

IMMUNOMEDICS INC  
Form 10-Q  
February 08, 2012  
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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 December 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**  
(State or other jurisdiction of

**61-1009366**  
(I.R.S. Employer

incorporation or organization)

Identification No.)

**300 The American Road, Morris Plains, New Jersey 07950**

(Address of principal executive offices) (Zip Code)

**(973) 605-8200**

(Registrant's Telephone Number, Including Area Code)

**Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report: Not Applicable**

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

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

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

Large Accelerated Filer ☐

Accelerated Filer ☒

Non-Accelerated Filer ☐

Smaller Reporting Company ☐

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

The number of shares of the registrant's common stock outstanding as of February 7, 2012 was 75,525,231.

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**IMMUNOMEDICS, INC.**

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

	December 31, 2011 (unaudited)	June 30, 2011 (audited)
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 16,334,410	\$ 27,097,610
Receivable from UCB	30,000,000	
Accounts receivable, net of allowance for doubtful accounts of \$41,000 at December 31, 2011 and \$32,000 at June 30, 2011	777,579	736,980
Inventory	579,160	289,604
Other receivables	570,811	974,331
Prepaid expenses	716,039	514,388
Other current assets	60,795	644,705
Total current assets	49,038,794	30,257,618
Property and equipment, net of accumulated depreciation of \$24,946,000 and \$24,211,000 at December 31, 2011 and June 30, 2011, respectively	3,023,153	3,456,150
Value of life insurance policies	600,005	581,005
Other long-term assets	30,000	30,000
Total Assets	\$ 52,691,952	\$ 34,324,773
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,921,696	\$ 5,548,318
Total current liabilities	5,921,696	5,548,318
Other liabilities	1,251,454	1,134,492
Commitments and Contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at December 31, 2011 and June 30, 2011		
Common stock, \$0.01 par value; authorized 110,000,000 shares; issued and outstanding, 75,519,529 shares at December 31, 2011 and 75,463,066 shares at June 30, 2011	755,195	754,630
Capital contributed in excess of par	247,617,955	245,023,414
Treasury stock, at cost, 34,725 shares at December 31, 2011 and at June 30, 2011	(458,370)	(458,370)
Accumulated deficit	(202,305,634)	(217,898,394)
Accumulated other comprehensive income	136,353	394,669
Total Immunomedics, Inc. stockholders' equity	45,745,499	27,815,949
Noncontrolling interest in subsidiary	(226,697)	(173,986)
Total stockholders' equity	45,518,802	27,641,963
Total Liabilities and Stockholders' Equity	\$ 52,691,952	\$ 34,324,773

See accompanying notes to unaudited condensed consolidated financial statements



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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND**

**COMPREHENSIVE INCOME (LOSS)**

**(UNAUDITED)**

	Three months ended December 31,		Six months ended December 31,	
	2011	2010	2011	2010
Revenues:				
License fee and other revenues	\$ 28,418,000	\$ 75,000	\$ 28,418,000	\$ 75,000
Product sales	1,064,426	728,843	1,924,293	1,859,114
Research and development	173,004	199,684	457,791	563,234
Total revenues	29,655,430	1,003,527	30,800,084	2,497,348
Costs and Expenses:				
Costs of goods sold	134,189	107,259	230,054	216,275
Research and development	6,225,531	5,762,305	11,037,783	11,607,319
Sales and marketing	239,678	175,958	451,564	358,121
General and administrative	1,880,516	1,474,258	3,048,039	3,531,751
Total costs and expenses	8,479,914	7,519,780	14,767,440	15,713,466
Operating income (loss)	21,175,516	(6,516,253)	16,032,644	(13,216,118)
Qualifying Therapeutic Discovery Project Program income		2,888,688		2,888,688
Interest and other income	20,559	251,919	28,440	504,482
Foreign currency transaction (loss)	(106,395)	(53,419)	(84,321)	(24,744)
Income (loss) before income tax (expense) benefit	21,089,680	(3,429,065)	15,976,763	(9,847,692)
Income tax (expense) benefit	(422,750)	1,679	(436,714)	(45,223)
Consolidated net income (loss)	20,666,930	(3,427,386)	15,540,049	(9,892,915)
Net loss attributable to noncontrolling interest	(26,597)		(52,711)	
Net income (loss) attributable to Immunomedics, Inc. stockholders	\$ 20,693,527	\$ (3,427,386)	\$ 15,592,760	\$ (9,892,915)
Income (loss) per common share attributable to Immunomedics, Inc. stockholders:				
Basic	\$ 0.27	\$ (0.05)	\$ 0.21	\$ (0.13)
Diluted	\$ 0.27	\$ (0.05)	\$ 0.20	\$ (0.13)
Weighted average shares used to calculate income (loss) per common share:				
Basic	75,458,494	75,289,346	75,466,812	75,279,240
Diluted	75,964,317	75,289,346	76,091,065	75,279,240
Comprehensive income (loss):				

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Consolidated net income (loss)	<b>\$ 20,666,930</b>	\$ (3,427,386)	<b>\$ 15,540,049</b>	\$ (9,892,915)
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustments	<b>(79,828)</b>	(31,360)	<b>(258,316)</b>	118,699
Unrealized gain on securities available for sale net		81,408		205,082
Other comprehensive (loss) income	<b>(79,828)</b>	50,048	<b>(258,316)</b>	323,781
Comprehensive income (loss)	<b>\$ 20,587,102</b>	\$ (3,377,338)	<b>\$ 15,281,733</b>	\$ (9,569,134)

See accompanying notes to unaudited condensed consolidated financial statements

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**IMMUNOMEDICS, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(UNAUDITED)**

	Six Months Ended December 31,	
	2011	2010
Cash flows from operating activities:		
Consolidated net income (loss)	\$ 15,540,049	\$ (9,892,915)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	735,008	811,510
License fee revenue	(28,418,000)	
Gain on insurance claim for equipment failure		(251,151)
Increase (decrease) in allowance for doubtful accounts	8,948	(20,351)
Amortization of discounts of auction rate securities		(120,114)
Gain on sale of auction rate securities		(40,650)
Non-cash expense related to stock compensation	997,814	997,443
Non-cash increase in value of life insurance policy	(19,000)	(28,018)
Amortization of deferred rent	116,962	53,288
Changes in other operating assets and liabilities	820,054	(533,052)
Other	(258,316)	118,699
Net cash used in operating activities	(10,476,481)	(8,905,311)
Cash flows from investing activities:		
Proceeds from sales of auction rate securities		957,000
Purchases of property and equipment	(302,011)	(360,905)
Proceeds from insurance claim for equipment failure		100,000
Net cash (used in) provided by investing activities	(302,011)	696,095
Cash flows from financing activities:		
Exercise of stock options, net	15,292	5,525
Net cash provided by financing activities	15,292	5,525
Net decrease in cash and cash equivalents	(10,763,200)	(8,203,691)
Cash and cash equivalents, beginning of period	27,097,610	29,533,230
Cash and cash equivalents, end of period	\$ 16,334,410	\$ 21,329,539
Supplemental information for the statement of cash flows:		
Issuance of common stock purchase warrant	\$ 1,582,000	\$

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, 2011, 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 continued to transition its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company 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, 2011 has been derived from the Company's audited fiscal 2011 consolidated financial statements. Operating results for the three and six-month periods ended December 31, 2011 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2012, or any other period.

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

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As of December 31, 2011, the Company had \$16.3 million of cash and cash equivalents. In January 2012, the Company received \$30.0 million of cash proceeds as a result of entering into the December 27, 2011 Amendment Agreement with UCB Pharma, S.A. (the "Amendment Agreement") to amend the Development and License Agreement between the parties, dated May 9, 2006, (the "UCB Agreement"). Based on available cash and cash equivalents after adjusting for the \$30.0 million from UCB received in January 2012, the Company has sufficient funds to continue its operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2012 are expected to be in the \$20.0 - \$22.0 million range, approximately the same level as in the previous fiscal year.

Research and development activities are expected to continue to expand over time. Clinical development and eventual registration of clivatuzumab are under discussions with the FDA and key opinion leaders. The Company does not believe it has adequate cash to complete development of all of its research and development compounds in its development pipeline in line with its corporate strategy. As a result, Immunomedics will continue to require additional financial resources in order to continue its research and development programs, clinical trials of product candidates and regulatory filings.

The Company continues to pursue partnering opportunities and other activities for its product candidates, which could provide up-front and milestone payments, as well as funding of development costs and other licensing possibilities. In the event that the Company is unable to secure funding from partnering arrangements, it would seek to raise additional capital or pursue other strategic options. Since its inception in 1982, the Company's 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 not, the Company's ability to continue its research and development will be materially and adversely affected. Furthermore, the terms of any such debt or equity financing may include covenants which limit the Company's future ability to manage the business.

## **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, 2011. 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.

### ***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, which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to the fair value with an allocation based on selling price. The Company

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applies ASU 2009-13 to its revenue arrangements containing multiple deliverables that are entered into. The Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or the Company's estimate of selling price when fair value is not available for a given unit of accounting. ASU 2009-13 was 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.

In April, 2010 the FASB issued ASU 2010-17 Revenue Recognition Milestone Method, which provides guidance to research and development companies on defining a milestone and determining when it may be appropriate to apply the milestone method when recognizing revenue. The milestone method of revenue recognition is an accounting policy election that has been adopted by the Company. In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the FASB guidance on the milestone method of revenue recognition at the inception of a collaboration agreement. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved.

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 obligations in the agreement are recorded as deferred revenue and recognized over the estimated service period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

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Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

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

***Financial Instruments***

The carrying amounts of cash and cash equivalents, other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments. 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 sheets as of December 31, 2011 and June 30, 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.

	(\$ in thousands)			
<b>December 31, 2011</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money Market Funds	\$ 10,307	\$	\$	\$ 10,307
Total	\$ 10,307	\$	\$	\$ 10,307
<b>June 30, 2011</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money Market Funds	\$ 22,297	\$	\$	\$ 22,297
Total	\$ 22,297	\$	\$	\$ 22,297

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

**Table of Contents*****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.

Inventory consisted of the following (in thousands):

	<b>December 31, 2011</b>	<b>June 30, 2011</b>
Work in process	\$	\$ 70
Finished goods	579	220
	<b>\$ 579</b>	<b>\$ 290</b>

***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.

For the three and six-month periods ended December 31, 2011 the Company provided for \$0.4 million of domestic income taxes, net of the utilization of deferred tax assets and the valuation allowance recorded upon it. The Company's effective tax rates for the three and six-month periods ended December 31, 2011 were significantly lower than the statutory rate due to its utilization of its net operating loss carryforwards, which offset the Company's domestic taxable income, except for Federal alternative minimum taxes that are not offset by the net operating losses. The Company's U.S. operations reported a net loss for the three and six-month periods ended December 31, 2010. Income taxes were also provided for profitable foreign jurisdictions at the applicable effective tax rate during the three and six-month periods ended December 31, 2011 and 2010. The income expense (benefit) for foreign jurisdictions for the three and six-month periods ended December 31, 2011 includes \$23 thousand and \$37 thousand, respectively, for activities resulting from taxable foreign entities, as compared to (\$2 thousand) and \$45 thousand for the three and six-month periods ended December 31, 2010, respectively.

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

Basic net income (loss) per share is based upon the number of weighted average number of shares of common stock and vested shares outstanding. For the three and six-month periods ended December 31, 2011, 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. For the three and six-month periods ended December 31, 2010 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. Potential shares of common stock result from the assumed

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exercise of outstanding stock options and warrant shares, with exercise prices less than the average market price of the Company's common stock during the three and six-month periods ended December 31, 2011 and 2010, are calculated under the treasury stock method. All other outstanding stock options and warrant shares have been excluded from the calculation.

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

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

### ***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 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 was received during the first quarter of fiscal 2012 based on qualifying expenses the Company 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 had already incurred all of the qualifying expenses. Since this program was non-recurring in nature, the Company elected to classify this payment as other income in the Condensed Consolidated Statements of Operations for the six-month period ended December 31, 2010.

### ***Recently Issued Accounting Pronouncements***

In December 2011, the FASB issued ASU No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*, which will require all companies to disclose their agreements for financial instruments and derivative instruments that are either offset in the balance sheet (presented on a net basis), or subject to an enforceable master netting arrangement. The Company is assessing the impact on its financial statements and will adopt this guidance on July 1, 2013, as required, which is not expected to have a significant impact on its financial statements.

In December 2011, the FASB issued ASU 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. ASU 2011-12 eliminated the requirement to reflect reclassification adjustments for items that are reclassified from other comprehensive income to net income. This had no impact on the Company's financial statements.

In May 2011, the FASB issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS)*, to improve the comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with U.S. GAAP and IFRS. The Company is assessing the impact on its financial statements and will adopt this guidance on January 1, 2012, as required, which is not expected to have a significant impact on its financial statements.

### **3. 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, 2011. The Company believes that such awards better align

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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, 12,000,000 shares of common stock were authorized for issuance. At December 31, 2011, there were 11,132,142 shares of common stock options that are authorized for issuance, which was comprised of 3,266,475 shares of common stock previously available under the 2002 Employee Share Option Plan (the "2002 Plan") and an additional 7,865,667 shares of common stock under the 2006 Plan. At December 31, 2011, 4,402,699 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 six-month period ended December 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:

	Six-month periods ended December 31,	
	2011	2010
Expected dividend yield	0%	0%
Expected option term (years)	5.32	5.42
Expected stock price volatility	80%	88%
Risk-free interest rate	1.45% - 2.46%	2.33% - 2.43%

The weighted average fair value at the date of grant for options granted during the six-month periods ended December 31, 2011 and 2010 were \$2.33 per share. 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.

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding, July 1, 2011	6,471,975	\$ 4.92		
Granted	84,000	\$ 3.52		
Exercised	(6,251)	\$ 2.45		
Cancelled or forfeited	(303,406)	\$ 17.80		
Outstanding, December 31, 2011	6,246,318	\$ 4.28	3.42	\$ 2,326,311
Exercisable, December 31, 2011	5,037,295	\$ 4.52	2.96	\$ 2,006,524

The Company has 1,209,023 non-vested options outstanding as of December 31, 2011. As of December 31, 2011, there was \$3.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is being



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recognized over a weighted-average period of 2.71 years. The Company recorded \$0.5 million and \$0.8 million for stock-based compensation expense related to stock options for the three and six-month periods ended December 31, 2011, respectively, as compared to \$0.5 million and \$0.9 million for the three and six-month periods ended December 31, 2010, respectively.

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 issued 25,000 restricted stock units to non-employee Board members in December 2011 under this plan. The Company recorded \$20 thousand and \$39 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for the three and six-month periods ended December 31, 2011, respectively, as compared to \$22 thousand and \$32 thousand for the three and six-month periods ended December 31, 2010, respectively.

On August 24, 2011, at the Compensation Committee Meeting, the Company awarded 370,000 restricted stock units to certain executive officers of the Company at the market price on that date (\$3.43 per share). These restricted stock units will vest over a four year period. As of December 31, 2011 there was \$1.4 million of total unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the Plan for these awards. That cost is being recognized over a weighted-average period of 3.29 years. The Company recorded \$0.1 million and \$0.2 million for stock-based compensation expense related to these restricted stock units for the three and six-month periods ended December 31, 2011, respectively, as compared to \$25 thousand and \$54 thousand for the three and six-month periods ended December 31, 2010.

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

<b>Outstanding Non-Vested Restricted Stock Units</b>	<b>Number of Awards</b>
Non-vested at July 1, 2011	151,875
Granted	395,000
Vested/Exercised	(63,750)
Forfeited	
Non-vested at December 31, 2011	483,125

## **4. Earnings Per Share**

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

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	Three Months Ended December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
Consolidated net income (loss)	\$ 20,667	\$ (3,427)	\$ 15,540	\$ (9,893)
<b>Basic earnings (loss) per share:</b>				
Weighted average basic common shares outstanding	75,458	75,289	75,447	75,279
Basic earnings (loss) per share	\$ 0.27	\$ (0.05)	\$ 0.21	\$ (0.13)
<b>Diluted earnings (loss) per share:</b>				
Weighted average basic common shares outstanding	75,458		75,447	
Dilutive effect of stock options outstanding	452		572	
Dilutive effect of restricted stock	54		72	
Weighted average diluted common shares outstanding	75,964	75,289	76,091	75,279
Diluted earnings (loss) per share	\$ 0.27	\$ (0.05)	\$ 0.20	\$ (0.13)
Stock options and stock warrant are excluded from the weighted average dilutive common shares outstanding because their inclusion would have been antidilutive				
	6,278	5,851	6,202	6,011

## 5. 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 six-months ended December 31, 2011 and 2010 (\$ in thousands):

	Three-Months Ended December 31, 2011		
	United States	Europe	Total
Total assets	\$ 48,294	\$ 4,398	\$ 52,692
Property and equipment, net	3,023		3,023
Revenues	28,603	1,052	29,655
Income before taxes	20,978	112	21,090

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	<b>Three-Months Ended December 31, 2010</b>		
	United States	Europe	Total
Total assets	\$ 32,981	\$ 5,480	\$ 38,461
Property and equipment, net	3,876	1	3,877
Revenues	276	728	1,004
(Loss) income before taxes	(3,472)	43	(3,429)

	<b>Six-Months Ended December 31, 2011</b>		
	United States	Europe	Total
Revenues	\$ 28,892	\$ 1,908	\$ 30,800
Income before taxes	15,787	190	15,977

	<b>Six-Months Ended December 31, 2010</b>		
	United States	Europe	Total
Revenues	\$ 647	\$ 1,850	\$ 2,497
(Loss) income before taxes	(10,059)	211	(9,848)

**6. Related Party Transactions**

Certain of the Company's affiliates, including members of its senior management and its Board of Directors, as well as their respective family members and other affiliates, have relationships and agreements among themselves as well as with the Company and its affiliates, that create the potential for both real, as well as perceived, conflicts of interest. These include Dr. David M. Goldenberg, the Chairman of the Board of Directors and Chief Medical Officer and Chief Scientific Officer, Ms. Cynthia L. Sullivan, the President and Chief Executive Officer, who is the wife of Dr. David M. Goldenberg, and certain companies with which the Company does business, including the Center for Molecular Medicine and Immunology, or CMMI, and the Company's majority-owned subsidiary, IBC Pharmaceuticals, Inc., or IBC. 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, 2011 and the notes to the audited financial statements contained therein.

The Company reimbursed CMMI for expenses incurred on behalf of Immunomedics pursuant to research contracts. For fiscal 2012, the Company also reimbursed one-half of the clean-up costs for the disposal of materials related to the Company's contract research at the CMMI facility. The facility was closed in calendar year 2011. The expenses relating to research contracts totaled approximately \$54 thousand and \$0.1 million for the three and six-month periods ended December 31, 2011, respectively, as compared to \$46 thousand and \$0.1 million for the three and six-month periods ended December 31, 2010, respectively. The Company also provides to CMMI, at no cost, laboratory materials and supplies. The Company leases approximately 1,400 square feet, at a cost of \$44.4 thousand per year, of the Immunomedics Morris Plains, NJ facility to CMMI. The Company incurred legal expenses on behalf of CMMI for patent related matters for the three and six-month period ended December 31, 2011 of \$14 thousand and \$22 thousand, respectively, as compared to \$16 thousand and \$27 thousand for the three and six-month periods ended December 31, 2010, respectively. The Company has first rights to license those patents and may decide whether or not to support them. However, any inventions made independently of the Company at CMMI are the property of CMMI.

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For each of the three and six-month periods ended December 31, 2011 and 2010, Dr. Goldenberg received \$13.5 thousand and \$27 thousand, respectively, in compensation for his services to IBC.

Effective July 1, 2011, the Company entered into the Third Amended and Restated Employment Agreement with Dr. Goldenberg for his service to the Company as the Chief Scientific Officer and Chief Medical Officer (the "Goldenberg Agreement"), which terminates July 1, 2016. This agreement covers aspects of his compensation as well as duties and responsibilities at Immunomedics. Under this new agreement Dr. Goldenberg's annual base salary is at a minimum of \$.5 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee, (increased 4% for the 2012 fiscal year). Dr. Goldenberg will also be eligible to participate in any Company incentive compensation plan in place for its senior level executives and is eligible to receive an annual discretionary bonus based upon certain performance standards to be determined by the Compensation Committee. Dr. Goldenberg's annual bonus target is 50% of his annual base salary, subject to achievement of performance goals, with a potential payout from 0 to 150% of the target amount. For a full description of the Goldenberg Agreement see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2011 and the notes to the audited financial statements contained therein.

As in the previous agreement, under 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 \$.2 million 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 six-month periods ended December 31, 2011 and 2010, no additional incentive compensation payments were made to Dr. Goldenberg other than the \$37.5 thousand minimum quarterly payments. During the three-month period ended December 31, 2011, in accordance with the terms of the Goldenberg Agreement, the Company has accrued an additional \$.4 million for additional incentive compensation for Dr. Goldenberg to be paid upon the completion of the 2012 fiscal year due to the expectation of the Company's profitability for the 2012 fiscal year. However, there can be no assurance that the Company will be profitable for the 2012 fiscal year.

## **7. License Agreements Nycomed GmbH**

On July 11, 2008, the Company entered into the Nycomed Agreement with Nycomed providing Nycomed a worldwide license to develop, manufacture and commercializeveltuzumab, 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.

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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 up to \$580.0 million in regulatory and sales potential cash milestone payments, based on the successful development of veltuzumab by Nycomed and the achievement of specified product sales thresholds. These potential milestone payments include clinical development and regulatory filings (\$97.0 million), regulatory approvals (\$123.0 million) to be achieved in Europe (\$37.0 million), the U.S. (\$75.0 million) and Japan (\$11.0 million), and up to \$360.0 million associated with the achievement of certain sales thresholds. The Company could also receive an escalating double digit royalty based on annual net sales, if any, by Nycomed, its affiliates or sublicensees under the Nycomed Agreement during the royalty term. There can be no assurance 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.

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.

Given that the Company's performance obligations have been satisfied upon its completion of its manufacturing and supply obligations and its responsibilities in the Phase I/II study in ITP and are not provided for over time, such milestone payments do not qualify for the milestone method of revenue recognition and are not deemed to be substantive. However, as the Company has no future performance obligations related to the Nycomed Agreement, revenue will be recognized when earned upon achievement of the agreed upon milestones.

In accordance with the Company's accounting policy and applicable revenue recognition guidance, royalties are not evaluated under the milestone method and are recognized when earned. Similarly, the Company treats sales-based milestone payments as royalties. As such, sales milestone payments, which are related to the achievement of specified product sales thresholds, are not evaluated under the milestone method and are recognized into revenue when earned.

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 \$0.2 million and \$1.7 million for the three and six-month periods ended December 31, 2011, respectively, as compared to \$1.4 million and \$2.1 million for the three and six-month periods ended December 31, 2010, respectively. These services are expected to continue to decline subsequent to December 31, 2011.

### **UCB, S.A.**

On May 9, 2006, the Company entered into an agreement with UCB, referred to herein as the UCB Agreement, providing UCB an exclusive worldwide license to develop, manufacture, market and sell epratuzumab for the treatment of all non-cancer indications. Under the terms of the UCB Agreement, the Company received from UCB a non-refundable cash payment totaling \$38.0 million. 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, 2011 and the notes to the audited financial statements contained therein.

On December 27, 2011, the Company entered into the Amendment Agreement with UCB. Under the terms of the Amendment Agreement, UCB received the right to sublicense its rights in epratuzumab to a third party for the United States and certain other territories upon execution of the Amendment Agreement. The Company also issued to UCB on December 27, 2011 a 5-year warrant to purchase one million shares of the Company's common stock, par value \$0.01 per share, at an exercise price of \$8.00 per share. In exchange for the right to sublicense its rights in epratuzumab to a third party and the warrant issuance, the Company received a non-refundable fee of \$30.0 million payable in cash in January 2012. Further, under the terms of the Amendment Agreement, UCB returned its buy-in right with respect to epratuzumab in the field of oncology, which had been granted under the UCB Agreement.

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Under the terms of the Amendment Agreement, in addition to the non-refundable fee of \$30.0 million that was received in January 2012, the Company is entitled to receive an additional \$30.0 million non-refundable fee contingent upon UCB entering into an effective sublicense agreement with a third party.

Furthermore, the Amendment Agreement entitles the Company to additional contingent revenue payments and/or amends such payments included in the UCB Agreement. Collectively, the UCB Agreement and the Amendment Agreement entitle the Company to receive up to \$170.0 million in cash payments and up to \$20.0 million in equity investments by UCB in Immunomedics Common Stock contingent upon various regulatory achievements related to the successful development of epratuzumab by UCB ( development milestone payments ) and up to \$260.0 million related to the achievement of specified product sales thresholds ( commercialization milestone payments ). Of these amounts, \$40.0 million in development milestones and \$125.0 million in commercialization milestones are contingent upon UCB sublicensing its rights to a third party. The development milestone payments of \$190.0 million relate to regulatory approvals and first commercial sales of licensed products to be achieved in Europe (\$40.0 million), the U.S. (\$80.0 million) and Japan (\$20.0 million) and include up to \$50.0 million for potential regulatory approvals for autoimmune disease indications not in clinical trials at the time these agreements became effective. The Company will also receive product royalties based upon a percentage of aggregate annual net sales under the UCB Agreement and Amendment Agreement during the product royalty term, the amount of which is subject to change in the event that UCB sublicenses its rights to a third party. No development milestone, commercialization milestone or royalty payments were achieved through December 31, 2011. There can be no assurance that these regulatory or sales achievements will be met and therefore there can be no assurance that the Company will receive such future payments.

In accordance with the applicable accounting guidance for multiple-element revenue arrangements (ASU 2009-13), the Company evaluated the terms and conditions of the Amendment Agreement to determine if such amendments represented a material modification of the UCB Agreement. A material modification requires an entity to account for an arrangement that was entered into prior to the prospective adoption of ASU 2009-13 under the provisions of ASU 2009-13 and to determine if an adjustment is required on the date of modification to reflect the accounting that would have resulted had the entity applied the requirements of ASU 2009-13 from the date of the inception of the contract. Given the additional rights provided to UCB under the Amendment Agreement, the warrant issuance, and the additional contingent revenue payments, the Company concluded that the Amendment Agreement did represent a material modification of the UCB Agreement. However, given that the Company had no remaining performance obligations related to the UCB Agreement, the Amendment Agreement did not impact the accounting for the \$38.0 million cash payment that was received from UCB in 2006 and recognized into revenue in prior years.

The Company assessed its obligations under the Amendment Agreement and concluded that it had two deliverables and two units of accounting including 1) providing UCB with the right to sublicense its rights in epratuzumab and 2) the warrant issuance, both of which were satisfied upon execution of the Amendment Agreement on December 27, 2011. UCB is fully responsible for all development and commercialization of epratuzumab. The Company has no other obligations for the development of the product under terms of the UCB Agreement and the Amendment Agreement. As such, the \$30.0 million non-refundable fee that was earned upon execution of the Amendment Agreement and subsequently received in January 2012 was allocated to the two units of accounting using a relative selling price method for each deliverable. Accordingly, as all deliverables were satisfied on December 27, 2012, the Company recorded \$28.4 million of license fee revenue, which was determined by the Company to represent an

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appropriate selling price for such rights granted to UCB, in the three and six-month periods ended December 31, 2011 and recorded the fair value of the warrant within capital contributed in excess of par in the amount of \$1.6 million. All contingent revenue payments relate specifically to the license and sublicense rights provided to UCB in the UCB Agreement and Amendment Agreement, respectively. However, such payments are not included in allocable consideration until the events that give rise to the contingent consideration occur, even if it is probable that such events will occur.

The Company used a discounted cash flow model to determine the \$1.6 million estimated fair value of the 5-year warrant as of December 27, 2011, using the Black-Scholes model. The warrant was accounted for as an equity transaction at December 31, 2011 as the warrant represents a freestanding financial instrument entitling UCB to a fixed number of unregistered shares for a fixed price, is not publically tradable or transferable, does not have a cash or net settlement option and can only be exercised by UCB. The significant assumptions used in preparing the discounted cash flow model include (i) Immunomedics common stock price volatility of 80%, (ii) the market yield risk free interest rate of 0.96% (estimated at the U.S. Treasury Five-Year Bond Rate on December 27, 2011), (iii) option price of the warrant at conversion (\$8.00/share), (iv) the common stock price of \$3.37/share at the close of business on December 27, 2011, (v) a dividend yield of 0% and (vi) the effective maturity period of five years (life of the warrant).

Given that the Company's performance obligations have been satisfied upon execution of the Amendment Agreement and are not provided for over time, development milestone payments do not qualify for the milestone method of revenue recognition and are not deemed to be substantive. However, as the Company has no future performance obligations related to the UCB Agreement and Amendment Agreement, revenue will be recognized when earned upon achievement of the agreed upon milestones.

In accordance with the Company's accounting policy and applicable revenue recognition guidance, royalties are not evaluated under the milestone method and are recognized when earned. Similarly, the Company treats sales-based milestone payments as royalties. As such, commercialization milestone payments, which are related to the achievement of specified product sales thresholds, are not evaluated under the milestone method and are recognized into revenue when earned.

## **8. Commitments and Contingencies**

### ***Employment Contracts***

On July 1, 2011, the Third Amended and Restated Employment Agreement with Dr. Goldenberg was executed and will continue for the period through July 1, 2016. Dr. Goldenberg's annual base salary under the agreement is \$.5 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee (increased by 4% for the 2012 fiscal year). Dr. Goldenberg's annual bonus target is 50% of his base salary, subject to achievement of performance goals, with a potential payout from 0 to 150% of the target amount.

Dr. Goldenberg will also be eligible to receive equity compensation awards under the Company's 2006 Stock Incentive Plan, as amended, or any such successor equity compensation plan as may be in place from time to time, at the discretion of the Compensation Committee. As part of this agreement a \$.2 million annual minimum payment is paid in the aggregate against all Revenue Incentive Compensation and Royalty Payments.

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On July 1, 2011, the Company and Cynthia L. Sullivan entered into the Fourth Amended and Restated Employment Agreement pertaining to Ms. Sullivan's service as the Company's President and Chief Executive Officer. The Amended Sullivan Agreement shall terminate on July 1, 2014. Ms. Sullivan's annual base salary under the agreement is \$.6 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee. Ms. Sullivan is also eligible to participate in the Company's incentive compensation plan in place for its senior level executives. Ms. Sullivan's annual bonus target is 50% of her base salary, subject to achievement of performance goals, with a potential payout from 0 to 150% of the target amount. Ms. Sullivan will also be eligible to receive equity compensation awards under the Company's 2006 Stock Incentive Plan, or any such successor equity compensation plan as may be in place from time to time.

For more information regarding employment contracts, see the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2011 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 ARS, inappropriately advising investment in ARS, 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 February 2012.



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

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report or in any document incorporated by reference might not occur. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Quarterly Report or the date of the document incorporated by reference in this Quarterly Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to Immunomedics 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 190 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 December 31, 2011, we employed 16 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. There may be a temporary delay in the enrollment of new patients in trials due to potential cutbacks in discretionary spending, if necessary.

### **Epratuzumab**

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

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randomized, double-blind studies designed to confirm the clinical efficacy and safety of epratuzumab in the treatment of patients with moderate to severe general SLE, in addition to continuing standard of care treatments. Each study will last a maximum of 54 weeks after first dose and will randomize 780 patients in the study, with approximately 130 planned investigational sites per study. Top-line results from these studies are expected in the first half of calendar year 2014.

Epratuzumab remains of interest to the oncology community and is being studied in diverse clinical trials conducted by outside third parties, 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 (ASH) 2010 Annual Meeting (ASH Annual Meeting Abstracts; 2010 116:427), which showed an 84% overall response rate with durable complete responses.

**The Diffuse Large B-Cell Lymphoma (DLBCL) study** conducted by the NCCTG Study Group received encouraging results from the first part of study with epratuzumab + rituximab + CHOP chemotherapy as upfront therapy (Cancer. 2006 Dec 15;107(12):2826-32). A total of 107 patients were enrolled in the second part of the study, a multicenter Phase II trial. The results, which showed a high rate of durable complete responses, were published in the October 13<sup>th</sup>, 2011 issue of *Blood* (Blood. 2011 Oct 13; 118(15): 4053-4061. PMID: 21673350). We are discussing the possibility of a NCI study group conducting a randomized Phase II/III trial comparing E+R+CHOP to R+CHOP.

**COG Study Group:** This clinical trial in relapsed pediatric acute lymphoblastic leukemia (ALL) enrolled a total of 128 patients, with 12 patients enrolled in the initial feasibility/Phase 1 portion (J Clin Oncol. 2008 Aug 1; 26(22):3756-62. PMID: 18669463), 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 were treated using a twice-weekly dosing schedule (as in the Phase 1 portion), in combination with chemotherapy. Results from the Phase 2 portion of the study were reported at the December 2011 Annual Meeting of the ASH.

A second study of epratuzumab combined with chemotherapy in relapsed pediatric ALL patients is being planned as a multi-center European trial by the IntreALL Inter-European study group. 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.

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

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

The SWOG Study Group is conducting a multicenter Phase II trial of epratuzumab combined with chemotherapy (clofaribine and cytarabine) in relapsed adult ALL. The primary objective of this trial is complete remission rate.

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### **<sup>90</sup>Y-Epratuzumab Tetraxetan**

GOELAMS Study of <sup>90</sup>Y-epratuzumab as a consolidation therapy in aggressive non-Hodgkin lymphoma (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 were presented at the Annual Meeting of the Society of Nuclear Medicine in June 2011 (J Nucl Med 2011; 52 (Supplement 1):355).

The Weill Cornell Medical College-NY Presbyterian Medical Center, New York is conducting a study of <sup>90</sup>Y-epratuzumab combined with velutuzumab 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 + velutuzumab in relapsed, aggressive, NHL, and is anticipated to enroll up to 70 patients. This trial is ongoing.

### **Veltuzumab**

Autoimmune Disease Indications: Nycomed has initiated their Phase II dose-ranging study of subcutaneous (SC) veltuzumab in rheumatoid arthritis. The current trial in immune thrombocytopenic purpura (ITP), run by Immunomedics and funded by Nycomed, is continuing patient enrollment to evaluate alternative dosing schedules. Updated results from this study were presented at the 2011 ASH Annual Meeting.

Oncology Indications: For NHL, the Company is evaluating plans to initiate a Phase III registration trial for veltuzumab in NHL. The Company will need to secure additional funding to advance veltuzumab into Phase III.

The SC veltuzumab trial has been completed and the results have been published (Haematologica. 2011 Apr; 96(4):567-73. Epub 2010 Dec 20). For chronic lymphocytic leukemia (CLL), the study is continuing after amending the protocol to evaluate a different dosing schedule.

### **<sup>90</sup> Y - Clivatuzumab Tetraxetan (<sup>90</sup>Y-hPAM4)**

The Phase Ib/II study of <sup>90</sup>Y-hPAM4 in patients with advanced pancreatic cancer has completed patient enrollment.

Results from the first part of this study were reported as an oral presentation at the June 2011 Society of Nuclear Medicine Annual Meeting. Final results from the two-part study were presented at the January 2012 Gastrointestinal Cancers Symposium.

The Company has consulted with regulatory authorities and key opinion leaders on several occasions to define further development plans for <sup>90</sup>Y-hPAM4. It was recommended that we address the benefit of adding low-dose gemcitabine to our <sup>90</sup>Y-hPAM4 before we use this combination in a registration trial, especially since our first Phase I study of <sup>90</sup>Y-hPAM4 given by itself to patients relapsing to prior therapies showed evidence of therapeutic activity. As a result of these consultations, a Phase Ib clinical trial will be opened to accrue patients with pancreatic cancer who have failed at least two prior therapies. These patients will be enrolled into one of two arms in the trial: <sup>90</sup>Y-hPAM4 versus <sup>90</sup>Y-hPAM4 + low-dose gemcitabine. The Company

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believes this clinical trial, and the completed Phase Ib trial in patients with pancreatic cancer who are naïve to therapy (discussed above), will support progressing into registration trials in the future. However, the planned Phase III trial will be postponed approximately six months until the comparison of <sup>90</sup>Y-hPAM4 to <sup>90</sup>Y-hPAM4 + low-dose gemcitabine has been completed in pancreatic cancer patients who have had at least two prior therapies. The Company believes this is not only responsive to our advisors' recommendations, but may ultimately provide a shortened clinical development program for this promising agent in pancreatic cancer therapy.

The Phase I dose-escalation, multicenter, trial of <sup>90</sup>Y-clivatuzumab tetraxetan given alone in relapsed, advanced pancreatic cancer patients was published in *Clinical Cancer Research* (Clin Cancer Res. 2011 Jun 15;17(12):4091-100. Epub 2011 Apr 28. PMID: 21527562).

### **Milatuzumab**

Early phase trials of milatuzumab in CLL and NHL, conducted by the Company and by Weill Cornell Medical College-NY Presbyterian Medical Center, respectively, are continuing patient accrual.

Milatuzumab is also being investigated in combination with velutuzumab by our collaborators at the Ohio State University, in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (NHL) after at least 1 prior therapy. Results from this Phase I/II study were updated at the 2011 ASH Annual Meeting. The milatuzumab+velutuzumab combination has previously demonstrated *in vitro* anti-tumor activity in preclinical studies performed by this group (*Blood*. 2011 Apr 28;117(17):4530-41. Epub 2011 Jan 12. PMID: 21228331).

### **Milatuzumab-DOX**

The Phase I/II clinical trial of this drug conjugate is ongoing and is enrolling patients with relapsed multiple myeloma, taking advantage of the rapid internalization property of milatuzumab when bound to CD74.

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

The Company has initiated this new drug conjugate, the second agent from its antibody-drug conjugate program, in a dose-escalation Phase I study in patients with colorectal cancer.

### **TF2**

TF2 is a <sup>90</sup>Y-based pretargeting radioimmunotherapeutic agent for the treatment of solid cancers expressing the carcinoembryonic antigen. The agent is currently being investigated for the therapy of patients with advanced colorectal cancer. Another trial in colorectal cancer is ongoing in the Netherlands sponsored by an investigator study group. A third trial has begun enrolling patients in Europe with small-cell-lung cancer, conducted by a French study group.

### **Critical Accounting Policies**

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. The following discussion highlights what we believe to be the critical accounting policies and judgments made in the preparation of these condensed consolidated financial statements.

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***Revenue Recognition***

In October 2009, the FASB, issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to the fair value with an allocation based on selling price. We apply ASU 2009-13 to our revenue arrangements containing multiple deliverables that are entered into. We allocate revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or our estimate of selling price when fair value is not available for a given unit of accounting. ASU 2009-13 was 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.

In April, 2010 the FASB issued ASU 2010-17 Revenue Recognition Milestone Method , which provides guidance to research and development companies on defining a milestone and determining when it may be appropriate to apply the milestone method when recognizing revenue. The milestone method of revenue recognition is an accounting policy election that has been adopted by us. In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the FASB guidance on the milestone method of revenue recognition at the inception of a collaboration agreement. The criteria requires that (i) we determine if the milestone is commensurate with either our performance to achieve the milestone or the enhancement of value resulting from our activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved.

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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 we have 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.

Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

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

### ***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 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 (loss).

### ***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, 2011 and Note 3 to our condensed consolidated financial statements in our Quarterly Report on Form 10-Q for the quarter ended December 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.

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

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

	Six-Month Periods Ended December 31,	
	2011	2010
Expected dividend yield	0.0%	0.0%
Expected life of options (years)	5.32	5.42
Expected stock price volatility	80%	88%
Risk-free interest rate	1.45% - 2.46%	2.33% - 2.43%

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

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

Research and development costs that are reimbursable under collaboration agreements are included as a reduction of research and development expenses. We record these reimbursements as a reduction of research and development expenses as our partner in the collaboration agreement has the financial risks and responsibility for conducting these research and development activities.

***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 December 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 December 31, 2011 Compared to 2010******Revenues***

Revenues for the three-month period ended December 31, 2011 were \$29.7 million, as compared to \$1.0 million for the same period in 2010, representing an increase of \$28.7 million or 2,870%. The increase was due to \$28.4 million of license fee revenue earned under the terms of the Amendment Agreement with UCB whereby UCB received the right to sublicense to a third party a license to develop, manufacture, market and sell our drug epratuzumab, for the



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United States and certain other territories. Product sales for the three-month period ended December 31, 2011 were \$1.1 million, as compared to \$0.7 million for the same period in 2010, representing an increase of \$0.4 million or 57%. This increase resulted from higher sales volume for sales of LeukoScan in Europe. Research and development revenues for the three-month periods ended December 31, 2011 and 2010 were both \$0.2 million.

### *Costs and Expenses*

Total costs and expenses for the three-month period ended December 31, 2011 were \$8.5 million, as compared to \$7.5 million for the same period in 2010, representing an increase of \$1.0 million or 13%. Research and development expenses for the three-month period ended December 31, 2011 were \$6.2 million as compared to \$5.8 million for the same period in 2010, an increase of \$0.4 million or 7%. The increase in research and development expenses resulted primarily from a decrease of \$1.2 million of research & development expense reimbursements from the previous year, partially offset by a decrease of \$0.8 million of clinical trial related expenses. Cost of goods sold for the three-month period ended December 31, 2011 was \$0.1 million for both periods. Gross profit margins were 87% and 85%, respectively, for the three-month periods ended December 31, 2011 and 2010. General and administrative costs increased to \$1.9 million or 27% for the three-month period ended December 31, 2011, from \$1.5 million for the same period of 2010, due primarily to an increase of \$0.4 million in additional incentive compensation due to our Chairman in accordance with his employment agreement, resulting from the expectation of the Company's profitability for the 2012 fiscal year. There can be no assurance that the Company will be profitable for the 2012 fiscal year.

### *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 we incurred during the 2011 fiscal year. We recognized the full \$2.9 million of the grant as of the date of notification since we had already incurred all of the qualifying expenses. We classified this payment as other income in the Condensed Consolidated Statement of Operations for the three-month period ended December 31, 2010 as this program was non-recurring in nature. There was no similar program in the three-month period ended December 31, 2011.

### *Interest Income and Other Income*

Interest and other income for the three-month periods ended December 31, 2011 and 2010 was \$20 thousand and \$0.3 million, respectively. The decrease was due in part to the \$0.1 million gain from an insurance claim for equipment failure and \$0.1 million for the amortization of the discount for the auction rate securities which were included in the prior year.

### *Foreign Currency Transaction (Loss) Gain*

Foreign currency transactions amounted to a loss of \$0.1 million for the three-month period ended December 31, 2011 as compared to a loss of \$53 thousand for the same period in 2010, primarily as a result of currency fluctuations between the U.S. Dollar and the Euro.

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### *Income Tax (Expense) Benefit*

Income tax expense was \$0.4 million for the three-month period ended December 31, 2011 as compared to an income tax benefit of \$2 thousand for the three-month period ended December 31, 2010, as a result of the profitability of the domestic and foreign subsidiaries in 2011.

### *Consolidated Net Income (Loss)*

Net income for the three-month period ended December 31, 2011 was \$20.7 million or \$0.27 per basic share as compared to a net loss of \$3.4 million or \$0.05 per basic share, for the same period in 2010 representing an increase of \$24.1 million. The increase in net income reported in fiscal 2012 as compared to fiscal 2011 resulted primarily from the \$28.4 million of license fee revenue recorded from the UCB Amendment Agreement during the second quarter of fiscal 2012, offset in part by the non-recurring \$2.9 million of grants under the QTDP program in fiscal 2011 and \$1.0 million of higher costs and expenses in fiscal 2012.

### *Six -Month Period Ended December 31, 2011 Compared to 2010*

#### *Revenues*

Revenues for the six-month period ended December 31, 2011 were \$30.8 million as compared to \$2.5 million for the same period in 2010, representing an increase of \$28.3 million or 1,132%. The increase was due to \$28.4 million of license fee revenue earned under the terms of the Amendment Agreement with UCB whereby UCB received the right to sublicense to a third party a license to develop, manufacture, market and sell our drug epratuzumab, for the United States and certain other territories. Product sales for the six-month periods ended December 31, 2011 and 2010 were \$1.9 million, as sales volume of LeukoScan in Europe were approximately the same for both periods. Research and development revenues for the six-month period ended December 31, 2011 were \$0.5 million as compared to \$0.6 million for the previous year, a decrease of \$0.1 million or 17% due to the timing of program spending and the number of grant programs in place during each period.

#### *Costs and Expenses*

Total costs and expenses for the six-month period ended December 31, 2011 were \$14.8 million, as compared to \$15.7 million for the same period in 2010, representing a decrease of \$0.9 million or 6%. Research and development expenses for the six-month period ended December 31, 2011 were \$11.0 million as compared to \$11.6 million for the same period in 2010, a decrease of \$0.6 million or 5%. The decrease in research and development expenses resulted primarily from a decrease of \$0.5 million of spending for clinical trials, \$0.2 million of lower material purchases and \$0.2 million for lower patent-related expenses, partially offset by \$0.4 million reduced research and development expense reimbursement. Cost of goods sold for each of the six-month periods ended December 31, 2011 and 2010 was \$0.2 million. Gross profit margins were 88% for the first six months of fiscal 2012 and fiscal 2011. General and administrative costs were \$3.0 million for the six-month period ended December 31, 2011, and \$3.5 million for the same period in 2010, a decrease of \$0.5 million or 14%. The decrease is primarily attributable to decreased legal expenses of \$1.0 million pertaining to the FINRA arbitration hearing. This was partially offset by the recognition in fiscal year 2012 of \$0.4 million of additional incentive compensation to our Chairman in accordance with his employment agreement, resulting from the expectation of the Company's profitability for the 2012 fiscal year. There can be no assurance that the Company will be profitable for the 2012 fiscal year.

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Reimbursement of research and development expenses for the six-month period ended December 31, 2011 totaled \$1.7 million as compared to \$2.1 million for the six-month period ended December 31, 2010, and is expected to decrease significantly subsequent to December 31, 2011.

### *Interest and Other Income*

Interest and other income for the six-month periods ended December 31, 2011 and 2010 was \$28 thousand and \$0.5 million, respectively. Included in fiscal 2010 results is \$0.3 million of a gain from an insurance claim for equipment failure.

### *Qualifying Therapeutic Discovery Project Program ( QTDP )*

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 related to qualifying expenses we had 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 was received during the first quarter of fiscal 2012 based on qualifying expenses we incurred during the 2011 fiscal year. We recognized the full \$2.9 million of the grant as of the date of notification since we had already incurred all of the qualifying expenses. Since this program was non-recurring in nature, we classified this payment as other income in the Condensed Consolidated Statement of Operations for the six-month period ended December 31, 2010. There was no similar program in the six-month period ended December 31, 2011.

### *Foreign Currency Transaction Gain (Loss)*

Foreign currency transactions amounted to a loss of \$84 thousand for the six-month period ended December 31, 2011 as compared to a loss of \$25 thousand in the same period in 2010 due to currency fluctuations between the U.S. Dollar and the Euro.

### *Income Tax Expense*

Income tax expense of \$0.4 million for the six-month period ended December 31, 2011 was primarily the result of Federal income taxes for the domestic operations as compared to \$45 thousand for the same period in 2010, representing foreign income taxes for wholly-owned subsidiaries.

### *Consolidated Net Income (Loss)*

Net income for the six-month period ended December 31, 2011 was \$15.5 million or \$0.21 basic per share, as compared to a net loss of \$9.9 million, or \$0.13 per basic share, for the same period in 2010, representing an increase of \$25.4 million. The increase in net income in 2011 as compared to the same period in 2010 resulted primarily from the \$28.4 million of license fee revenue recorded from the UCB Amendment Agreement during the second quarter of fiscal 2012, offset in part by the non-recurring \$2.9 million of grants under the QTDP program.

## **Liquidity and Capital Resources**

### **Discussion of Cash Flows**

*Cash flows from operations.* Net cash used in operating activities for the six-month period ended December 31, 2011 was \$10.5 million compared to \$8.9 million net cash used in operating activities for the six months ended December 31, 2010 due principally to proceeds received in 2010 from the QTDP (\$2.5 million) which were not received in 2011, and \$0.8 million in a decrease of other assets and a \$0.5 million increase in accounts payable and accrued expenses.

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*Cash flows from investing.* Net cash used in investing activities for the six-months ended December 31, 2011 was \$0.3 million compared to \$0.7 million of net cash provided by investing activities for the six-months ended December 31, 2010. The decrease in cash flow from investing activities for fiscal 2012 is primarily due to the prior year's receipt of \$1.0 million from the proceeds from the sale of ARS and \$0.1 million in proceeds from an insurance claim, which were not repeated in the 2012 fiscal year.

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

## **Working Capital and Cash Requirements**

At December 31, 2011, we had working capital of \$43.1 million, which was approximately \$18.4 million higher than the working capital of \$24.7 million at June 30, 2011. The increase in working capital was primarily a result of the \$30.0 million receivable from UCB as a result of the Amendment Agreement, partially offset by our use of \$10.5 million of cash and cash equivalents in operations.

Our cash and cash equivalents amounted to \$16.3 million at December 31, 2011, representing a decrease of \$10.8 million from \$27.1 million at June 30, 2011. The decrease was primarily attributable to the \$10.5 million of cash used in operations during the six-month period ended December 31, 2011.

During January 2012 we received \$30.0 million of cash proceeds related to the receivable from UCB. After receipt of the \$30.0 million, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2012 are expected to be in the \$20.0 - \$22.0 million range, approximately the same level as the previous fiscal year.

Research and development activities are expected to continue to expand over time. Clinical development and eventual registration of clivatuzumab are under discussions with the FDA and key opinion leaders. 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. As a result, we will continue to require additional financial resources in order to continue our research and development programs, clinical trials of product candidates and regulatory filings.

We are pursuing partnering opportunities and other activities for our other product candidates, which could provide up-front and milestone payments, as well as funding of development costs and other licensing possibilities. In the event that we are unable to secure funding from partnering arrangements, we would seek to raise additional capital or pursue other strategic options. Since our inception in 1982, our 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 we will be able to raise the additional capital we will need on commercially acceptable terms, if at all. If not, our ability to continue our research and development will be materially and adversely affected. Furthermore, the terms of any such debt or equity financing may include covenants which limit our future ability to manage the business.

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

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10-Q. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources when necessary to fund our strategic priorities.

**Effects of Inflation**

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

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

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

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

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**ITEM 4. CONTROLS AND PROCEDURES**

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

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

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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

*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 ARS, inappropriately advising investment in ARS, 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 February 2012.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

On December 27, 2011, we issued and sold to UCB a 5-year warrant to purchase one million (1,000,000) shares of our common stock, par value \$0.01 per share, at an exercise price equal to \$8.00 per share. The warrant was issued to UCB in connection with the Amendment Agreement we entered into with them whereby UCB received the right to sublicense to a third party a license to develop, manufacture, market and sell our drug epratuzumab, for the United States and certain other territories, as described elsewhere in this quarterly report. The issuance of the warrant was deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Section 4(2) of the Securities Act as transactions not involving a public offering.



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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 December 31, 2011, we had an accumulated deficit of approximately \$202.3 million. We continue to spend our cash resources to fund our research and development programs and, subject to adequate funding, we expect these expenses to increase for the foreseeable future. Our only significant sources of revenue in recent years have been derived from our existing licensing agreements with UCB and 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. 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:

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;

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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 both fiscal years 2011 and 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, and \$30.0 million in fiscal 2012 for the amended restructuring of the agreement;

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

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limited product sales of CEA-Scan® and LeukoScan®, licenses, grants and interest income from our investments. Based on our expected cash utilization rate, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. Cash requirements in fiscal year 2012 are expected to be in the \$20.0 - \$22.0 million range, approximately the same level as in the previous fiscal year.

Over the long term, 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 velvutuzumab 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 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

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

We have licensed the exclusive worldwide rights to two 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, unsuccessful 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.

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

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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 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

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proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or otherwise gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

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

The biotechnology industry is highly competitive, particularly in the area of diagnostic and therapeutic oncology and autoimmune disease products. In recent years, there have been extensive technological innovations achieved in short periods of time, and it is possible that future technological changes and discoveries by others could result in our products and product candidates quickly becoming uncompetitive or obsolete. A number of companies, including Biogen Idec, Roche, GlaxoSmithKline, Human Genome Sciences, Seattle Genetics, Emergent BioSolutions, Merck Serono, Genmab, Amgen, Bristol-Myers Squibb, Bayer Healthcare Pharmaceuticals, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic autoimmune and oncology products. For example, Human Genome Sciences 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 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

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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 six months ended December 31, 2011, we have incurred \$0.1 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.***

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 or (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 increased the minimum Medicaid drug rebates for pharmaceutical companies, expanded the 340B drug discount program, and made changes to affect the Medicare Part D coverage gap, or "donut hole." The law also revised 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 imposed 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.



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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;

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

If the clinical development process is completed successfully, our ability to derive revenues from the sale of therapeutics will depend on our first obtaining FDA or other comparable foreign regulatory approvals, each of which are subject to unique risks and uncertainties;

There is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates;

We have not received regulatory approval in the United States or any foreign jurisdiction for the commercial sale of any of our product candidates; and

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

## **Risks Related to Our Securities**

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

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

If our stock is not accepted for listing on the NASDAQ, we will make every possible effort to have it listed on the Over the Counter Bulletin Board, or the OTC Bulletin Board. If our common stock were to be traded on the OTC Bulletin Board, the Securities Exchange Act of 1934, as amended, and related Securities and Exchange Commission, or SEC, rules would impose additional sales practice requirements on broker-dealers that sell our securities. These rules may adversely affect the ability of stockholders to sell our common stock and otherwise negatively affect the liquidity, trading market and price of our common stock.

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



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markets and, often time, the difference between the bid and the asked prices are substantial. As a result, if our common stock were traded on the Pink Sheets, there would likely be a further negative affect on the liquidity, trading market and price of our common stock even compared to what we might suffer if we were traded on the OTC Bulletin Board.

As a result of the above, we cannot assure you that our common stock will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the Pink Sheets; or if it is to be listed, whether or not there would be an interruption in the trading of our common stock. We believe that the listing of our stock on a recognized national trading market, such as 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 our ability to benefit from the use of its operations and expansion plans, including for use in licensing agreements, joint ventures, the development of strategic relationships and acquisitions, which are critical to our business and strategy and none of which is currently the subject of any agreement, arrangement or understanding, with respect to any future financing or strategic relationship it may undertake. The delisting from NASDAQ would result in negative publicity and would negatively impact our ability to raise capital in the future.

***If we were delisted from 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 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.

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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.

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 February 7, 2012, we had 75,525,231 shares of common stock outstanding 6,718,443 additional shares reserved for the exercise of outstanding options and restricted stock units, 4,404,324 additional shares of common stock authorized for issuance and remaining to be granted under our stock option plans, and 1,000,000 shares of common stock reserved for warrant shares.

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

As of December 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



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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 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

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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.

***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 February 7, 2012, we had 75,525,231 shares of common stock outstanding, 6,718,443 additional shares reserved for the exercise of outstanding options and restricted stock units, 4,404,324 additional shares of common stock authorized for issuance and remaining to be granted under our stock option plan, and 1,000,000 shares of common stock reserved for warrant shares.

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**ITEM 6. EXHIBITS**

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



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**SIGNATURES**

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

IMMUNOMEDICS, INC.

February 8, 2012

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

February 8, 2012

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

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<b>Number</b>	<b>Description of Document</b>
10.1	Amendment Agreement by and between the Company and UCB Pharma, S.A., dated December 27, 2011. *
10.2	Form of Warrant issued by the Company to UCB Pharma, S.A., dated December 27, 2011.*
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language) and furnished electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss); (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.**
101.INS	XBRL Instance Document. **
101.SCH	XBRL Taxonomy Extension Schema. **
101.CAL	XBRL Taxonomy Extension Calculation Linkbase. **
101.LAB	XBRL Taxonomy Extension Label Linkbase. **
101.PRE	XBRL Taxonomy Extension Presentation Linkbase. **

\* Filed herewith.

\*\* Pursuant to Rule 406Tof Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections. Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.