

IMMUNOMEDICS INC  
Form 10-Q  
May 10, 2011  
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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 March 31, 2011

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)

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**Delaware** **61-1009366**  
(State or other jurisdiction of **(I.R.S. Employer**  
**incorporation or organization)** **Identification No.)**  
**300 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 definition 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 May 9, 2011 was 75,418,430.

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**IMMUNOMEDICS, INC.**

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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	March 31, 2011 (unaudited)	June 30, 2010 (audited)
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 23,701,723	\$ 29,533,230
Auction rate securities – current		957,000
Accounts receivable, net of allowance for doubtful accounts of \$28,000 at March 31, 2011 and \$52,000 at June 30, 2010	706,063	428,574
Inventory	299,970	534,709
Other receivables	1,120,332	766,441
Prepaid expenses	702,564	449,809
Other current assets	956,237	329,928
Total current assets	27,486,889	32,999,691
Property and equipment, net of accumulated depreciation of \$23,828,000 and \$22,733,000 at March 31, 2011 and June 30, 2010, respectively	3,631,021	4,327,801
Auction rate securities – non current		8,222,154
Value of life insurance policies	565,625	542,463
Other long-term assets	30,000	30,000
Total Assets	\$ 31,713,535	\$ 46,122,109
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,908,735	\$ 4,424,216
Total current liabilities	5,908,735	4,424,216
Other liabilities	1,059,210	979,278
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at March 31, 2011 and June 30, 2010		
Common stock, \$0.01 par value; authorized 110,000,000 shares; issued and outstanding, 75,362,688 shares at March 31, 2011 and 75,296,565 shares at June 30, 2010	753,626	752,965
Capital contributed in excess of par	244,353,349	242,910,779
Treasury stock, at cost, 34,725 shares at March 31, 2011 and at June 30, 2010	(458,370)	(458,370)
Accumulated deficit	(220,178,094)	(202,827,973)
Accumulated other comprehensive income	421,023	341,214
Total Immunomedics, Inc. stockholders' equity	24,891,534	40,718,615
Noncontrolling interest in subsidiary	(145,944)	
Total stockholders' equity	24,745,590	40,718,615
Total Liabilities and Stockholders' Equity	\$ 31,713,535	\$ 46,122,109

See accompanying notes to unaudited condensed consolidated financial statements.



**Table of Contents****IMMUNOMEDICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND****COMPREHENSIVE (LOSS) INCOME**

	Three months ended March 31,		Nine months ended March 31,	
	2011	2010	2011	2010
			(unaudited)	
<b>Revenues:</b>				
Product sales	\$ 848,819	\$ 969,982	\$ 2,707,933	\$ 2,648,181
License fee and other revenues	14,350	8,913,800	89,350	50,685,385
Research and development	233,882	810,905	797,116	1,482,506
<b>Total revenues</b>	<b>1,097,051</b>	<b>10,694,687</b>	<b>3,594,399</b>	<b>54,816,072</b>
<b>Costs and Expenses:</b>				
Costs of goods sold	98,272	681,575	314,547	833,893
Research and development	7,037,847	6,267,987	18,645,166	14,709,765
Sales and marketing	224,013	201,714	582,134	621,163
General and administrative	1,749,453	1,353,735	5,281,204	4,072,397
<b>Total costs and expenses</b>	<b>9,109,585</b>	<b>8,505,011</b>	<b>24,823,051</b>	<b>20,237,218</b>
Operating (loss) income	(8,012,534)	2,189,676	(21,228,652)	34,578,854
Qualifying Therapeutic Discovery Project Program income			2,888,688	
Gain on auction rate securities, net	413,778	204,450	454,428	204,450
Interest and other income	21,379	157,591	485,211	655,800
Foreign currency transaction gain	48,137	44,765	23,393	105,988
(Loss) income before income tax (expense) benefit	(7,529,240)	2,596,482	(17,376,932)	35,545,092
Income tax (expense) benefit	(73,910)	873,243	(119,133)	706,587
<b>Consolidated net (loss) income</b>	<b>(7,603,150)</b>	<b>3,469,725</b>	<b>(17,496,065)</b>	<b>36,251,679</b>
Less net loss attributable to noncontrolling interest	(145,944)		(145,944)	
<b>Net (loss) income attributable to Immunomedics, Inc. stockholders</b>	<b>\$ (7,457,206)</b>	<b>\$ 3,469,725</b>	<b>\$ (17,350,121)</b>	<b>\$ 36,251,679</b>
<b>(Loss) earnings per common share attributable to Immunomedics, Inc. stockholders:</b>				
Basic	\$ (0.10)	\$ 0.05	\$ (0.23)	\$ 0.48
Diluted	\$ (0.10)	\$ 0.05	\$ (0.23)	\$ 0.48
<b>Weighted average shares used to calculate (loss) earnings per common share</b>				
Basic	75,317,976	75,225,668	75,291,963	75,188,779
Diluted	75,317,976	75,757,357	75,291,963	75,817,109
<b>Comprehensive (loss) income:</b>				
<b>Consolidated net (loss) income</b>	<b>\$ (7,603,150)</b>	<b>\$ 3,469,725</b>	<b>\$ (17,496,065)</b>	<b>\$ 36,251,679</b>

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Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustments	169,806	(158,408)	288,505	(136,525)
Unrealized gain on securities available for sale net	(413,778)	(134,551)	(208,696)	
<b>Other comprehensive (loss) income</b>	<b>(243,972)</b>	<b>(292,959)</b>	<b>79,809</b>	<b>(136,525)</b>
<b>Comprehensive (loss) income</b>	<b>\$ (7,847,122)</b>	<b>\$ 3,176,766</b>	<b>\$ (17,416,256)</b>	<b>\$ 36,115,154</b>

See accompanying notes to unaudited condensed consolidated financial statements

**Table of Contents****IMMUNOMEDICS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Nine Months Ended March 31,	
	2011	2010
	(unaudited)	
Cash flows from operating activities:		
Consolidated net (loss) income	\$ (17,496,065)	\$ 36,251,679
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	1,095,223	1,093,079
Amortization of deferred revenue		(45,685,385)
Gain on insurance claim for equipment failure	(251,151)	
Decrease in allowance for doubtful accounts	(24,360)	(23,388)
Increase in inventory reserve		600,000
Impairment charge on auction rate securities		447,417
Amortization of discounts of auction rate securities	(120,114)	(395,144)
Gain on redemption of auction rate securities	(454,428)	(651,867)
Non-cash expense relating to issuance of stock options	1,431,007	1,422,881
Non-cash increase in value of life insurance policy	(23,162)	(32,000)
Amortization of deferred rent	79,932	79,933
Changes in other operating assets and liabilities	233,174	(463,686)
Other	288,505	(136,525)
<b>Net cash used in operating activities</b>	<b>(15,241,439)</b>	<b>(7,493,006)</b>
Cash flows from investing activities:		
Proceeds from sales of auction rate securities	9,545,000	5,620,000
Purchases of property and equipment	(398,443)	(681,633)
Proceeds from insurance claim for equipment failure	251,151	
<b>Net cash provided by investing activities</b>	<b>9,397,708</b>	<b>4,938,367</b>
Cash flows from financing activities:		
Exercise/settlement of stock options, net	12,224	17,937
<b>Net cash provided by financing activities</b>	<b>12,224</b>	<b>17,937</b>
Net decrease in cash and cash equivalents	(5,831,507)	(2,536,702)
Cash and cash equivalents, beginning of period	29,533,230	27,390,778
<b>Cash and cash equivalents, end of period</b>	<b>\$ 23,701,723</b>	<b>\$ 24,854,076</b>

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, 2010, which contains our audited consolidated financial statements and the notes thereto.

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

Immunomedics, Inc. is a biopharmaceutical company focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has transitioned its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company manufactures and commercializes its LeukoScan® product in territories where regulatory approvals have previously been granted. LeukoScan is indicated for diagnostic imaging for determining the location and extent of infection/inflammation in bone in patients with suspected osteomyelitis, including patients with diabetic foot ulcers. The Company has two foreign subsidiaries, Immunomedics B.V. in the Netherlands and Immunomedics GmbH in Darmstadt, Germany, 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 majority-owned subsidiaries, have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and the instructions to the Quarterly Report on Form 10-Q and Rule 10-01 of 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 balance sheet at June 30, 2010 has been derived from the Company's audited fiscal 2010 consolidated financial statements. Operating results for the three and nine-month periods ended March 31, 2011 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2011, or any other period.

Immunomedics is subject to significant risks and uncertainties, including, without limitation, 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 the Company may be unable to successfully obtain financing for product development; 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

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technologies and regulations in the United States and internationally. For more details regarding such risks and uncertainties please refer to the section entitled Item 1A Risk Factors included in this Quarterly Report on Form 10-Q.

As of March 31, 2011, the Company has \$23.7 million of unrestricted cash and cash equivalents. Based on the Company's historical cash utilization rate, the Company believes it has sufficient funds to continue its operations and research and development programs for at least the next twelve months. The use of funds during the 2011 fiscal year has been at a higher rate than previous years, primarily due to increased spending for legal professional services. The Company is evaluating plans to initiate a Phase III registration trial of veltuzumab in non-Hodgkin's lymphoma and a Phase III registration trial of clivatuzumab in pancreatic cancer. The Company will need to secure additional funding to advance veltuzumab and clivatuzumab into these Phase III trials. The Company does not believe, as currently funded, it will have adequate cash on hand to complete its pipeline of research and development programs in accordance with its corporate strategy. Immunomedics is actively considering financing alternatives to fund these programs as market conditions permit, potentially through equity or debt financings and through collaborative agreements. The Company continues to evaluate various financing options to raise additional capital and to seek additional revenues from the licensing of its proprietary technologies.

Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of debt and equity securities and revenues from licensing agreements. There can be no assurance that Immunomedics will be able to raise the additional capital it will need on commercially acceptable terms, if at all. If the Company is unable to raise capital on acceptable terms or enter into new licensing agreements, its ability to continue its business will be materially and adversely affected.

## **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, 2010. 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 majority-owned 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.

### ***Correction of a Prior Period Error***

During the third quarter of fiscal year 2011, the Company corrected an error in its condensed consolidated financial statements regarding the financial reporting for noncontrolling interests related to its IBC Pharmaceuticals Inc. subsidiary in its consolidated financial statements. Beginning July 1, 2009, the Company's consolidated financial statements did not report the net loss incurred by noncontrolling interest, which should have been specifically identified in the balance sheet, statement of operations and the statement of changes in stockholders' equity. The amounts related to errors identified in the financial reporting resulted in an immaterial understatement of net income attributable to common stockholders during the fiscal year ended June 30, 2010, and an immaterial overstatement in net loss attributable to common stockholders for the six month period ended December 31, 2010. Since the Company determined

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that the errors were not material to the consolidated financial statements in the periods in which they originated or the period in which they were corrected, the Company recorded the total correction of \$0.1 million during the three-month period ended March 31, 2011.

***Revenue Recognition***

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC 605. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this amendment did not have a material impact on its condensed consolidated financial statements. The Company concluded that the License and Collaboration Agreement with Nycomed GmbH, or the Nycomed Agreement, and the Development, Collaboration and License Agreement dated May 9, 2006 with UCB, S.A., or the UCB Agreement, should be each accounted for as a single unit of accounting. Under the single unit of accounting method, for purposes of revenue recognition the revenue is deferred and amortized over the obligation period.

The Company amortized the \$40.0 million payment received as part of the Nycomed Agreement through March 2010, which was when the Company fulfilled its obligations associated with the upfront fees under this agreement, and accordingly an aggregate of \$40.0 million has been recorded as revenue, of which \$14.5 million was recorded in the nine-month period ended March 31, 2010.

The Company also concluded that the \$38.0 million payment received from UCB should be amortized over the expected obligation period of the UCB Agreement. In August 2009, UCB relieved the Company of its remaining obligation to supply UCB with any further supplies. Therefore, as its last obligation under the agreement was legally terminated, the Company amortized the remainder of the upfront payment (\$31.1 million) received from UCB as revenue in the first quarter of the 2010 fiscal year.

Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there is no continuing performance obligations associated with the milestone payment.

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through collaborative development are deferred and recognized as revenue over the period of continuing involvement. The Company estimates the period of continuing involvement based on the best available evidential matter available to it at each reporting period. If its estimated time frame for continuing involvement changes, this change in estimate could impact the amount of revenue recognized in future periods.

Payments received under contracts to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed. Upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement are

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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.

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

Revenue from product sales is recorded when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable and collectability is reasonably assured. Allowances, if any, are established for uncollectible amounts based on historical trends, 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. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

**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 sheet as of March 31, 2011 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.

	As of March 31, 2011			Total
	Level 1	Level 2	Level 3	
Money Market Funds	\$ 20,291	\$	\$	\$ 20,291
Total	\$ 20,291	\$	\$	\$ 20,291

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

The following is a reconciliation of the beginning and ending balances of the financial assets categorized as Level 3 in the table above (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction Rate Securities
Beginning balance at June 30, 2010	\$ 8,222
Total gains (realized or unrealized, net):	
Included in earnings	454
Included in other comprehensive income	
Settlements	
Transfers out of Level 3 (sold during 2011)	(8,676)
Ending balance at March 31, 2011	\$

**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.

**Inventory**

Inventory, which consists of the finished product of LeukoScan, is stated at the lower of average cost (which approximates first-in, first-out) or market, and includes materials, labor and manufacturing overhead. An inventory reserve is recorded for finished product that is not deemed to be saleable, if necessary. During the 2010 fiscal year, the Company's standard quality control testing procedures for certain batches of LeukoScan inventory (total value of \$0.6 million) did not meet the Company's quality control standards. The Company therefore established an inventory reserve for this specific LeukoScan inventory.

Inventory consisted of the following (in thousands):

	March 31, 2011	June 30, 2010
Work in process	\$	\$ 1,112
Finished goods	900	23
Reserve for obsolescence	(600)	(600)
	\$ 300	\$ 535

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### ***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.

Benefits received resulting from the sale of certain of our State of New Jersey Net Operating Losses ( NOL ) are recognized as a tax benefit when the NOL is approved for sale by the State of New Jersey and collectability is reasonably assured. During the three month and nine-month periods ended March 31, 2010, the Company sold and received benefits of approximately \$1.1 million as a result of the State of New Jersey NOLs. No benefits were sold during the three and nine-month periods ended March 31, 2011. For the three and nine-month periods ended March 31, 2011, U.S. taxes of \$65,000 and were provided for, net of the utilization of deferred tax assets and the valuation allowance recorded upon it. For the three and nine-month periods ended March 31, 2010, U.S. taxes of \$72,000 and \$122,000 were provided for, net of the utilization of deferred tax assets and the valuation allowance recorded upon it.

Income taxes were provided for profitable foreign jurisdictions at the applicable effective tax rate during the three and nine-month periods ended March 31, 2011 and 2010. The income (benefit) provision for foreign jurisdictions for the three and nine-month periods ended March 31, 2011 includes \$9,000 and \$54,000 respectively, for activities resulting from taxable foreign entities, as compared to \$89,000 and \$206,000 for the three and nine month periods ended March 31, 2010, respectively.

### ***Net (Loss) Income Per Share Allocable to Common Stockholders***

Basic net (loss) income per share is based upon the number of weighted average number of shares of common stock and vested shares outstanding. For the three and nine-month periods ended March 31, 2011 the diluted net loss per common share is calculated based on the weighted average number of shares outstanding excluding the exercise or conversion of all potential common shares because their effect would have been anti-dilutive, due to the net loss recorded. For the three and nine-month periods ended March 31, 2010, diluted net income per share is based upon the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding. Potential shares of common stock result from the assumed exercise of outstanding stock options, with exercise prices less than the average market price of the Company's common stock during the three and nine month periods ended March 31, 2011 and 2010, calculated under the treasury stock method.

### ***Comprehensive (Loss) Income***

Comprehensive (loss) income consists of net (loss)/income, net unrealized (losses)/gains on securities available for sale and foreign exchange translation adjustments and is presented in the Condensed Consolidated Statements of Operations and Comprehensive Income.

### ***Qualifying Therapeutic Discovery Project Program***

On October 29, 2010, the Company was notified that it had been awarded a total cash grant of approximately \$2.9 million under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, of which approximately \$2.5

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million relates to qualifying expenses the Company had previously incurred during the 2010 fiscal year which was received during the second quarter of fiscal 2011. The remainder of the grant of approximately \$0.4 million will be received during the first quarter of fiscal 2012 based on qualifying expenses the Company has incurred during the 2011 fiscal year. The Company recognized the full \$2.9 million of the grant as of the date of notification since the Company has already incurred all of the qualifying expenses. Since this program is non-recurring in nature, the Company elected to classify this payment as other income in the Condensed Consolidated Statements of Operations for the nine-month period ended March 31, 2011.

***Recently Issued Accounting Pronouncement***

There have been no recently issued accounting pronouncements not adopted by the Company that are expected to have a significant impact on the Company in the future.

**3. Auction Rate Securities**

Immunomedics securities for which there is not the positive intent and ability to hold to maturity 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 classified as a separate component of accumulated other comprehensive loss. Immunomedics considered all of its investments to be available-for-sale. Auction rate securities ( ARS ) at March 31, 2011 and June 30, 2010 consist of the following (\$ in thousands):

	Adjusted Cost Basis	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
<b><u>March 31, 2011</u></b>				
Auction Rate Securities	\$	\$	\$	\$
	\$	\$	\$	\$
<b><u>June 30, 2010</u></b>				
Auction Rate Securities	\$ 8,970	\$ 209	\$	\$ 9,179
	\$ 8,970	\$ 209	\$	\$ 9,179

ARS are debt instruments that represent investments in pools of assets. These ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. ARS that were held had long-term scheduled maturities, ranging from 2042 to 2045, but with interest rates that are typically reset at pre-determined intervals (every 28 days for the securities purchased by the Company), at which time the securities can typically be purchased or sold, creating a liquid market. When there is an active market for such investments, the reset rate for each instrument is an opportunity to accept the rates that reset or sell the instrument at its face value in order to seek an alternative investment. In the past, the auction process has allowed investors to roll over their holdings or obtain immediate liquidity by selling the securities at par. During fiscal 2008, the auctions failed and have not settled in an active market since that time.

The ARS that were held were AAA rated collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and backed by insurance companies. There are no ARS securities held by the Company as of March 31, 2011.

During the three and nine-month periods ended March 31, 2011, the Company sold its remaining ARS for \$8.6 million and \$9.6 million, respectively, to brokers in the secondary market,

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resulting in realized gains of \$0.4 million and \$0.5 million, respectively.

During the three and nine-month periods ended March 31, 2011, the Company reported no interest and \$0.1 million, respectively, as interest income for the recognition of a portion of the market value discount of the ARS, as compared to \$0.1 million and \$0.4 million, respectively, for the three and nine-month periods ended March 31, 2010.

**4. Stock Incentive Plan**

A summary of the 2006 Stock Incentive Plan, as amended (the Plan), is provided in Note 7 to the audited financial statements contained in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010. The Company believes that such awards better align the interests of its employees with those of its shareholders. 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 7-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 7-year contractual terms. Under the plan at March 31, 2011, there were 11,309,290 shares of common stock authorized for issuance, which was comprised of 3,678,475 shares of common stock previously available under the 2002 Employee Share Option Plan (the 2002 Plan) and an additional 7,630,815 shares of common stock under the 2006 Plan. At March 31, 2011, 4,735,857 stock options were still available for future grant and shares of common stock were reserved for possible future issuance upon exercise of stock options both currently outstanding and which may be issued in the future.

The fair value of each option granted during the nine-month periods ended March 31, 2011 and 2010 is estimated on the date of grant using the Black-Scholes option-pricing model with the weighted-average assumptions in the following table:

	Nine-month periods ended	
	March 31,	
	2011	2010
Expected dividend yield	0%	0%
Expected option term (years)	5.42	5.78
Expected stock price volatility	88%	92%
Risk-free interest rate	2.33% - 2.76%	2.80% - 3.32%

The weighted average fair value at the date of grant for options granted during the nine-month periods ended March 31, 2011 and 2010 were \$2.33 and \$2.60 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. Expected stock price volatility was calculated based on ten-year 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.



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Information concerning options for the nine-month period ended March 31, 2011 is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding, July 1, 2010	6,225,621	\$ 5.80		
Granted	547,000	\$ 3.27		
Exercised	(4,688)	\$ 2.61		
Cancelled or forfeited	(365,750)	\$ 14.70		
Outstanding, March 31, 2011	6,402,183	\$ 5.08	3.77	\$ 4,141,471
Exercisable, March 31, 2011	4,894,095	\$ 5.71	3.22	\$ 2,936,418

The Company has 1,508,088 non-vested options outstanding as of March 31, 2011. As of March 31, 2011, there was \$3.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is being recognized over a weighted-average period of 2.48 years. The Company recorded \$0.5 million and \$1.4 million for stock-based compensation expense for the three and nine-month periods ended March 31, 2011, respectively, as well as for the three and nine-month periods ended March 31, 2010.

As part of the Plan, on the date of each annual stockholder meeting, each non-employee Board member who continues to serve as a non-employee Board member shall automatically be granted restricted stock units covering not more than an additional 5,000 shares of common stock provided such individual has served as a non-employee Board member for a period of at least three months. The Company recorded stock-based compensation expense for these non-employee Board members restricted stock units of \$21,000 and \$53,000 for the three and nine-month periods ended March 31, 2011, respectively, as compared to \$23,000 and \$47,000 for the three and nine-month periods ended March 31, 2010, respectively.

A summary of the Company's non-vested restricted stock units at July 1, 2010, and changes during the nine-month period ended March 31, 2011 is presented below:

Outstanding Non-Vested Restricted Stock Units	Number of Awards
Non-vested at July 1, 2010	233,542
Granted	25,000
Vested/Exercised	(82,292)
Forfeited	(5,000)
Non-vested at March 31, 2011	171,250

**5. Earnings Per Share**

Per share data is based on the weighted average outstanding number of shares of the Company's common stock during the relevant period. Basic (loss) earnings per share are calculated using the weighted average number of outstanding shares of common stock. Diluted (loss) earnings per share computations, as calculated under the treasury stock method, include the weighted average number of shares of additional outstanding common stock issuable for stock options and restricted stock whether or not currently exercisable. Diluted (loss) earnings per share for all the periods presented do not include securities if their effect was antidilutive (in thousands, except per share amounts).



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	Three Months Ended March 31,		Nine Months Ended March 31,	
	2011	2010	2011	2010
Net (loss) income attributable to Immunomedics, Inc. shareholders	\$ (7,457)	\$ 3,470	\$ (17,350)	\$ 36,252
<b>Basic (loss) earnings per share:</b>				
Weighted average basic common shares outstanding	75,318	75,226	75,292	75,189
Basic (loss) earnings per share attributable to Immunomedics, Inc. shareholders	\$ (0.10)	\$ 0.05	\$ (0.23)	\$ 0.48
<b>Diluted (loss) earnings per share:</b>				
Weighted average basic common shares outstanding	75,318	75,226	75,292	75,189
Dilutive effect of stock options outstanding		430		503
Dilutive effect of restricted stock		101		125
Weighted average diluted common shares outstanding	75,318	75,757	75,292	75,817
Diluted (loss) earnings per share	\$ (0.10)	\$ 0.05	\$ (0.23)	\$ 0.48
Stock options excluded from the weighted average dilutive common shares outstanding because their inclusion would have been antidilutive	5,964	5,935	5,993	5,862
Restricted stock units excluded from the weighted average dilutive common shares outstanding because their inclusion would have been antidilutive	116	181	110	158

**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 markets outside the United States.

The following table presents financial information based on the geographic location of the facilities of Immunomedics for the three and nine-months ended March 31, 2011 and 2010 (\$ in thousands):

	Three Months Ended March 31, 2011		
	United States	Europe	Total
Total assets	\$ 28,723	\$ 2,991	\$ 31,714
Property and equipment, net	3,630	1	3,631
Revenues	251	846	1,097
(Loss) income before taxes	(7,596)	67	(7,529)

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	<b>Three Months Ended March 31, 2010</b>		
	United States	Europe	Total
Total assets	\$ 42,373	\$ 2,658	\$ 45,031
Property and equipment, net	4,666	2	4,668
Revenues	9,728	967	10,695
Income before taxes	2,266	330	2,596

  

	<b>Nine-Months Ended March 31, 2011</b>		
	United States	Europe	Total
Revenues	\$ 898	\$ 2,696	\$ 3,594
(Loss) income before taxes	(17,655)	278	(17,377)

  

	<b>Nine-Months Ended March 31, 2010</b>		
	United States	Europe	Total
Revenues	\$ 52,186	\$ 2,630	\$ 54,816
Income before taxes	34,758	787	35,545

**7. Related Party Transactions**

Certain of the Company's affiliates, including members of 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, and certain companies with which the Company does business, including the Center for Molecular Medicine and Immunology, or CMMI, and the Company's majority-owned subsidiary, IBC Pharmaceuticals, Inc., or IBC. Dr. Goldenberg and Ms. Sullivan are husband and wife. For a description of these relationships and transactions, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and the notes to the audited financial statements contained therein.

The Company reimbursed CMMI for expenses incurred on behalf of Immunomedics, including amounts incurred pursuant to research contracts, in the amount of approximately \$0.1 million and \$0.2 million for the three and nine-month periods ended March 31, 2011, respectively, as compared to \$0.1 million and \$0.4 million, respectively, for the three and nine-month periods ended March 31, 2010. The Company also provides to CMMI, at no cost, laboratory materials and supplies. The Company leases approximately 1,400 square feet of the Immunomedics Morris Plains, NJ facility to CMMI, at a cost of \$3,700 per month, (which approximates fair market value). The Company has entered into an agreement with CMMI for certain general services as part of their occupancy, for which CMMI has been charged \$8,000 for these services through March 31, 2011. The Company incurred legal expenses on behalf of CMMI for patent related matters for the three and nine-month periods ended March 31, 2011 of \$18,000 and \$45,000, respectively, as compared to \$13,000 and \$43,000 for the three and nine-month periods ended March 31, 2010, respectively. The Company has first rights to license those patents and may decide whether or not to support

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them. However, any inventions made independently of the Company at CMMI are the property of CMMI.

For each of the three and nine-month periods ended March 31, 2011 and 2010, Dr. Goldenberg received \$13,750 and \$41,250, respectively, in compensation for his services to IBC.

The Company has a Second 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 June 30, 2011. This agreement covers aspects of his compensation as well as duties and responsibilities of his employment at Immunomedics. For a description of the Goldenberg Agreement see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and the notes to the audited financial statements contained therein.

As part of the Goldenberg Agreement, Dr. Goldenberg is eligible to receive certain additional incentive compensation during the agreement term as described in the notes to the audited financial statements, 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.

Under the terms of the Goldenberg Agreement, the Company makes a minimum payment of \$150,000 to Dr. Goldenberg during each of the fiscal years during the Goldenberg Agreement, payable in equal quarterly payments, as an advance against the amounts due as additional incentive compensation, royalty payments and dispositions of undeveloped assets. For the three and nine-month periods ended March 31, 2011, no additional incentive compensation payment was made to Dr. Goldenberg other than the \$37,500 minimum quarterly payments. During the nine-month-period ended March 31, 2010, in accordance with the terms of the Goldenberg Agreement, the Company accrued \$0.7 million for additional incentive compensation for Dr. Goldenberg due to the Company's profitability for the 2010 fiscal year. The additional incentive compensation was the result of the recognition of deferred revenues resulting from the UCB and Nycomed agreements.

## **8. License Agreements Nycomed GmbH**

On July 11, 2008, the Company entered into a License and Collaboration Agreement (the Nycomed Agreement) with Nycomed GmbH (Nycomed) providing Nycomed a worldwide license to develop, manufacture and commercialize veltuzumab, the Company's humanized anti-CD20 antibody, veltuzumab in the subcutaneous formulation, for the treatment of all non-cancer indications. The Company retains the rights to develop, manufacture and commercialize veltuzumab in the field of oncology.

Under the terms of the Nycomed Agreement, Immunomedics received a non-refundable initial cash payment of \$40.0 million on August 21, 2008. Immunomedics could also receive potential cash milestone payments of up to \$580.0 million. The Company will also receive an escalating double digit royalty based on annual net sales, if any, by Nycomed, its affiliates or sublicenses under the Nycomed Agreement during the royalty term. There can be no assurance

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that the clinical, regulatory or sales milestones will be met and therefore there can be no assurance that the Company will receive any future payments.

As the Company had continuing obligations under the Nycomed Agreement, the Company recorded the \$40 million non-refundable payment as deferred revenue and the Company recognized this amount through March 2010, when the Company fulfilled its obligations under the Nycomed Agreement. For the three and nine-month periods ended March 31, 2010, the Company recognized \$3.9 million and \$14.5 million as License Fee Revenue.

Nycomed is 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 Nycomed for the quantity of materials for the period of time specified in the Nycomed Agreement. The Company completed its manufacturing and supply obligations and its responsibilities in the Phase I/II study in immune thrombocytopenic purpura, or ITP during the 2010 fiscal year.

Nycomed has subsequently requested additional services beyond what the Company was obligated to perform and the reimbursement of these services are recognized as a reduction of research and development expenses. The Company billed Nycomed \$0.1 million and \$1.6 million for the three and nine-month periods ended March 31, 2011, respectively, as compared to \$0.8 million and \$5.1 million for the three and nine-month periods ended March 31, 2010, respectively. These services are not expected to continue subsequent to the end of the 2011 fiscal year.

**UCB, S.A.**

On May 9, 2006, the Company entered into an agreement with UCB, S.A., the UCB Agreement, providing UCB an exclusive worldwide license to develop, manufacture, market and sell epratuzumab for the treatment of all autoimmune disease indications. Under the terms of the UCB Agreement, the Company received from UCB a non-refundable cash payment totaling \$38.0 million. The Company recorded the \$38.0 million non-refundable payment as deferred revenue and was to amortize the \$38.0 million payment received over the expected obligation period, originally estimated to end in November 2009. For a description of this agreement and related transactions, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and the notes to the audited financial statements contained therein.

Immunomedics received a letter dated July 30, 2009 from UCB stating that UCB has relieved the Company of its remaining obligation under the UCB Agreement, to supply UCB with additional epratuzumab if requested. As this was the only obligation remaining for Immunomedics under the terms of the UCB Agreement, the Company recorded the \$31.1 million deferred revenue under the UCB Agreement as licensing fee revenue during the nine-month period ended March 31, 2010.

**9. Commitments and Contingencies**

***Employment Contracts***

On June 28, 2007, the Amended and Restated Employment Agreement with Dr. Goldenberg was executed and continues for the period through June 30, 2011. As part of this agreement a \$150,000 annual minimum payment is paid in the aggregate against all Revenue Incentive Compensation and Royalty Payments. The Amended and Restated Employment Agreement with Dr. Goldenberg was later amended and restated by Amendment No.1 to the

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Second Amended and Restated Employment Agreement, dated January 31, 2008 and the Second Amended and Restated Employment Agreement, dated December 17, 2008.

On June 15, 2010, the Company and Cynthia L. Sullivan entered into the Third Amended and Restated Employment Agreement pertaining to Ms. Sullivan's service as the Company's President and Chief Executive Officer. The Amended Sullivan Agreement (scheduled to terminate on December 31, 2010), was automatically extended for one year, and will automatically be extended for successive one-year periods unless either the Company or Ms. Sullivan provides a written notice at least 90 days preceding the date of any such extension.

For more information regarding employment contracts, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and the notes to the audited financial statements contained therein.

***Legal Matters***

*Former Investment Advisor/Broker*

On April 15, 2009, the Company initiated an arbitration proceeding before the Financial Industry Regulatory Authority (FINRA) against its former investment advisor/broker, Banc of America Investment Services, Inc. and Banc of America Securities, LLC. In the arbitration, the Company claims that the respondents violated the New Jersey Uniform Securities Law, the North Carolina Securities Act, and certain FINRA rules by, among other things, making false representations and/or material omissions concerning auction rate securities, inappropriately advising investment in auction rate securities, and failing to supervise their employees. The Company continues to seek relief pursuant to the New Jersey Uniform Securities Law and the North Carolina Securities Act for the difference between the par value of its ARS and the amount it received when it sold the ARS on the secondary market, (\$2.9 million). Also, the Company continues to seek consequential damages, punitive damages, and other relief. The FINRA arbitration hearing in this matter began in September 2010 and is scheduled to resume in June 2011.

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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 similar substance used in 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 or to any person authorized to act on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

#### **Overview**

Immunomedics is a 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 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 believe that our portfolio of intellectual property, which includes approximately 173 issued patents in the United States, and more than 400 other issued patents worldwide, 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 March 31, 2011, we employed 17 professionals in our research and development departments and 22 professionals in our pre-clinical and clinical research departments. In addition to salaries and benefits, the other costs associated with research and development include the costs associated with producing biopharmaceutical compounds, laboratory equipment and supplies, the costs of conducting clinical trials, legal fees and expenses associated with pursuing patent protection, as well as facilities costs.

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

## **Clinical Pipeline Update**

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

### **Epratuzumab**

Phase III Randomized Trials in Moderate-Severe Lupus:

UCB: Two Phase III studies of epratuzumab are underway in patients with systemic lupus erythematosus (SLE). These are multicenter, placebo-controlled, randomized, double-blind

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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. Enrollment started at the end of 2010. Each study will last a maximum of 54 weeks and will randomize 780 patients in the study, with approximately 130 planned investigational sites per study.

Epratuzumab remains of interest to the oncology community, and is being studied in diverse clinical trials including the following:

**CALGB Study Group:** Patient follow-up continues for the fully-enrolled trial with 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. Encouraging results were presented at the American Society of Hematology 2010 meeting (ASH Annual Meeting Abstracts; 2010 116:427), which showed an 84% overall response rate with durable complete responses.

**COG Study Group:** The initial results based on complete response rates (CR) in relapsed pediatric ALL are now available. This clinical trial enrolled a total of 128 patients, with 12 patients enrolled in the initial feasibility/Phase 1 portion and 116 patients in the follow-on Phase 2 portion, where the first 56 patients were treated using a once-weekly dosing schedule of epratuzumab and the subsequent 60 patients treated using a twice-weekly dosing schedule (as in the Phase 1 portion), in combination with chemotherapy. The primary efficacy focus of the study was to assess complete response rate in the last group. Relying on this endpoint (without pending results related to minimal residual disease measurements or survival), it was concluded that the study did not provide adequate evidence to show any additional benefit by combining epratuzumab with the repeated multiple blocks of intense chemotherapy used in this study. Hence, the study was deemed not to have met its expected primary efficacy endpoint. There were no new adverse safety signals identified in this trial.

A second study of epratuzumab combined with chemotherapy in relapsed pediatric ALL patients is being planned as a multi-center European trial by the IntraALL Inter-European study group. In contrast to the COG study, epratuzumab may be included in this very large (400 patients), randomized, trial to evaluate its role in combination with chemotherapy in the treatment of relapsed pediatric ALL, but not relying on CR rates. This study will assess the efficacy of this combination therapy using event-free survival as the surrogate for survival as the primary endpoint. This trial will be partially funded by the European Commission.

The Diffuse Large B-Cell Lymphoma (DLBCL) study conducted the North Central Cancer Treatment Group of the NCI received encouraging results for upfront therapy of DLBCL with epratuzumab + rituximab + CHOP chemotherapy. We are discussing the possibility of an NCI study group conducting a randomized Phase II/III trial comparing E+R+CHOP to R+CHOP. A total of 107 patients were enrolled in the multicenter Phase II trial. The results, which showed a high rate of durable complete responses, were presented at the 2009 annual meeting of ASCO, and are expected to be published in 2011.

MARALL trial, led by St. Bartholomew's Medical Center, London, is an ongoing, multicenter Phase II study being conducted in the UK, using epratuzumab and veltuzumab combined with chemotherapy in relapsed adult ALL, which is expected to enroll 30 patients.

The GRAALL CheprALL study is an ongoing, multicenter, study being conducted in France and sponsored by the GRAALL study group in adult patients with relapsed ALL, using epratuzumab combined with chemotherapy (Hyper-CVAD).

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The SWOG Study Group is conducting a multicenter trial in relapsed adult ALL using epratuzumab combined with chemotherapy (clofaribine and cytarabine). The primary objective is CR rate.

### **Y-90-Epratuzumab**

The Company reported the results of a multicenter Phase I/II trial in the August 2010 issue of *Journal of Clinical Oncology*, showing high rates of durable complete responses in patients with relapsed NHL.

GOELAMS Study of <sup>90</sup>Y-epratuzumab as a consolidation therapy in aggressive NHL: This multicenter Phase II study in France is completing accrual of 75 patients with DLBCL who received radiolabeled epratuzumab as a consolidation therapy after R-CHOP. Encouraging interim efficacy results will be presented at the meeting of the Society of Nuclear Medicine in June, 2011.

The Weill Cornell Medical College-NY Presbyterian Medical Center, New York is conducting a study of <sup>90</sup>Y-epratuzumab combined with veltuzumab in relapsed/refractory follicular lymphoma. This is a small, NCI grant-funded study awarded to this institution, and is currently enrolling patients.

Immunomedics is conducting a NCI-funded multicenter trial examining the combination of <sup>90</sup>Y-epratuzumab + veltuzumab in relapsed, aggressive, NHL, and is anticipated to enroll up to 70 patients. This trial is ongoing.

### **Epratuzumab-SN-38**

The Company has developed an antibody-drug conjugate consisting of epratuzumab conjugated with the principal metabolite of irinotecan, SN-38. It reported excellent preclinical efficacy and safety results in several lymphoma/leukemia preclinical models at the recent annual 2010 meeting of the American Association for Cancer Research and has been submitted for publication.

### **Veltuzumab**

Autoimmune Disease Indications: Nycomed continues plans for their Phase II dose-ranging study of subcutaneous (SC) veltuzumab in rheumatoid arthritis. The first patient is anticipated to be enrolled during the first half of calendar year 2011. The current ITP trial run by Immunomedics, funded by Nycomed, is continuing patient enrollment to evaluate alternative dosing schedules.

Non-Hodgkin's lymphoma Indications: The Company is evaluating plans to initiate a Phase III registration trial for veltuzumab in non-Hodgkin's lymphoma. The Company will need to secure additional funding to advance veltuzumab into Phase III.

Oncology Indications: The SC veltuzumab trial has been completed. The results have been published. The study in CLL is continuing after being amended to evaluate a different dosing schedule.

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### **<sup>90</sup>Y-hPAM4 (clivatuzumab tetraxetan)**

The phase II study of <sup>90</sup>Y-PAM4 continues with a recent amendment allowing greater flexibility to evaluate repeated dosing cycles. Study results from the initial cohort of 42 patients treated with low-dose gemcitabine are currently being summarized for publication. An update on this clinical trial will be reported as an oral presentation at the June 2011 Society of Nuclear Medicine meeting. The Phase I dose-escalation, multicenter, trial of <sup>90</sup>Y-clivatuzumab tetraxetan given alone in relapsed, advanced pancreatic cancer patients is in press in *Clinical Cancer Research*.

Plans for Phase III trials continue after discussion with the FDA in January for conducting two study designs proposed for registration trials. A meeting with potential investigators is scheduled in Chicago, preceding the American Society of Clinical Oncology (ASCO) meeting, to seek their input and recommendations on our registration trial plans. The Company will require additional funding after it utilizes its current liquid assets in order to continue these Phase III trials as is currently planned for the next year.

### **Milatuzumab**

Early phase trials of milatuzumab in CLL and NHL are continuing patient accrual.

Veltuzumab plus Milatuzumab Update: An Ohio State University study of this combination for treatment of follicular NHL is continuing, with encouraging results presented in December 2010 at ASH. A preclinical study of the combination of milatuzumab with rituximab was published by this group online in *Blood* on January 10, 2011, and the print version is in press.

### **Milatuzumab-DOX**

A Phase I clinical trial of this drug conjugate is underway, currently enrolling patients with advanced multiple myeloma at several study sites. Hematologic toxicity was encountered at initial dose levels during the first few treatment cycles. The protocol was revised with an alternative dosing schedule intended to allow administration of multiple treatment cycles, but no patients have yet been enrolled.

### **IMMU-130 (labetuzumab-SN-38)**

The IND for studies with this new drug conjugate in colorectal cancer was accepted by FDA. We plan to conduct this study at the Memorial Sloan-Kettering Cancer Center, and it is anticipated to begin patient accrual this coming summer.

### **TF2**

TF2 is a Y-90-based pretargeting radioimmunotherapy for the treatment of solid cancers expressing the CEA antigen. The Garden State Cancer Center (GSCC) initially obtained an IND from the FDA to conduct an initial therapy clinical study of TF2 in patients with metastatic colorectal cancer. GSCC recently transferred the IND and responsibilities for conducting all TF2 studies over to Immunomedics. The initial study is currently being opened at several US investigational sites and enrollment is anticipated to begin this summer.

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### **Critical Accounting Policies**

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, 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***

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC 605. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon our estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this amendment did not have a material impact on our condensed consolidated financial statements. We concluded that the License and Collaboration Agreement, or the Nycomed Agreement, with Nycomed GmbH, and the Development, Collaboration and License Agreement dated May 9, 2006 with UCB, S.A., or the UCB Agreement, should each be accounted for as a single unit of accounting. Under the single unit of accounting method, for purposes of revenue recognition the revenue is deferred and amortized over the obligation period.

We amortized the \$40.0 million payment received as part of the Nycomed Agreement through March 2010, which was when we fulfilled our obligations associated with the upfront fees under the agreement, and accordingly, an aggregate of \$40.0 million has been recorded as revenue.

We also concluded that the \$38.0 million payment received from UCB should be amortized over the expected obligation period of the UCB Agreement. In August 2009, we were relieved by UCB of our remaining obligation to supply UCB with any further supplies. Therefore, as our last obligation under the agreement was legally terminated, we amortized the remainder of the upfront payment (\$31.1 million) received from UCB as revenue in the first quarter of the 2010 fiscal year.

Milestone payments are recognized as revenue upon the achievement of mutually agreed milestones, provided that (i) the milestone event is substantive and its achievement is not reasonably assured at the inception of the agreement, and (ii) there is no continuing performance obligations associated with the milestone payment.

Contract revenue from collaborative research agreements is recorded when earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees and certain guaranteed payments where we continue involvement through collaborative development are deferred and recognized as revenue over the period of continuing involvement. We estimate the period of continuing involvement based on the best available evidential matter available to us at each reporting period. If our estimated time frame for continuing involvement changes, this change in estimate could impact the amount of revenue recognized in future periods.

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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. Upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement are recorded as deferred revenue and recognized over the estimated service period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

Research and development costs that are reimbursable under collaboration agreements are recognized 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.

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

### ***Auction Rate Securities***

We held a number of interest bearing auction rate securities, or ARS, that represent investments in pools of assets. These ARS investments were intended to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, allowing investors to either roll over their holdings or gain immediate liquidity by selling such interests at par. ARS have long-term scheduled maturities, but have interest rates that are typically reset at pre-determined intervals (every 28 days for the securities purchased by us), at which time the securities can typically be purchased or sold, creating a liquid market. In an active market for such investments, the rate reset for each instrument is an opportunity to accept the reset rate or sell the instrument at its face value in order to seek an alternative investment. In the past, the auction process had allowed investors to roll over their holdings or obtain immediate liquidity by selling the securities at par. The auctions failed during fiscal 2008 and have not settled in an active market since that time. The uncertainties in the credit markets affected our holdings in ARS investments as the auctions for these securities had failed to settle on their respective settlement dates.

The ARS that were held were AAA rated collateralized by student loans, guaranteed by the U.S. Government under the Federal Family Education Loan Program and backed by insurance companies. During the three and nine month periods ended March 31, 2011, we sold the remaining ARS to brokers in a secondary market that resulted in realized gains of \$0.4 million and \$0.5 million for the three and nine-month periods ended March 31, 2011, respectively. We no longer have any investments in ARS.

During each of the three and nine-month periods ended March 31, 2011, we reported no interest and \$0.1 million of amortization of the market value discount of the ARS, as compared to \$0.1 million and \$0.4 million, of amortization of the market value discount of the ARS for the three and nine-month periods ended March 31, 2010, respectively.

### ***Estimated Fair Value of Financial Instruments***

We have categorized our financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth in Note 2, Summary of

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Significant Accounting Policies. We do 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.

**Foreign Currency Risks**

For subsidiaries outside of the United States that operate in a local currency environment, income and expense items are translated to United States dollars at the monthly average rates of exchange prevailing during the year, assets and liabilities are translated at the period-end exchange rates, and equity accounts are translated at historical exchange rates. Translation adjustments are accumulated in a separate component of stockholders' equity and are included in the determination of comprehensive income. Transaction gains and losses are included in the determination of net income.

**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 employee's interest. This plan is described more fully in Note 7 to our audited financial statements included in our Annual Report on Form 10-K for the year ended June 30, 2010 and Note 4 to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 included elsewhere herein.

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

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

The following table sets forth the weighted-average assumptions used to calculate the fair value of options granted for the nine-month periods ended March 31, 2011 and 2010:

	Nine-Month Periods Ended March 31,	
	2011	2010
Expected dividend yield	0.0%	0.0%
Expected life of options (years)	5.42	5.78
Expected stock price volatility	88%	92%
Risk-free interest rate	2.33% - 2.76%	2.80% - 3.32%

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

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### ***Reimbursement of Research & Development Costs***

Research and development costs that are reimbursable under collaboration agreements are included as a reduction of research and development expenses. 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.

### ***Impairment of Assets***

We review our long-lived assets for impairment, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based upon our judgment of our ability to recover the asset from the expected future undiscounted cash flows of the related operations. Actual future cash flows may be greater or less than estimated. Based on our review, we believe there is no impairment at March 31, 2011.

### **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 March 31, 2011 Compared to 2010***

#### ***Revenues***

Revenues for the three-month period ended March 31, 2011 were \$1.1 million, as compared to \$10.7 million for the same period in 2010, representing a decrease of \$9.6 million or 90%. The decrease was primarily due to a reduction in license fees revenue. The current fiscal period does not reflect any license fee revenues from the Nycomed Agreement, which had amounted to \$3.9 million in the three-month period ended March 31, 2010, as we had completed amortization of the upfront fees deferred under the Nycomed Agreement in fiscal year 2010. In addition, the previous year included a \$5.0 million milestone payment under the terms of the Nycomed Agreement upon completion of our obligation in connection with the ITP study. There was no milestone payment for the current fiscal year. Product sales for the three-month period ended March 31, 2011 were \$0.9 million as compared to \$1.0 million for the same period in 2010, representing a decrease of \$0.1 million or 10%. Research and development revenues for the three-month period ended March 31, 2011 were \$0.2 million as compared to \$0.8 million for the same period of 2010, representing a decrease of \$0.6 million or 75% due to the timing and size of the grant programs in place during the current period.

#### ***Costs and Expenses***

Total costs and expenses for the three-month period ended March 31, 2011 were \$9.1 million, as compared to \$8.5 million for the same period in 2010, representing an increase of \$0.6 million or 7%. Research and development expenses for the three-month period ended March 31, 2011 were \$7.0 million as compared to \$6.3 million for the same period in 2010, an increase of \$0.7 million or 11%. This increase in research and development expenses resulted primarily from a decrease of \$0.7 million of research & development expense reimbursements under a collaborative agreement from the amount of the reimbursement in the previous year. Cost of goods sold was \$0.1 million for the three-month period ended March 31, 2011 as compared to \$0.7 million for the same period in 2010. During the three-month period ended March 31, 2010, cost of goods sold were increased by a \$0.6 million inventory reserve as Leukoscan<sup>®</sup> work-in-process inventories were deemed to be unsaleable due to a third-party manufacturer's process deviation that resulted in product that did not meet our quality control standards. Excluding the



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impact of the inventory reserve adjustment for work-in-process, the gross profit margins were 88% and 92%, respectively, for the three-month periods ended March 31, 2011 and 2010.

Sales and marketing expenses for the three-month periods ended March 31, 2011 and 2010 were \$0.2 million. General and administrative costs increased \$0.3 million to \$1.7 million or 21% for the three-month period ended March 31, 2011, from \$1.4 million for the same period of 2010. This increase was due primarily to increased legal expenses of \$0.5 million pertaining to the FINRA arbitration hearing related to our ARS, partially offset by a reduction in outside testing expenses (\$0.1 million) and other reductions.

### *Gains on Auction Rate Securities, net*

A gain of \$0.4 million was reported for the three-month period ended March 31, 2011 on the sales of auction rate securities with a carrying value of \$9.0 million (par value of \$9.9 million), as compared to a \$0.7 million gain on the sale of auction rate securities that had a carrying value of \$5.0 million (par value of \$6.0 million) for the same period in 2010. Partially offsetting the gain in 2010 was a charge of \$0.5 million for an other than temporary impairment charge on marketable securities associated with our investments in auction rate securities. See discussion in Note 3 to the condensed consolidated financial statements for more information on our investments in auction rate securities and this other than temporary impairment charge.

### *Interest Income and Other Income*

Interest and other income for the three-month period ended March 31, 2011 decreased to \$21,000 compared to \$0.2 million for the same period in 2010, primarily due to lower levels of investments as well as lower rates of return on investments.

### *Foreign Currency Transaction Gain*

Foreign currency transactions amounted to a gain of \$48,000 for the three-month period ended March 31, 2011 as compared to a gain of \$45,000 for the same period in 2010, primarily as a result of currency fluctuations between the U.S. Dollar and the Euro.

### *Income Tax (Expense) Benefit*

An income tax expense of \$0.1 million was reported for the three-month period ended March 31, 2011 as compared to an income tax benefit of \$0.9 million for the three-month period ended March 31, 2010. The income tax benefit for 2010 was the result of the sale of our NOLs for \$1.0 million that was approved by the State of New Jersey, partially offset by the income tax expenses due to the profitability of the U.S. and foreign subsidiaries. There was no sale of our NOLs for the three-month period ended March 31, 2011.

### *Net (Loss) Income*

Net (loss) for the three-month period ended March 31, 2011 was \$7.6 million or \$0.10 per share as compared to net income of \$3.5 million or \$0.05 per share, for the same period in 2010. The decline in net income reported in fiscal 2011 as compared to fiscal 2010 resulted primarily from \$9.6 million in lower revenues and \$0.6 million in higher costs and expenses during the third quarter of the 2011 fiscal year. Another factor causing the decline in net income was the receipt of \$1.0 million in proceeds from the sale of NOLs in the 2010 fiscal period. There was no sale of NOLs in the 2011 fiscal period.

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**Table of Contents*****Nine-Month Period Ended March 31, 2011 Compared to 2010******Revenues***

Revenues for the nine-month period ended March 31, 2011 were \$3.6 million as compared to \$54.8 million for the same period in 2010, representing a decrease of \$51.2 million or 93%. The current fiscal period does not reflect any license fee revenues from either the UCB Agreement or the Nycomed Agreement, which had amounted to \$31.2 million and \$14.5 million, respectively, for the nine month period ended March 31, 2010. We had completed amortization of the upfront fees deferred under these agreements in fiscal year 2010. In addition, during the nine-month period ended March 31, 2010, we recognized as revenue the receipt of a \$5.0 million milestone payment with the completion of our obligations under the terms of the Nycomed Agreement in connection with the ITP study. Product sales for the nine-month period ended March 31, 2011 were \$2.7 million as compared to \$2.6 million for the same period in 2010, representing an increase of \$0.1 million or 4%. Research and development revenues for the nine-month period ended March 31, 2011 were \$0.8 million as compared to \$1.5 million for the same period of 2010 due to the timing and reduction in the size of the grant programs in the current period.

***Costs and Expenses***

Total costs and expenses for the nine-month period ended March 31, 2011 were \$24.8 million as compared to \$20.2 million for the same period in 2010, representing an increase of \$4.6 million or 23%. Research and development expenses for the nine-month period ended March 31, 2011 were \$18.6 million as compared to \$14.7 million for the same period in 2010, representing an increase of \$3.9 million or 27%. The increase in research and development expenses resulted primarily from a \$3.2 million decrease of research and development expense reimbursement, \$0.6 million of higher spending for clinical trials, and \$0.5 million for higher patent-related expenses, partially offset by reduced outside services. Reimbursement of research and development expenses for the nine-month period ended March 31, 2011 totaled approximately \$1.6 million and is not expected to continue subsequent to June 30, 2011. For the nine months ended March 31, 2010 reimbursement of research and development expenses totaled \$5.1 million. Also, we do not expect the level of reimbursement for the remainder of the 2011 fiscal year to be at the 2010 level.

General and administrative costs were \$5.3 million for the nine-month period ended March 31, 2011 and \$4.1 million for the same period in 2010, an increase of \$1.2 million or 29%. This increase is primarily attributable to increased legal expenses of \$1.6 million pertaining to the FINRA arbitration hearing related to our ARS. This was partially offset by the recognition in fiscal year 2010 of \$0.6 million of additional incentive compensation to our Chairman in accordance with his employment agreement, resulting from the expectation of our profitability for the 2010 fiscal year.

Cost of goods sold for the nine-month period ended March 31, 2011 was \$0.3 million as compared to \$0.8 million for the same period in 2010, a decrease of \$0.5 million or 62%. During the nine-month period ended March 31, 2010, cost of goods sold was increased by a \$0.6 million increase in the inventory reserve as our Leukoscan<sup>®</sup> work-in-process inventories were deemed to be unsaleable due to a third-party manufacturer's process deviation that resulted in product that did not meet our quality control standards. Excluding the impact of the inventory reserve adjustment for work-in-process, the gross profit margins were 88% for the nine-month period ended March 31, 2011 compared to 91% for the nine-month period ended March 31, 2010. Sales and marketing expenses for the nine-month periods ended March 31, 2011 and 2010 were \$0.6 million for both periods.

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*Qualifying Therapeutic Discovery Project Program*

On October 29, 2010, we received notification from the Department of the Treasury that we had been awarded a total cash grant of approximately \$2.9 million under the QTDP program administered under Section 48D of the Internal Revenue Code, of which approximately \$2.5 million relates to qualifying expenses we had previously incurred during the 2010 fiscal year and was received during the second quarter of fiscal 2011. The remainder of the grant of approximately \$0.4 million will be received during the first quarter of fiscal 2012 based on qualifying expenses we have incurred during the 2011 fiscal year. We recognized the full \$2.9 million of the grant as of the date of notification since we have already incurred all of the qualifying expenses. Since this program is non-recurring in nature, we elected to classify this payment as other income in the Condensed Consolidated Statement of Operations for the nine-month period ended March 31, 2011.

*Gains on Auction Rate Securities, net*

A gain of \$0.5 million was reported for the nine-month period ended March 31, 2011 on the sales of auction rate securities with a carrying value of \$9.0 million (par value of \$11.0 million), as compared to a \$0.7 million gain on the sale of auction rate securities that had a carrying value of \$9.7 million (par value of \$11.1 million) for the same period in 2010. Partially offsetting the gain in 2010 was a charge of \$0.5 million for an other than temporary impairment charge on marketable securities associated with our investments in auction rate securities. See discussion in Note 3 to the condensed consolidated financial statements for more information on our investments in auction rate securities and this other than temporary impairment charge.

*Interest and Other Income*

Interest and other income of \$0.5 million for the nine-month period ended March 31, 2011 decreased by \$0.2 million from \$0.7 million for the same period in 2010. This decline was primarily the result of lower rates of return on investments and lower cash balances during the nine months ended March 31, 2011. This decline for the nine-month period ended March 31, 2011 included the lower level of the amortization of the discount for the ARS of \$0.1 million for the nine-month period ended March 31, 2011 as compared to \$0.4 million for the nine-month period ended March 31, 2010.

*Foreign Currency Transaction Gain*

Foreign currency transactions amounted to a gain of \$23,000 for the nine-month period ended March 31, 2011 as compared to a gain of \$0.1 million in the same period in 2010 due to currency fluctuations between the U.S. Dollar and the Euro.

*Income Tax (Expense) Benefit*

Income tax expense was \$0.1 million for the nine-month period ended March 31, 2011 as compared to an income tax benefit of \$0.7 million for the same period in 2010. The decline in the income tax benefit was primarily a result of the sale of our NOLs for \$1.0 million that was approved by the State of New Jersey in 2010. There was no comparable sale in fiscal 2011.

*Net (Loss) Income*

Net (loss) for the nine-month period ended March 31, 2011 was \$17.5 million or \$0.23 per share, as compared to net income of \$36.3 million, or \$0.48 per share, for the same period in 2010, representing a decrease of \$53.8 million. The decline in net income as compared to the same period in 2010 resulted primarily from \$51.2 million of lower revenues and \$4.6 million of

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higher expenses in fiscal 2011 offset in part by \$2.9 million in other income in fiscal 2011 from the QTDP program.

## **Liquidity and Capital Resources**

### **Discussion of Cash Flows**

*Cash flows from operations.* Net cash used in operating activities for the nine-month period ended March 31, 2011 was \$15.2 million compared to net cash used in operating activities of \$7.5 million for the nine-month period ended March 31, 2010 due to a decline in profitability in the current fiscal period.

*Cash flows from investing.* Net cash provided by investing activities for the nine-months ended March 31, 2011 was \$9.4 million compared to \$4.9 million net cash used in investing activities for the nine months ended March 31, 2010. The increase in cash flow from investing activities for fiscal 2011 is primarily due to a \$3.9 million increase in the proceeds from the sale of auction rate securities, proceeds from an insurance claim of \$0.3 million and a reduction in capital expenditures of \$0.3 million.

*Cash flows from financing.* Net cash provided by financing activities for the nine-month periods ended March 31, 2011 and 2010 were less than \$0.1 million.

### **Working Capital and Cash Requirements**

At March 31, 2011, we had working capital of \$21.6 million, which was approximately \$7.0 million lower than the working capital of \$28.6 million at June 30, 2010. The decline in working capital was caused by \$15.2 million of cash used in operations offset in part by the proceeds received from the sale of non current ARS.

Our cash and cash equivalents amounted to \$23.7 million at March 31, 2011, representing a decrease of \$5.8 million from \$29.5 million at June 30, 2010. The decrease was primarily attributable to the \$15.2 million of cash used in operations during the nine-month period ended March 31, 2011, offset in part by the \$9.5 million in proceeds from the sale of ARS.

We have \$23.7 million of unrestricted cash and cash equivalents at March 31, 2011. Based on our historical 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. The use of funds during the 2011 fiscal year has been at a higher rate than previous years, primarily due to increased spending for legal professional services. We are also evaluating plans to initiate a Phase III registration trial of veltuzumab in non-Hodgkin's lymphoma and a Phase III registration trial of clivatuzumab in pancreatic cancer. We will need to secure additional funding to advance veltuzumab and clivatuzumab into these Phase III trials.

We do not believe we will have adequate cash to complete our research and development compounds in our development pipeline in line with our corporate strategy. We will require additional financial resources in order to continue 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 may be negatively impacted by the downturn in the economy. There can be no assurances that financing will be available when we need it on terms acceptable to us, if at all.

We continue to evaluate various programs to raise additional capital and to seek additional revenues from the licensing of our proprietary technologies. There can be no

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assurance that we will be able to raise the additional capital we will need on commercially acceptable terms, 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. 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 Quarterly Report on Form 10-Q. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources when necessary to fund our strategic priorities.

**Effects of Inflation**

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

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

We may be exposed to fluctuations in foreign currencies in regards 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**

*Former Investment Advisor/Broker*

On April 15, 2009, we initiated an arbitration proceeding before the Financial Industry Regulatory Authority ( FINRA ) against our former investment advisor/broker, Banc of America Investment Services, Inc. and Banc of America Securities, LLC. In the arbitration, we claim that the respondents violated the New Jersey Uniform Securities Law, the North Carolina Securities Act, and certain FINRA rules by, among other things, making false representations and/or material omissions concerning auction rate securities, inappropriately advising investment in auction rate securities, and failing to supervise their employees. We continue to seek relief pursuant to the New Jersey Uniform Securities Law and the North Carolina Securities Act for the difference between the par value of its ARS and the amount it received when we sold the ARS on the secondary market (\$2.9 million). Also, we continue to seek consequential damages, punitive damages, and other relief. The FINRA arbitration hearing in this matter began in September 2010 and is scheduled to resume in June 2011.



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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 March 31, 2011, we had an accumulated deficit of approximately \$220.2 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 to date have been derived from our existing licensing agreements with UCB and 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 products. In addition, we have made the strategic decision to de-emphasize sales of our diagnostic products and focus on our therapeutic pipeline. We have never had product sales of any therapeutic product. 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. Given the current downturn in the economy, 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:

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later-stage clinical trials may raise safety or efficacy concerns not readily apparent in earlier trials;

unforeseen difficulties in manufacturing the product candidate in compliance with all regulatory requirements and in the quantities needed to complete the trial may be cost-prohibitive;

while underway, the continuation of clinical trials may be delayed, suspended or terminated due to modifications to the clinical trial protocols based on interim results obtained;

our collaboration partner may suspend or cease trials in their sole discretion;

during the long trial process, alternative therapies may become available which make further development of the product candidate impracticable; and

if we are unable to obtain the additional capital we need to fund all of the clinical trials we foresee, we may be forced to cancel or otherwise curtail some important trials.

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 and veltuzumab, could severely harm our business and results of operation.

***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:

\$40.0 million from Nycomed in fiscal 2009 to license the rights to develop, manufacture and commercialize veltuzumab for the treatment of all non-cancer indications, and \$10.0 million in milestone payments in fiscal 2010 under the terms of this agreement with Nycomed;

\$38.0 million from UCB in fiscal 2006 to license the rights to develop, manufacture and commercialize epratuzumab for the treatment of all autoimmune disease indications;



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approximately \$259.0 million from the public and private sale of our debt and equity securities through March 31, 2011; and

limited product sales of CEA-Scan<sup>®</sup> and LeukoScan<sup>®</sup>, licenses, grants and interest income from our investments.

Based on our historical cash utilization rate, we believe we have adequate cash to fund our operations and research and development programs through the next twelve months. The use of funds during the 2011 fiscal year has been at a higher rate than previous years primarily due to increased spending for legal professional services. We are also evaluating plans to initiate a Phase III registration trial of veltuzumab in non-Hodgkin's lymphoma and a Phase III registration trial for clivatuzumab in pancreatic cancer. We will need to obtain additional funding in the event we decide to begin these trials. We will need to raise additional capital in order to obtain the necessary regulatory approvals and then commercialize our therapeutic product candidates. 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 Nycomed and UCB in meeting the clinical development and commercial milestones for veltuzumab and epratuzumab, respectively; 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.

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 downturn in the economy and 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. While we have completed construction on the major expansion of our manufacturing facilities in New Jersey in anticipation of our current and future



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needs, 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 Nycomed for the final development and commercialization of veltuzumab for the treatment of all non- cancer indications worldwide and upon UCB for the final development and commercialization of epratuzumab for the treatment of autoimmune disease indications worldwide and they may not be successful.***

We have licensed the exclusive worldwide rights of our most advanced therapeutic compounds, *veltuzumab* (to Nycomed) and *epratuzumab* (to UCB). As a result, Nycomed and UCB are 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, successful or are terminated by them for any other reason, our ability to commercialize these product candidates 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 agreements with Nycomed and UCB, and our ability to fund the development and testing of our other product candidates would be adversely affected.

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

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

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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 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

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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, Genentech, GlaxoSmithKline, Human Genome Sciences, Seattle Genetics, Trubion Pharmaceuticals, Zymogenetics, Merck Serono, Genmab, Medarex, Amgen Inc., Bristol-Myers Squibb, Bayer Schering Pharma AG, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic autoimmune and oncology products. For example, Human Genome Sciences and their corporate partner, GlaxoSmithKline recently received approval from the FDA for their human monoclonal antibody against B-lymphocyte stimulator or BlyS, for the therapy of patients with SLE. Many of these companies have significantly greater financial, technical and marketing resources than we do. In addition, many of these companies have more established positions in the pharmaceutical industry and are therefore better equipped to develop, commercialize and market oncology and autoimmune disease products. Even some smaller competitors may obtain a significant competitive advantage over us if they are able to discover or otherwise acquire patentable inventions, form collaborative arrangements or merge with larger pharmaceutical companies.

We expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the field of antibody-based technologies, and they are increasingly aware of the commercial value of their findings. As a result, they are demanding greater patent and other proprietary rights, as well as licensing and future royalty revenues.

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

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

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

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



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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 use to conduct certain research activities. For the nine months ended March 31, 2011, we have incurred \$0.2 million of research expenses for activities conducted by CMMI on our behalf. Further, 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. 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.

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 \$20,000 per treatment, 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.*

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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.*

A portion of our funding to date has been derived from federal government grants and research contracts. 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 decide to scale back these programs or terminate them due to their own budgetary constraints, as they have recently been doing. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing awards may be less than those received to date. In those circumstances, we would need to provide funding on our own, obtain other funding, or scale back or terminate the affected program. In particular, we cannot assure you that any currently-contemplated or future efforts to obtain funding for our product candidate programs through government grants or contracts will be successful, or that any such arrangements which we do conclude will supply us with sufficient funds to complete our development programs without providing additional funding on our own or obtaining other funding.

### **Risks Related to Government Regulation of our Industry**

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

In both the 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. Effective January 1, 2010, the new law increases the minimum Medicaid drug rebates for pharmaceutical companies, expands the 340B drug discount program, and makes changes to affect the Medicare Part D coverage gap, or "donut hole." The law also revises the definition of "average manufacturer price" for reporting purposes (effective October 1, 2011), which could increase the amount of the Company's Medicaid drug rebates to states, once the provision is effective. The new law also imposes a significant annual fee on companies that manufacture or import branded prescription drug products (beginning in 2010). 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 change 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;

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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;

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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.

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 that 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 the 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 the company's 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.

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

Delisting from the 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. The market price of our common stock is currently less than \$5.00 per share. 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.

*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 generally 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 partner, 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.



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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 May 9, 2011, we had 75,418,430 shares of common stock outstanding 6,511,162 additional shares reserved for the exercise of outstanding options and restricted stock units and 4,739,106 additional shares of common stock authorized for issuance and remaining to be granted under our stock option plans.

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

As of March 31, 2011, 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 11% 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.

***We have adopted anti-takeover provisions that may frustrate any unsolicited attempt to acquire our company or remove or replace our directors and executive officers.***

Provisions of our certificate of incorporation, our by-laws and Delaware corporate law could make it more difficult for a third party to acquire control of our company in a transaction not approved by our Board of Directors. For example, we have adopted a stockholder rights plan that makes it more difficult for a third party to acquire control of our company without the support of our Board of Directors. In addition, our Board of Directors may issue up to ten million shares of preferred stock and determine the price, rights, preferences and privileges, including voting and conversion rights, of these shares without any further vote or action by our stockholders. The issuance of preferred stock could have the effect of delaying, deterring or preventing an unsolicited change in control of our company, or could impose various procedural and other requirements that could make it more difficult for holders of our common stock to effect certain corporate actions, including the replacement of incumbent directors and the completion of transactions opposed by the incumbent Board of Directors. The rights of the holders of our common stock would be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future.

We are also subject to Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits us from engaging in a business combination with any interested stockholder (as defined in Section 203 of the DGCL) for a period of three years from the date the person became an interested stockholder, unless certain conditions are met.

***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

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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 therefrom. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors, and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Given the difficult environment and potential for incurring liabilities currently facing directors of publicly-held corporations, we believe that director indemnification is in our and our stockholders' best interests because it enhances our ability to attract and retain highly qualified directors and reduce a possible deterrent to entrepreneurial decision-making.

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

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

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



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*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.

At May 9, 2011, we had 75,418,430 shares of common stock outstanding, 6,511,162 additional shares reserved for the exercise of outstanding options and restricted stock units and 4,739,106 additional shares of common stock authorized for issuance and remaining to be granted under our stock option plan.

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**ITEM 6. EXHIBITS**

- 10.1 Sixth Amendment Extension Agreement, dated February 11, 2011, between Immunomedics, Inc. and WU/LH 300 American L.L.C.
- 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.

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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.

May 10, 2011

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

May 10, 2011

By: /s/ Gerard G. Gorman  
Gerard G. Gorman  
Senior Vice President, Finance and Business  
Development, and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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**EXHIBIT INDEX**

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