$ 11,144	\$	\$	\$ 11,144
Marketable Securities	20,083			20,083
<b>Total</b>	<b>\$ 31,227</b>	<b>\$</b>	<b>\$</b>	<b>\$ 31,227</b>

<b>June 30, 2013</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
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Money Market Funds	\$ 38,327	\$	\$	\$ 38,327
Total	\$ 38,327	\$	\$	\$ 38,327

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

***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.

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

Inventory consisted of the following (in thousands):

	September 30, 2013	June 30, 2013
Work in process	\$ 914	\$ 914
Finished goods	60	116
	\$ 974	\$ 1,030

***Income Taxes***

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change. We have recorded a full valuation allowance against our net deferred tax assets as of September 30, 2013.

Income taxes were provided for profitable foreign jurisdictions at the estimated annual tax rate during the three-month periods ended September 30, 2013 and 2012. The Company's U.S. operations reported a net loss for the three-month periods ended September 30, 2013 and 2012, 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, 2013.

***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, 2013 and 2012. The common stock equivalents excluded from the diluted per share calculation are 7,708,560 and 7,596,825 shares at September 30, 2013 and 2012, 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.



**Table of Contents*****Reclassification***

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

***Accounting Pronouncements***

In July 2013, the FASB issued Accounting Standard Update ( ASU ) 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carry-forward, a Similar Tax Loss, or a Tax Credit Carry-forward Exists. This ASU will eliminate the diversity in practice in presentation of unrecognized tax benefits when a net operating loss carry-forward, a similar tax loss, or a tax credit carry-forward exists at the reporting date. This new guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carry-forward that would apply in settlement of the uncertain tax positions. Under the new guidance, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carry-forward that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. This guidance is effective prospectively, but allows optional retrospective adoption (for all periods presented), for reporting periods beginning after December 15, 2013. As this guidance relates to presentation only, the adoption of this guidance will not impact our financial position or results of operations.

In February 2013, the FASB issued ASU 2013-02, Comprehensive Income: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income ( AOCI ). ASU requires entities to disclose additional information about reclassification adjustments, including changes in AOCI balances by component and significant items reclassified out of AOCI. The Company adopted this pronouncement in the first quarter of fiscal year 2014.

**3. Marketable Securities**

During the three months ended September 30, 2013, the Company invested \$20.1 million of cash and cash equivalents into debt securities and municipal bonds. Immunomedics utilized 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, 2013 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
September 30, 2013				
U.S. Treasury Bonds	\$ 9,048	\$ 1	\$ (1)	\$ 9,048
Corporate Debt Securities	11,040	3	(8)	11,035
	\$ 20,088	\$ 4	\$ (9)	\$ 20,083



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Maturities of debt securities classified as available-for-sale were as follows at September 30, 2013 (in thousands):

	Amortized Cost	Estimated Fair Value
Due within one year	\$ 10,063	\$ 10,062
Due after one year through five years	10,025	10,021
	\$ 20,088	\$ 20,083

**4. Stockholders Equity*****Accumulated Other Comprehensive Income***

The components of accumulated other comprehensive income were as follows:

	Currency Translation Adjustments	Net Unrealized Losses on Available-for-Sale Securities	Accumulated Other Comprehensive Income
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>			
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.

<sup>(a)</sup> For the three months ended September 30, 2013, there were no amounts reclassified from accumulated other comprehensive income.

## **5. Stock Incentive Plan**

A summary of the 2006 Stock Incentive Plan (the Plan), is provided in Note 6 to the audited financial statements contained in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2013. The Company believes that awards under 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, 2013, there were 10,381,123 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (6,708,560 shares) and which were available to be issued for future grants (3,672,563 shares).



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The fair value of each option granted during the three-month periods ended September 30, 2013 and 2012 is estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumptions in the following table:

	<b>Three-month period ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Expected dividend yield	0%	0%
Expected option term (years)	5.20	5.29
Expected stock price volatility	67%	69%
Risk-free interest rate	1.56%-1.74%	0.98%-1.11%

The weighted average fair value at the date of grant for options granted during the three-month periods ended September 30, 2013 and 2012 were \$3.07 and \$2.02 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, 2013 is summarized as follows:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, July 1, 2013	5,726,874	\$ 3.30		
Granted	800,131	\$ 5.32		
Exercised	(265,000)	\$ 3.44		
Cancelled or forfeited	(468,786)	\$ 5.29		
Outstanding, September 30, 2013	5,793,219	\$ 3.43	3.32	\$ 16,242,254
Exercisable, September 30, 2013	4,487,484	\$ 3.21	2.52	\$ 13,421,695

A summary of the Company's non-vested restricted and performance stock units at July 1, 2013, and changes during the three-month period ended September 30, 2013 are presented below:

<b>Outstanding Non-Vested Restricted and Performance Stock Units</b>	<b>Number of Awards</b>
Non-vested at July 1, 2013	488,575
Restricted Units Granted	136,452
Performance Units Granted	389,864

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Vested	(74,550)
Cancelled	(25,000)

Non-vested at September 30, 2013	915,341
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The Company has 2,221,076 non-vested options, restricted and performance stock units outstanding as of September 30, 2013. As of September 30, 2013, 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 \$0.4 million and \$0.5 million for total stock-based compensation expense for employees, executive officers and non-employee Board members for the three-month periods ended September 30, 2013 and 2012, respectively.

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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 \$55 thousand and \$16 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for the three-month periods ended September 30, 2013 and 2012, respectively.

On August 16, 2013, the Company awarded an additional 136,452 restricted stock units to certain executive officers of the Company at the market price on that date (\$5.13 per share). These restricted stock units will vest over a four year period. As of September 30, 2013, 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 \$1.8 million cost is being recognized over a weighted-average period of 2.94 years. The Company recorded \$0.1 million for stock-based compensation expense for each of the three-month periods ended September 30, 2013 and 2012.

On August 16, 2013, the Company also awarded certain executive officers Performance 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 shall 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, 2013, there are 389,864 Performance Units available if all performances are achieved within five years of grant date. The Company recorded \$0.2 million for the stock-based compensation for the three-months ended September 30, 2013. There is \$1.5 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of September 30, 2013. That cost is being recognized over a weighted-average period of 1.3 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, 2013 and 2012 (\$ in thousands):

	<b>As of and for the Three Months Ended September 30, 2013</b>		
	<b>United States</b>	<b>Europe</b>	<b>Total</b>
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	(4,325)	(35)	(4,360)
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	<b>As of and for the Three Months Ended September 30, 2012</b>		
	<b>United States</b>	<b>Europe</b>	<b>Total</b>
Total assets	\$ 27,500	\$ 3,601	\$ 31,101
Property and equipment, net	2,386		2,386
Revenues	327	724	1,051
(Loss) income before taxes	(7,426)	38	(7,388)

**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 \$5 thousand and \$8 thousand of legal expenses on behalf of CMMI for patent related matters for each of the three-month periods ended September 30, 2013 and 2012. 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. There were zero and \$25 thousand dollars in research related activities charged to the Company for the periods ending September 30, 2013 and 2012 respectively.

For each of the three-month periods ended September 30, 2013 and 2012, Dr. Goldenberg received approximately \$20 thousand in compensation for his services to IBC.

**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) effective the same day.

On October 3, 2013, the Company received notification from Takeda Pharmaceutical Company Limited/Nycomed GmbH of termination of the licensing agreement between Nycomed GmbH and Immunomedics for the worldwide rights to veltuzumab, the humanized anti-CD20 antibody, in a subcutaneous formulation for all non-cancer indications.



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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 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 and both parties have begun discussions regarding the transition of veltuzumab back to the Company. In addition, the Company will continue 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 filed its Statement of Defense with a counterclaim alleging wrongful termination of the licensing agreement. The Company will respond within 30 days. The Company expects an arbitrator to be selected on or before that date and that the arbitration will continue while the product transition takes place.

Takeda-Nycomed was solely responsible for the development, manufacturing and commercialization of veltuzumab, for 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 has completed all of its obligations under the agreement, namely its manufacturing and supply obligations and its responsibilities in the Phase I/II study in immune thrombocytopenic purpura (ITP).

### **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 flexibility to sublicense epratuzumab, subject to obtaining our prior consent, to a third party for the United States and certain other territories. As of September 30, 2013, 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 fee of \$30.0 million in January 2012. Further, under the terms of the Amendment Agreement, UCB returned its buy-in right with respect to epratuzumab in the field of oncology, which had been granted under the UCB Agreement.

Collectively, the UCB Agreement and the Amendment Agreement anticipated the Company would receive certain cash payments and equity investments by UCB in Immunomedics Common Stock contingent upon various regulatory achievements related to the successful development of epratuzumab by UCB (development milestone payments) and certain cash payments related to the achievement of specified product sales thresholds (commercialization milestone payments). The Company is also entitled to product royalties based upon a percentage of aggregate annual net sales under the UCB Agreement and





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Amendment Agreement during the product royalty term. No development milestone, commercialization milestone or royalty payments were achieved through September 30, 2013. There can be no assurance that the development, commercialization or royalty milestone payments 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.

### **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 antibody to Algeta, which has rights to evaluate the potential of a Targeted Thorium Conjugate (TTC), linking thorium-227 to epratuzumab, for the treatment of cancer. Algeta will fund all preclinical and clinical development costs up to the end of Phase I testing. Upon successful completion of Phase I 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 September 30, 2013, the Company recognized all of the initial cash payments as revenue as the aspects of delivery for the clinical supply material have been satisfied.

## **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% for the 2014 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 must pay to external third parties.



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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, 2013 and 2012, no additional incentive compensation payments were made to Dr. Goldenberg other than the \$37.5 thousand minimum quarterly payments.

On July 1, 2011, the Company and Cynthia L. Sullivan entered into the Fourth 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, 2014. 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 2014 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.

## ***Legal Matters***

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 management's opinion, would have a material adverse effect on the Company's business, financial condition or results of operations.

## **10. Subsequent Event**

On October 3, 2013, the Company received notification from Takeda Pharmaceutical Company/Nycomed GmbH of the termination of the licensing agreement between Nycomed GmbH and Immunomedics for the worldwide rights to veltuzumab, the humanized anti-CD20 antibody, in a subcutaneous formulation for all non-cancer indications.

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 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 and both parties have begun discussions regarding the transition of veltuzumab back to the Company. In addition, the Company will continue 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 filed its Statement of Defense with a counterclaim alleging wrongful termination of the licensing agreement. The Company will respond within 30 days. The Company expects an arbitrator to be selected on or before that date and that the arbitration will continue while the product transition takes place.

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

**Cautionary Note Regarding Forward-Looking Statements**

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

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of substance used in connection with any discussion of future operating or financial performance, are intended to identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, among other things: our inability to further identify, develop and achieve commercial success for new products and technologies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to obtain additional capital through strategic collaborations, licensing, convertible debt securities or equity financing in order to continue our research and development programs as well as 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 biopharmaceutical company focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. We have developed a number of advanced proprietary technologies that allow us to create humanized antibodies that can be used either alone in unlabeled or naked form, or



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conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins, in each case to create highly targeted agents. Using these technologies, we have built a pipeline of therapeutic product candidates that utilize several different mechanisms of action. We also have a majority ownership in IBC Pharmaceuticals, Inc., which is developing a novel DOCK-AND-LOCK (DNL) method with us for making fusion proteins and multifunctional antibodies. DNL is being used particularly to make bispecific antibodies targeting cancers and infectious diseases as a T-cell redirecting immunotherapy, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies. 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 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;

the financial resources available to us during any particular period; and

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

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

## **Research and Development**

As of September 30, 2013, we employed 15 professionals in our research and development departments and 18 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.

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**Epratuzumab**

UCB: Two Phase III studies of epratuzumab are ongoing in patients with systemic lupus erythematosus (SLE). These are multinational, placebo-controlled, randomized, double-blind studies designed to confirm the clinical efficacy and safety of epratuzumab in the treatment of patients with moderate to severe general SLE, in addition to continuing standard of care treatments. Each study lasts a maximum of 54 weeks after first dose and randomizes 780 patients in the study, with approximately 130 planned investigational sites per study. Top-line results from these studies are expected in the first quarter of calendar year 2015.

In addition, new data from an open-label extension of UCB's EMBLEM Phase IIb study evaluating the long-term effects of epratuzumab treatment in adult patients with moderate-to-severe SLE were presented at the 2013 EULAR Congress (Ann Rheum Dis. 2013; 72(Suppl3): Abstracts 257 and 259). In 2012, results from the open-label extension study of the ALLEVIATE trials were presented at the American College of Rheumatology Annual Scientific Meeting (Arthritis Rheum. Oct 2012; 64(Supplement S10): S276-7 and S953-4). These studies showed that continued cycles of epratuzumab therapy maintained improvements or further reduced the lupus disease activity of patients over a timeframe of approximately 4 years. Also, there was a reduction in corticosteroid doses, a tolerable safety profile, and no new safety concerns identified. Patients also reported clinically meaningful improvements in health-related quality of life that were sustained over approximately 4 years of treatment. Results from the ALLEVIATE trials have also been published (Rheumatology (Oxford). 2013 Jul; 52(7): 1313-22. doi: 10.1093/rheumatology/ket129. Epub 2013 Mar 28. PMID: 23542611).

Epratuzumab remains of interest to the oncology community. In January 2013 we entered into a collaboration agreement with Algeta ASA, or Algeta, for the development of epratuzumab conjugated with Algeta's proprietary thorium-227 alpha-pharmaceutical payload. Under the terms of this agreement, we have manufactured and supplied clinical-grade antibody to Algeta, which has rights to evaluate the potential of a conjugated thorium-227 epratuzumab for the treatment of cancer. Algeta will fund all preclinical and clinical development costs up to the end of Phase I testing. Upon successful completion of Phase I testing, the parties shall negotiate terms for a license agreement at Algeta's request. We have agreed with Algeta to certain parameters to be included in the license agreement.

Epratuzumab has already been studied in several large trials and continues to be studied in diverse clinical trials conducted by outside third parties. Examples of these studies include:

In the United States, the Southwest Oncology Group (SWOG) Study Group has completed a multicenter Phase II trial of epratuzumab combined with chemotherapy (clofaribine and cytarabine) in relapsed adult ALL. The primary objective of this trial is complete remission rate. Initial results from this study were reported at the American Society of Hematology (ASH) 2012 Annual Meeting (Blood, ASH Annual Meeting Abstracts. Nov 2012; 120: 2603).

The Cancer and Leukemia Group B (CALGB) Study Group has completed a Phase II trial of epratuzumab in combination with rituximab in untreated follicular lymphoma patients. Sixty patients were enrolled in this multicenter trial where patients received 8 doses of epratuzumab and rituximab over 9 months. Results from this trial have been published (Cancer. 2013 Aug 6. doi: 10.1002/cncr.28299. Epub ahead of print. PMID: 23922187).

The Diffuse Large B-Cell Lymphoma (DLBCL) study conducted by the NCCTG Study Group received encouraging results from the first part of study with epratuzumab + rituximab + CHOP chemotherapy as upfront therapy (Cancer. 2006 Dec 15;107(12):2826-32). A total of 107 patients were enrolled in the second part of the study, a multicenter Phase II trial. The results, which showed a high rate of durable complete responses, were published in the journal Blood (Blood. 2011 Oct 13; 118(15):4053-4061. doi: 10.1182/blood-2011-02-336990. PMID: 21673350).





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IntreALL Inter-European Study Group: A large multi-center International trial by the IntreALL Inter-European study group is being planned for epratuzumab in combination with chemotherapy in pediatric patients with relapsed acute lymphoblastic leukemia (ALL). Partially funded by the European Commission, this Phase III study will assess the efficacy of this combination therapy using event-free survival as the surrogate for survival as the primary endpoint.

For adult ALL, there are two clinical trials that are ongoing. The MARALL trial, led by St. Bartholomew's Medical Center, London, is a multicenter Phase I/II study conducted in the UK, combining epratuzumab, veltuzumab and chemotherapy in relapsed adult ALL, and is expected to enroll 55 patients.

Sponsored by the French GRAALL Study Group, the CheprALL study is a multicenter Phase II study conducted in France using epratuzumab combined with chemotherapy in adult patients with relapsed ALL, with an estimated enrollment of 55 patients.

### **(Y-90) Clivatuzumab Tetraxetan**

We have completed a Phase Ib trial of Y-90 clivatuzumab tetraxetan administered alone as fractionated, multi-doses, or in combination with low-dose gemcitabine in patients with pancreatic cancer who have received at least 2 prior therapies. Results from this study, presented at the 15<sup>th</sup> World Congress on Gastrointestinal Cancer organized by the European Society of Medical Oncology (Ann Oncol. 2013; 24(suppl 4): iv12. doi: 10.1093/annonc/mdt201.4) and updated at the 2013 Annual Congress of the European Association of Nuclear Medicine, were encouraging. We have decided to proceed with a Phase III clinical trial, positioning clivatuzumab as a therapy for patients with advanced pancreatic cancer relapsed after at least 2 prior treatments. The Company will provide further estimates regarding cash flow requirements and funding once the full Phase III Trial expense estimates have been determined.

We have also completed a Phase I/II, open-label trial of Y-90 clivatuzumab tetraxetan administered as fractionated, multi-doses, in combination with gemcitabine as frontline therapy for patients with Stage III or Stage IV pancreatic cancer. The Phase I portion of this study has been published (Cancer. 2012 Nov 15; 118(22):5497-506. doi: 10.1002/cncr.27592. Epub 2012 May 8. PMID: 22569804). Final results from this study were reported at the June 2012 American Society of Clinical Oncology Annual Meeting (J Clin Oncol. 30, 2012 (suppl; abstr 4043)), and at the 2012 Annual Meeting of the Society of Nuclear Medicine (SNM) (J Nucl Med. 2012; 53 (Supplement 1): 495).

A Phase I dose-escalation, multicenter, trial of Y-90 clivatuzumab tetraxetan given alone in relapsed, advanced pancreatic cancer patients has been published in *Clinical Cancer Research* (Clin Cancer Res. 2011 Jun 15;17(12): 4091-100. doi:10.1158/1078-0432.CCR-10-2579. Epub 2011 Apr 28. PMID: 21527562).

### **Veltuzumab**

The trial in immune thrombocytopenia, conducted by Immunomedics and funded by Takeda-Nycomed, to evaluate alternative dosing schedules has completed patient enrollment. Results from the Phase I portion of this study have been published (Br J Haematol. 2013 Sep; 162(5): 693-701. doi: 10.1111/bjh.12448. Epub 2013 Jul. PMID: 23829485). The study was updated in an oral presentation at the 2012 ASH meeting (Blood, ASJ Annual Meeting Abstracts. Nov 2012; 120:622).

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The SC velutuzumab trial in patients with NHL has been completed and the results have been published (Haematologica. 2011 Apr; 96(4): 567-73. doi: 10.3324/haematol.2010.037390. Epub 2010 Dec 20. PMID: 21173095). For chronic lymphocytic leukemia (CLL), after amending the protocol to evaluate a different dosing schedule, the study is now completed. Results from 18 assessable patients with CLL were presented in an oral presentation at the 2012 ASH Annual Meeting (Blood, ASH Annual Meeting Abstracts. Nov 2012; 120: 192).

### **(Y-90) Epratuzumab Tetraxetan**

We have received funding from the Small Business Innovation Research program of the National Cancer Institute to conduct a multicenter trial examining the combination of Y-90 epratuzumab tetraxetan and velutuzumab in relapsed, aggressive NHL. Initial clinical experience with this combination was reported at the 2012 Annual Meeting of SNM, and was updated at the 54<sup>th</sup> ASH Annual Meeting (Blood, ASH Annual Meeting Abstracts. Nov 2012; 120: 3680).

At the same ASH Annual Meeting, updated results from a multicenter Phase II prospective trial of Y-90 epratuzumab tetraxetan as a consolidation therapy following R-CHOP in elderly patients with diffuse large B-cell lymphoma were reported by the French LYSA study group in an oral presentation (Blood, ASH Annual Meeting Abstracts. Nov 2012; 120: 906).

### **Milatuzumab**

Milatuzumab is being investigated in combination with velutuzumab by our collaborators at the Ohio State University, in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (NHL) after at least one prior therapy. Results from this Phase I/II study were updated at the 2011 ASH Annual Meeting. Patient enrollment for this study is now completed. The milatuzumab+velutuzumab combination has previously demonstrated *in vitro* anti-tumor activity in preclinical studies performed by this group (Blood. 2011 Apr 28; 117(17): 4530-41. doi: 10.1182/blood-2010-08-303354. Epub 2011 Jan 12. PMID: 21228331).

### **Milatuzumab-DOX**

Milatuzumab conjugated with doxorubicin is our first antibody-drug conjugate (ADC) to enter into clinical development, taking advantage of the rapid internalization property of milatuzumab when bound to CD74. The Phase I/II clinical trial of this ADC first enrolled patients with relapsed multiple myeloma and was later expanded to include NHL and CLL. Patient enrollment is completed for multiple myeloma and ongoing for NHL and CLL.

### **IMMU-130**

This is the second agent from our ADC programs which has completed two Phase I clinical trials. IMMY-130 includes SN-38 is the active metabolite of irinotecan, a FDA approved chemotherapeutic. SN-38 cannot be given directly to patients because of its toxicity and poor solubility. By conjugating SN-38 to labetuzumab, our anti-carcinoembryonic antigen antibody (anti-CEACAM 5), the potent drug can be delivered selectively to tumors, thereby selectively targeting the tumors and minimizing damage to normal tissues and organs.

This ADC is in two Phase I dose-escalation expansion trials in heavily-pretreated patients with metastatic colorectal cancer. Initial results from one of the studies using the once-every-2-weeks dosing schedule were reported at the 2013 Annual Meeting of the American Association for Cancer Research (AACR Meeting Abstracts, Apr 2013; 2013: LB-159) and updated at the European Cancer Congress 2013.



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### **IMMU-132**

Our third ADC in clinical development involves our TROP-2 antibody, an internalizing humanized anti-epithelial glycoprotein-1 (EGP-1) antibody and SN-38. TROP-2 is a cell-surface receptor expressed by many human tumors, such as cancers of the breast, cervix, colon and rectum, lung, pancreas, ovary, and prostate, but with only limited expression in normal human tissues.

A Phase II trial examining the safety and tolerability in patients with colorectal, gastric, hepatocellular, bladder, head and neck, prostate, small-cell and non-small-cell lung, breast, pancreatic, esophageal, kidney or ovarian cancer is currently enrolling patients. Results from this study were presented at the 2013 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on October 22, 2013 in Boston, Massachusetts.

A total of 25 patients have been enrolled, with 21 patients having at least 1 CT assessment. Objective partial responses by RECIST 1.0 were observed in 3 patients, or 14% of evaluable patients, with one patient each with colon cancer, triple-negative breast cancer, and small cell lung cancer. Lesser degrees of tumor shrinkage, or disease stabilization, were observed in 15 patients for an 86% overall disease control rate in this population.

### **TF2**

TF2 is an isotope-based pretargeting radioimmunotherapeutic agent for the treatment of solid cancers expressing the carcinoembryonic antigen. This agent is currently in three investigator-sponsored clinical trials in France. The first study is a multicenter Phase I/II trial for pretargeted radioimmunotherapy of patients with CEA-expressing small-cell-lung cancer, while the other two trials are for pretargeted immunoPET imaging of patients with breast or medullary thyroid cancer.

In addition, our collaborators at Radboud University Nijmegen, The Netherlands, have completed a Phase I trial of TF2 in patients with advanced colorectal cancer. Encouraging results from this study were presented at the 2012 Annual Meeting of the Society of Nuclear Medicine. (J Nucl Med. 2012; 53(Supplement 1): 496).

### **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.

#### ***Revenue Recognition***

We have accounted for revenue arrangements that include multiple deliverables as a separate unit of accounting if: a) the delivered item has value to the customer on a standalone basis, and b) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered items is considered probable and substantially in the control of the vendor, in accordance with the accounting standard for multiple-element arrangements. 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 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.



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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 or the product is delivered. Upfront nonrefundable fees associated with license and development agreements where we have continuing obligations in the agreement are recorded as deferred revenue and recognized over the estimated service 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.

***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. We consider all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Investments in marketable securities are available-for-sale to fund operations. The portfolio at September 30, 2013 primarily consists of corporate debt securities and municipal bonds.

***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 6 to our audited financial statements included in our Annual Report on Form 10-K for the year ended June 30, 2013 and Note 5 to our condensed consolidated financial statements in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 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.





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The expected term of the option is based upon the contractual term and expected employee exercise and expected post-vesting employment termination behavior. The expected volatility of the price of the underlying stock is based upon the historical volatility of the Company's stock computed over a period of time equal to the expected term of the option. The risk free interest rate is based upon the implied yields currently available from the U.S. Treasury yield curve in effect at the time of the grant. Pre-vesting forfeiture rates are estimated based upon past voluntary termination behavior and past option forfeitures.

The following table sets forth the weighted-average assumptions used to calculate the fair value of options granted for the three-month periods ended September 30, 2013 and 2012:

	<b>Three-Month Periods Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Expected dividend yield	0%	0.0%
Expected life of options (years)	5.20	5.29
Expected stock price volatility	67%	69%
Risk-free interest rate	1.56%-1.74%	0.98%-1.11%

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

***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, 2013 Compared to 2012******Revenues***

Revenues for the three-month period ended September 30, 2013 were \$5.5 million as compared to \$1.1 million for the three-month period ended September 30, 2012. 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 the previous year. This increase resulted from revenue earned upon fulfilling the Company's obligations under the Algeta ASA Service Agreement, as amended. Product sales for the three-month period ended September 30, 2013 were \$0.6 million as compared to \$0.7 million for the same period in 2012. This decrease resulted primarily from lower sales volume of LeukoScan in Europe as a result of regulatory delays in releasing product for sale that we are in the process of resolving. Research and development revenues for both of the three-month periods ended September 30, 2013 and 2012 were \$0.3 million.



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*Costs and Expenses*

Total costs and expenses for the three-month period ended September 30, 2013 were \$9.9 million as compared to \$8.6 million for the same period in 2012, representing an increase of \$1.3 million or 15%. Research and development expenses for the three-month period ended September 30, 2013 were \$6.7 million as compared to \$7.0 million for the same period in 2012, a decrease of \$0.3 million or 4%. This decrease was primarily due to a \$1.2 million reversal of a previous clinical trial accrual. This decrease was partially offset by the increased costs for the antibody-drug conjugates clinical trials.

Cost of goods sold for both the three-month periods ended September 30, 2013 and 2012 were \$0.1 million. Gross profit margins were 86% for the first quarter of fiscal 2013 as compared to 87% for the first quarter of fiscal 2012. Cost of license fee and other revenues resulted from the recognition of deferred manufacturing costs related to the Algeta service agreement which was completed during the three-month period ended September 30, 2013. Sales and marketing expenses for both of the three-month periods ended September 30, 2013 and 2012 were \$0.2 million. General and administrative expenses were \$1.7 million for the three month period ended September 30, 2013 representing an increase of \$0.4 million or 31% compared to \$1.3 million for the three-month period ended September 30, 2012. This increase is primarily attributable to increased legal expenses incurred as part of arbitration proceedings with Takeda-Nycomed initiated during the three-month period ended September 30, 2013.

*Interest and Other Income*

Interest and other income for the three-month period ended September 30, 2013 was \$6 thousand as compared to \$0.1 million of interest and other income for the three-month period ended September 30, 2012. Included in the interest and other income in the prior fiscal period was \$0.1 million that was recorded as proceeds from an insurance claim for equipment failure during the 2011 fiscal year.

*Foreign Currency Transaction Gain*

Foreign currency transaction gain amounted to \$5 thousand for the three-month period ended September 30, 2013 as compared to a gain of \$30 thousand for the same period in 2012, 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, 2013 was \$4.3 million or \$0.05 per share as compared to a net loss of \$7.4 million or \$0.10 per share for the same period in 2012. The \$3.1 million decrease in the net loss this quarter was primarily due to higher license fee revenue less the cost of license fee and other revenues related to the Algeta agreement.

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**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, 2013 was \$7.3 million as compared to \$7.4 million net cash used in operating activities for the three months ended September 30, 2012.

*Cash flows from investing activities.* Net cash used in investing activities for the three-months ended September 30, 2013 was \$20.2 million compared to \$40 thousand of net cash provided by investing activities for the three months ended September 30, 2012. The increase in cash flow used in investing activities for fiscal 2013 is primarily due to \$20.1 million purchase of marketable securities in the current period.

*Cash flows from financing activities.* Net cash provided by financing activities for the three-month periods ended September 30, 2013 was \$0.8 million compared to \$79 thousand of net cash used in financing activities for the three months ended September 30, 2012. The increase in cash flow during the current period resulted principally from \$0.9 million in proceeds received from the exercise of stock options.

**Working Capital and Cash Requirements**

At September 30, 2013, we had working capital of \$32.2 million, which was approximately \$3.1 million lower than the working capital of \$35.3 million at June 30, 2013. Our cash, cash equivalents and marketable securities amounted to \$34.7 million at September 30, 2013, representing a decrease of \$6.6 million from \$41.3 million at June 30, 2013. The decreases were primarily a result of our use of \$7.3 million of cash in operations.

As of September 30, 2013, we have \$34.7 million of cash, cash equivalents and marketable securities. Based on our expected cash utilization rate, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2014 are expected to be in the \$24.0 - \$26.0 million range, which includes expenses related to our ongoing ADC programs and certain expenses to initiate our anticipated clivatuzumab tetraxetan Phase III clinical trial for the treatment of patients with pancreatic cancer. Our Phase Ib clinical trial of clivatuzumab tetraxetan in patients with advanced pancreatic cancer was completed during the 2013 fiscal year. Based on the encouraging results, we reported at the 15<sup>th</sup> World Congress on Gastrointestinal Cancer and updated at the 2013 Annual Congress of the European Association of Nuclear Medicine, we decided to proceed with a Phase III clinical trial. We will provide further guidance regarding cash flow requirements once the full Phase III Trial estimated expenses have been determined. We recognize that this trial will require additional funding. There can be no assurances that financing will be available when needed on terms acceptable to it, 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.

We plan to continue pursuing sources of financing including, potential payments from partners, (including any cash payment that the Company might receive in connection with a sublicense involving a third party and UCB, which is not within the Company's control), licensing arrangements, grants or other financing sources.

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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 conduct 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, to evaluate 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, we may be subject to legal proceedings and claims. At this time, we are not a party to any legal proceedings, claims or assessments that, in managements opinion, would have a material adverse effect on our business, financial condition or results of operations.



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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, 2013, we had an accumulated deficit of approximately \$233.6 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 agreements with UCB and Takeda-Nycomed. 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.

***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.***

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;



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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 III 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.

***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 downturn in 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.

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Based on our expected cash utilization rate, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2014 are expected to be in the \$24.0 - \$26.0 million range, which includes expenses related to our ADC programs and certain expenses to initiate our anticipated clivatuzumab tetraxetan Phase III clinical trial for the treatment of patients with pancreatic cancer. Our Phase Ib clinical trial of clivatuzumab tetraxetan in patients with advanced pancreatic cancer was completed during the 2013 fiscal year. Based on the encouraging results, we reported at the 15<sup>th</sup> World Congress on Gastrointestinal Cancer and updated at the 2013 Annual Congress of the European Association of Nuclear Medicine, we decided to proceed with a Phase III clinical trial. We will provide further guidance regarding cash flow requirements once the full Phase III Trial estimated expenses have been determined. We recognize that this trial will require additional funding. There can be no assurances that financing will be available when needed on terms acceptable to it, 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.

We plan to continue pursuing sources of financing including, potential payments from partners, (including any cash payment that the Company might receive in connection with a sublicense involving a third party and UCB, which is not within the Company's control), licensing arrangements or other financing sources.

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 conduct 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 United States, Europe and possibly elsewhere;

Our need to establish the manufacturing capabilities necessary to produce the quantities of our product candidates we project we will need;

The time and costs involved in obtaining FDA and foreign regulatory approvals;

The cost of first obtaining, and then defending, our patent claims and other intellectual property rights;

The 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 off-set 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.

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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, or 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. Certain of our contract manufacturers have received Form 483 notices. 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 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.

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***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.

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





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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, Inc. 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 systemic lupus erythematosus. 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.

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

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

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

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

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

We are heavily dependent upon the talents of Dr. 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 NIH 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.

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**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 United States 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 United States 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 the NASDAQ.

If our stock is not accepted for listing on the NASDAQ, we will make every possible effort to have it listed on the Over the Counter Bulletin Board, or 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 Securities and Exchange Commission, or 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.

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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 customer's 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 customer's 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.



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***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.

At November 1, 2013, we had 83,134,280 shares of common stock outstanding, 6,693,060 additional shares reserved for the exercise of outstanding options and restricted stock units 3,672,563 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, 2013, Dr. Goldenberg, our Chairman and 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 10% 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.

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***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 DGCL 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-



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Oxley Act. Compliance with Section 404 requires substantial accounting expense and significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in our internal controls that would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, the NASDAQ GMS or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock.

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

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our 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 our common stock's market price for appreciation.

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**ITEM 6. EXHIBITS**

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

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**SIGNATURES**

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

IMMUNOMEDICS, INC.

November 4, 2013

By: /s/ Cynthia L. Sullivan  
Cynthia L. Sullivan  
President and Chief Executive Officer

(Principal Executive Officer)

November 4, 2013

By: /s/ Peter P. Pfreundschuh  
Peter P. Pfreundschuh  
Vice President, Finance and Chief Financial Officer

(Principal Financial and Accounting Officer)

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<b>Exhibit Number</b>	<b>Description of Document</b>
10.1	Form of Restricted Stock Unit Issuance Agreement (Incorporated by reference to the Current Report filed on August 22, 2013).
10.2	Form of Performance-Based Restricted Stock Unit Issuance Agreement (Incorporated by reference to the Current Report filed on August 22, 2013).
10.3	Separation from Employment Agreement, effective September 3, 2013, by and between the Company and Gerard G. Gorman. *
10.4	Employment Letter, dated August 15, 2013, by and between the Company and Peter Pfreundschuh.*
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, 2013, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.

\* Filed herewith.