

IMMUNOMEDICS INC  
Form 10-Q  
May 06, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2015**

**or**

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

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

**Commission File Number: 0-12104**

**Immunomedics, Inc.**

**(Exact name of Registrant as specified in its charter)**

**Delaware** **61-1009366**  
**(State or other jurisdiction of** **(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 May 5, 2015 was 93,464,463.

**Table of Contents**

**IMMUNOMEDICS, INC.**

**TABLE OF CONTENTS**

**PART I: FINANCIAL INFORMATION**

ITEM 1. FINANCIAL STATEMENTS:

Unaudited Condensed Consolidated Balance Sheets as of March 31, 2015 and June 30, 2014 1

Unaudited Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended March 31, 2015 and 2014 2

Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended March 31, 2015 and 2014 3

Notes to Unaudited Condensed Consolidated Financial Statements 4

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS 23

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK 39

ITEM 4. CONTROLS AND PROCEDURES 40

**PART II: OTHER INFORMATION**

ITEM 1. LEGAL PROCEEDINGS 41

ITEM 1A. RISK FACTORS 43

ITEM 6. EXHIBITS 62

SIGNATURES 63

EXHIBIT INDEX 64

**Table of Contents**

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

	<b>March 31, 2015</b>	<b>June 30, 2014</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 16,063,159	\$ 6,961,494
Marketable securities	90,129,300	34,871,120
Accounts receivable, net of allowance for doubtful accounts of \$62,024 at March 31, 2015 and \$88,609 at June 30, 2014	598,164	674,617
Inventory	624,367	778,989
Other receivables	185,381	303,102
Prepaid expenses	1,637,025	1,614,897
Other current assets	378,513	180,678
<b>Total current assets</b>	<b>109,615,909</b>	<b>45,384,897</b>
Property and equipment, net of accumulated depreciation of \$27,721,469 and \$27,312,924 at March 31, 2015 and June 30, 2014, respectively	2,065,311	1,895,475
Other long-term assets	152,405	206,110
<b>Total Assets</b>	<b>\$ 111,833,625</b>	<b>\$ 47,486,482</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 8,824,995	\$ 6,886,682
Deferred revenues	230,759	240,158
<b>Total current liabilities</b>	<b>9,055,754</b>	<b>7,126,840</b>
Convertible senior notes net of unamortized debt issuance costs of \$3,557,878 at March 31, 2015	96,442,122	
Other liabilities	1,574,881	1,500,244
Commitments and Contingencies		
Stockholders Equity:		
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at March 31, 2015 and June 30, 2014		
Common stock, \$0.01 par value; authorized 155,000,000 shares at March 31, 2015 (135,000,000 at June 30, 2014); issued 93,479,501 shares and outstanding 93,444,776 shares at March 31, 2015; and issued 93,113,480 shares and outstanding 93,078,755 shares at June 30, 2014	934,794	931,134
Capital contributed in excess of par	302,180,742	300,080,804

Edgar Filing: IMMUNOMEDICS INC - Form 10-Q

Treasury stock, at cost, 34,725 shares at March 31, 2015 and at June 30, 2014	<b>(458,370)</b>	(458,370)
Accumulated deficit	<b>(297,067,440)</b>	(261,465,638)
Accumulated other comprehensive (loss) income	<b>(243,729)</b>	261,837
<b>Total Immunomedics, Inc. stockholders equity</b>	<b>5,345,997</b>	39,349,767
Noncontrolling interest in subsidiary	<b>(585,129)</b>	(490,369)
<b>Total stockholders equity</b>	<b>4,760,868</b>	38,859,398
<b>Total Liabilities and Stockholders Equity</b>	<b>\$ 111,833,625</b>	\$ 47,486,482

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

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

	Three months ended March 31,		Nine months ended March 31,	
	2015	2014	2015	2014
<b>Revenues:</b>				
Product sales	\$ 694,329	\$ 925,235	\$ 2,183,626	\$ 2,434,159
License fee and other revenues	250,000		250,000	4,623,333
Research and development	238,369	229,106	823,861	797,120
<b>Total revenues</b>	<b>1,182,698</b>	<b>1,154,341</b>	<b>3,257,487</b>	<b>7,854,612</b>
<b>Costs and Expenses:</b>				
Costs of goods sold	72,771	90,253	218,040	270,523
Costs of license fee and other revenues				1,189,170
Research and development	10,385,422	8,141,744	30,142,289	23,221,651
Sales and marketing	285,708	243,692	689,140	886,234
General and administrative	1,564,536	2,200,526	7,239,764	5,975,278
<b>Total costs and expenses</b>	<b>12,308,437</b>	<b>10,676,215</b>	<b>38,289,233</b>	<b>31,542,856</b>
<b>Operating loss</b>	<b>(11,125,739)</b>	<b>(9,521,874)</b>	<b>(35,031,746)</b>	<b>(23,688,244)</b>
Interest expense	(720,795)		(720,795)	
Interest and other income, net	32,838	15,179	69,126	39,695
Foreign currency transaction gain (loss)	28,873	(25,894)	29,035	(7,902)
<b>Loss before income tax expense</b>	<b>(11,784,823)</b>	<b>(9,532,589)</b>	<b>(35,654,380)</b>	<b>(23,656,451)</b>
Income tax expense	(3,327)	(1,372)	(42,182)	(1,372)
<b>Net loss</b>	<b>(11,788,150)</b>	<b>(9,533,961)</b>	<b>(35,696,562)</b>	<b>(23,657,823)</b>
Net loss attributable to noncontrolling interest	(32,003)	(28,359)	(94,760)	(78,778)
<b>Net loss attributable to Immunomedics, Inc. stockholders</b>	<b>\$ (11,756,147)</b>	<b>\$ (9,505,602)</b>	<b>\$ (35,601,802)</b>	<b>\$ (23,579,045)</b>
<b>Loss per common share attributable to Immunomedics, Inc. stockholders:</b>				
Basic and diluted	\$ (0.13)	\$ (0.11)	\$ (0.38)	\$ (0.28)

Edgar Filing: IMMUNOMEDICS INC - Form 10-Q

Weighted average shares used to calculate loss  
per common share:

Basic and diluted	<b>93,351,708</b>	<b>83,340,329</b>	<b>93,201,307</b>	<b>83,127,073</b>
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustments	<b>(253,502)</b>	<b>3,355</b>	<b>(511,335)</b>	<b>123,236</b>
Unrealized gain (loss) on available-for-sale securities	<b>16,220</b>	<b>(4,138)</b>	<b>5,769</b>	<b>10,884</b>
Other comprehensive (loss) income	<b>(237,282)</b>	<b>(783)</b>	<b>(505,566)</b>	<b>134,120</b>
Net comprehensive loss	<b>(12,025,432)</b>	<b>(9,534,744)</b>	<b>(36,202,128)</b>	<b>(23,523,703)</b>
Net loss attributable to noncontrolling interest	<b>(32,003)</b>	<b>(28,359)</b>	<b>(94,760)</b>	<b>(78,778)</b>
Net comprehensive loss attributable to Immunomedics, Inc. stockholders	<b>\$ (11,993,429)</b>	<b>\$ (9,506,385)</b>	<b>\$ (36,107,368)</b>	<b>\$ (23,444,925)</b>

See accompanying notes to unaudited condensed consolidated financial statements

Table of Contents

**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	Nine Months Ended March 31,	
	2015	2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (35,696,562)	\$ (23,657,823)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	408,643	424,084
Amortization of debt issuance costs	99,337	
Gain on sale of marketable securities	(10,203)	(4,193)
(Decrease) increase in allowance for doubtful accounts	(20,752)	12,037
Non-cash expense related to stock compensation	2,117,582	2,403,293
Amortization of deferred revenue	(9,399)	(2,532,016)
Non-cash decrease in value of life insurance policy	53,705	32,822
Amortization of deferred rent	74,637	74,637
Amortization of bond premiums	307,227	155,280
Changes in operating assets and liabilities	2,296,242	1,650,434
<b>Net cash used in operating activities</b>	<b>(30,379,543)</b>	<b>(21,441,445)</b>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(82,298,796)	(20,097,204)
Proceeds from sales of marketable securities	26,748,771	4,015,460
Purchases of property and equipment	(581,528)	(317,571)
<b>Net cash used in investing activities</b>	<b>(56,131,553)</b>	<b>(16,399,315)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible senior notes	100,000,000	
Payment of debt issuance costs	(3,657,214)	
Tax withholding payments for stock compensation	(518,995)	(286,786)
Exercise of stock options	505,011	1,663,346
<b>Net cash provided by financing activities</b>	<b>96,328,802</b>	<b>1,376,560</b>
Effect of changes in exchange rates on cash and cash equivalents	(716,041)	127,839
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>9,101,665</b>	<b>(36,336,361)</b>
Cash and cash equivalents, beginning of period	6,961,494	41,326,000

Cash and cash equivalents, end of period	<b>\$ 16,063,159</b>	<b>\$ 4,989,639</b>
--	----------------------	---------------------

See accompanying notes to unaudited condensed consolidated financial statements.

---

Table of Contents

**IMMUNOMEDICS, INC. AND SUBSIDIARIES**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED**  
**FINANCIAL STATEMENTS**

Reference is made to the Annual Report on Form 10-K of Immunomedics, Inc., a Delaware corporation ( Immunomedics, the Company, we, our or us ), for the fiscal year ended June 30, 2014, which contains our audited consolidated financial statements and the notes thereto.

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

Immunomedics is a clinical-stage biopharmaceutical company that develops monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has continued to transition its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company still manufactures and commercializes its LeukoScan<sup>®</sup> product in territories where regulatory approvals have previously been granted in Europe, Canada and in other markets outside the U.S. LeukoScan<sup>®</sup> is indicated for diagnostic imaging for determining the location and extent of infection and inflammation in bone of patients with suspected osteomyelitis, including patients with diabetic foot ulcers. The Company has two foreign subsidiaries, Immunomedics B.V. in the Netherlands and Immunomedics GmbH in Darmstadt, Germany, that assist the Company in managing sales efforts and coordinating clinical trials in Europe. In addition, included in the accompanying condensed financial statements is the majority-owned U.S. subsidiary, IBC Pharmaceuticals, Inc. ( IBC ), which works on the development of novel cancer radiotherapeutics using patented pre-targeting technologies with proprietary, bispecific antibodies.

The accompanying unaudited condensed consolidated financial statements of Immunomedics, which incorporate our subsidiaries, have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ), for interim financial information and the instructions to the Quarterly Report on Form 10-Q and Regulation S-X. Accordingly, the statements do not include all of the information and footnotes required by GAAP for complete annual financial statements. With respect to the financial information for the interim periods included in this Quarterly Report on Form 10-Q, which is unaudited, management believes that all adjustments (consisting of normal recurring accruals), considered necessary for a fair presentation of the results for such interim periods have been included. Operating results for the three and nine-month periods ended March 31, 2015 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2015, or any other period.

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



---

**Table of Contents**

As of March 31, 2015, the Company had cash, cash equivalents and marketable securities totaling \$106.2 million. In February, 2015 the Company issued \$100 million of 4.75% Convertible Senior Notes due 2020 (the Convertible Notes ) in the aggregate. After deducting the initial purchasers' fees and offering expenses, the Company received net proceeds of \$96.3 million, (see note 4 to the condensed consolidated financial statements).

Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of equity and debt securities and revenues from licensing agreements, which could provide up-front and milestone payments, as well as funding of development costs and other licensing possibilities.

The Company's budgeted cash requirements in fiscal year 2015 includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, as well as for expenses for the ongoing Phase 2 expansion ADC clinical trials (sacituzumab govitecan and labetuzumab govitecan). For the nine-month period ended March 31, 2015 the Company utilized cash aggregating \$30.4 million related to its operating activities. Based on the Company's cash flow projections, it believes it has sufficient funds to continue its operations and research and development programs for at least the next twelve months.

Future financial demands include ongoing operating expenses, Phase 3 clinical trials, the Phase 2 clinical trials and further development of various clinical trial programs in fiscal 2016 and 2017. The Company will continue to require additional funding in order to fund its operations and programs.

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

Until the Company can generate significant cash from its operations, the Company expects to continue to fund its operations with its available financial resources. These financial resources may not be adequate to sustain its operations and the Company will be required to finance future cash needs through strategic collaboration agreements, or the sale of additional equity or debt securities. However, the Company cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to the Company or its stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainties with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require the Company to delay, scale-back or eliminate some or all of its programs or renegotiate less favorable terms than it would otherwise choose. Failure to obtain adequate financing also may adversely affect its ability to operate as a going concern. Additionally, if the Company raises funds by issuing equity securities, dilution to existing stockholders would result; and, if the Company raises additional funds by incurring debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit its ability to operate its 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, 2014. The Company adheres to the same accounting policies in preparation of its interim financial statements.



## **Table of Contents**

### ***Principles of Consolidation and Presentation***

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

### ***Financial Instruments***

The carrying amounts of cash and cash equivalents, other current assets and current liabilities approximate fair value due to the short-term maturity of these instruments. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

### ***Marketable Securities***

Marketable securities, all of which are available-for-sale, consists of corporate debt securities, U.S. bonds and U.S. sponsored agencies and municipal bonds. Corporate debt securities include Eurodollar issues of U.S. corporations, and U.S. dollar denominated issues of foreign corporations. Marketable securities are carried at fair value, with unrealized gains and losses, net of related income taxes, reported as accumulated other comprehensive (loss) income, except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses, and declines in value judged to be other-than-temporary on available-for-sale securities are included in the determination of net (loss) income and are included in interest and other income (net), at which time the average cost basis of these securities are adjusted to fair value. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in interest and other income (net).

### ***Inventory***

Inventory, which consists only of the finished product of LeukoScan<sup>®</sup>, is stated at the lower of cost (which approximates first-in, first-out) or market, and includes materials, labor and manufacturing overhead.

### ***Revenue Recognition***

The Company has accounted for revenue arrangements that include multiple deliverables as a separate unit of accounting if both of the following criteria are met: a) the delivered item has value to the customer on a standalone basis, and b) if the right of return exists, delivery of the undelivered items is considered probable and substantially in the control of the vendor. If these criteria are not met, the revenue elements must be considered a single unit of accounting for purposes of revenue recognition. The Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Relative selling prices are determined using vendor specific objective evidence, if it exists; otherwise third-party evidence or the Company's best estimate of selling price is used for each deliverable.

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



---

**Table of Contents**

development agreements where the Company has continuing involvement in the agreement are recorded as deferred revenue and recognized over the estimated service period. The Company estimates the period of continuing involvement based on the best evidential matter available at each reporting period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

In order to determine the revenue recognition for contingent milestones, the Company evaluates the contingent milestones using the criteria as provided by the Financial Accounting Standards Boards ( FASB ) guidance on the milestone method of revenue recognition, as explained in ASU 2010-17, *Milestone Method of Revenue Recognition*, at the inception of a collaboration agreement. The criteria requires that (i) the Company determines if the milestone is commensurate with either its performance to achieve the milestone or the enhancement of value resulting from the Company's activities to achieve the milestone, (ii) the milestone be related to past performance, and (iii) the milestone be reasonable relative to all deliverable and payment terms of the collaboration arrangement. If these criteria are met then the contingent milestones can be considered as substantive milestones and will be recognized as revenue in the period that the milestone is achieved. Royalties are recognized as earned in accordance with the terms of various research and collaboration agreements.

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

***Research and Development Costs***

Research and development costs are expensed as incurred. Costs incurred for clinical trials for patients and investigators are expensed as services are performed in accordance with the agreements in place with their clinical sites.

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

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

***Stock-Based Compensation***

At the Annual Stockholder Meeting on December 3, 2014, the Company's stockholders approved the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the Plan). The Plan replaced the Company's 2006 Stock Incentive Plan (the 2006 Plan), which terminated on December 3, 2014. The approval authorized the sum of 9,000,000 shares plus the number of unallocated shares available for issuance as of the effective date under the 2006 Plan that were not subject to outstanding awards.

The Plan enables the grant of stock options, stock appreciation rights, stock awards, stock unit awards, performance shares, cash-based performance units and other stock-based awards, each of which may be granted separately or in tandem with other awards. The Plan is described more fully in Note 7 to these condensed consolidated financial statements.



**Table of Contents**

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

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

The following table sets forth the weighted-average assumptions used to calculate the fair value of options granted for the nine-month periods ended March 31, 2015 and 2014:

	<b>Nine-Month Period Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Expected dividend yield	0%	0%
Expected option term (years)	5.07	3.47
Expected stock price volatility	59%	66%
Risk-free interest rate	1.60%-1.67%	0.03%-1.79%

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

**Income Taxes**

The Company uses the asset and liability method to account for income taxes, including the recognition of deferred tax assets and deferred tax liabilities for the anticipated future tax consequences attributable to differences between financial statement amounts and their respective tax bases. The Company reviews its deferred tax assets for recovery. A valuation allowance is established when the Company believes that it is more likely than not that its deferred tax assets will not be realized. Changes in valuation allowances from period to period are included in the Company's tax provision in the period of change. The Company has recorded a full valuation allowance against its net deferred tax assets as of March 31, 2015.

At June 30, 2014, the Company has available net operating loss carry forwards for federal income tax reporting purposes of approximately \$173.4 million and for state income tax reporting purposes of approximately \$66.2 million, which expire at various dates between fiscal 2015 and 2034. Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, the annual utilization of a company's net operating loss and research credit carry forwards may be limited if the Company experiences a change in ownership of more than 50 percentage points within a three-year period.

The majority-owned subsidiary of the Company (IBC Pharmaceuticals, Inc.) is currently under examination by the Internal Revenue Service for the fiscal year ended December 31, 2013.



## **Table of Contents**

Income taxes were provided for profitable foreign jurisdictions at the estimated annual tax rate during the three and nine-month periods ended March 31, 2015 and 2014. The Company's U.S. operations reported a net loss for the three and nine-month periods ended March 31, 2015 and 2014, resulting in a tax benefit that was fully offset by a valuation allowance.

The Company has no liability for uncertain tax positions as of March 31, 2015.

### ***Net Loss Per Share Allocable to Common Stockholders***

Net loss per basic and diluted common share allocable to common stockholders is based on the net loss for the relevant period, divided by the weighted-average number of common shares outstanding during the period. For purposes of the diluted net loss per common share calculations, the exercise or conversion of all potential common shares is not included because their effect would have been anti-dilutive, due to the net loss recorded for the three and nine-month periods ended March 31, 2015 and 2014. The common stock equivalents excluded from the diluted per share calculation are 26,759,915 and 7,388,212 shares at March 31, 2015 and 2014, respectively.

### ***Net Comprehensive Loss***

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

### ***Reclassification***

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

### ***Accounting Pronouncements***

In April 2015, the FASB issued Accounting Standard Update ( ASU ) 2015-03, *Interest Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs* . Under the new ASU, debt issuance costs will be reported in the balance sheet as a direct deduction from the related debt liability rather than as a separate asset. Amortization of the costs is reported as interest expense. The amendments in this update are effective for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early application is permitted for financial statements that have not been previously issued. The Company has adopted this standard in the current interim period and have presented the debt issuance costs related to the Convertible Notes as a direct deduction from the related face value in the accompanying condensed consolidated balance sheet.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* . This guidance clarifies that an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The amendments in this update are effective for annual reporting periods ending after December 15, 2016, and annual and interim periods thereafter, and early application is permitted. The Company is assessing ASU 2014-15's impact and will adopt it when effective.

In June 2014, the FASB issued ASU 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* . This guidance clarifies that awards with these provisions should be



**Table of Contents**

treated as performance conditions that affect vesting, and do not impact the award's estimated grant-date fair value. The amendments in this update are effective for annual reporting periods beginning after December 31, 2015, including interim periods, and early application is permitted. The Company is assessing ASU 2014-12's impact and will adopt it when effective.

In June 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. This ASU was initiated as a joint project by the FASB and the International Accounting Standards Board (IASB) to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and IFRS. For a public company, the amendments in this update are effective for annual reporting periods beginning after December 15, 2016, including interim periods, and early application is not permitted for public companies. On April 1, 2015, the FASB voted to propose to defer the effective date on the new revenue recognition standard by one year. Therefore, public organizations would apply the new standard to annual reporting periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is assessing ASU 2014-09's impact and will adopt it when effective.

**3. Marketable Securities**

Immunomedics adopted Accounting Standards Codification No. 320, *Accounting for Investments Debt and Equity Securities*, to account for investments in marketable securities. Under this accounting standard, securities for which there are no positive intent and ability to hold to maturity, the securities are classified as available-for-sale and are carried at fair value. Unrealized holding gains and losses, which are deemed to be temporary, on securities classified as available-for-sale are carried as a separate component of accumulated other comprehensive (loss) income. Immunomedics considers all of its current investments to be available-for-sale.

Marketable securities at March 31, 2015 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
March 31, 2015				
U.S. Treasury Bonds	\$ 13,690	\$ 12	\$	\$ 13,702
U.S. Government Sponsored Agencies	46,383	21	(9)	46,395
Corporate Debt Securities	30,051	5	(24)	30,032
	\$ 90,124	\$ 38	\$ (33)	\$ 90,129

Maturities of debt securities classified as available-for-sale were as follows at March 31, 2015 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	\$ 38,344	\$ 38,442
Due after one year through five years	51,785	52,064

\$ 90,129      \$ 90,506

**Table of Contents**

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

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
<b>June 30, 2014</b>				
U.S. Treasury Bonds	\$ 8,537	\$ 1	\$ (1)	\$ 8,537
U.S. Government Sponsored Agencies	7,458		(1)	7,457
Corporate Debt Securities	18,876	12	(11)	18,877
	\$ 34,871	\$ 13	\$ (13)	\$ 34,871

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

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

**4. Convertible Senior Notes**

In February 2015, the Company issued \$100.0 million of Convertible Notes (net proceeds of \$96.3 million after deducting the initial purchasers' fees and offering expenses) in a private offering exempt from registration under the Securities Act of 1933, as amended (the Securities Act), in reliance upon Rule 144A under the Securities Act. The Convertible Notes will mature on February 15, 2020, unless earlier purchased or converted. The debt issuance costs of approximately \$3.7 million, primarily consisting of underwriting, legal and other professional fees, will be amortized over the term of the Convertible Notes. The Convertible Notes were senior unsecured obligations of the Company. Interest at 4.75% will be payable semiannually on February 15 and August 15 of each year, beginning on August 15, 2015. The effective interest rate on the Convertible Note was 5.48% for the period from the date of issuance through March 31, 2015.

The Convertible Notes are convertible at the option of holders into approximately 19.6 million shares of Immunomedics common stock at any time prior to the close of business on the day immediately preceding the maturity date. The conversion rate will initially be 195.8336 shares of common stock per \$1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately \$5.11 per share of Immunomedics common stock).

If the Company undergoes a fundamental change (as defined in the indenture governing the Convertible Notes), holders may require Immunomedics to purchase for cash all or part of the Convertible Notes at a purchase price equal to 100% of the principal amount of the Convertible Notes to be purchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date, subject to certain exceptions. In addition, if certain make-whole

fundamental changes (as defined in the indenture governing the Convertible Notes) occur, Immunomedics will, in certain circumstances, increase the conversion rate for any Convertible Note converted in connection with such make-whole fundamental change.

The indenture does not limit the amount of debt which may be issued by the Company under the indenture or otherwise, does not contain any financial covenants or restrict the Company from paying dividends or issuing or repurchasing its other securities. The indenture contains customary terms and covenants and events of default.

## **Table of Contents**

If an event of default with respect to the Convertible Notes occurs, holders may, upon satisfaction of certain conditions, accelerate the principal amount of the Convertible Notes plus premium, if any, and accrued and unpaid interest, if any. In addition, the principal amount of the Convertible Notes plus premium, if any, and accrued and unpaid interest, if any, will automatically become due and payable in the case of certain types of bankruptcy or insolvency events of default involving the Company.

Total interest expense for the Convertible Notes was \$0.7 million for the three and nine-month period ended March 31, 2015 including amortization of debt issuance costs of \$0.1 million.

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

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses, and Convertible Notes. The carrying amount of accounts receivable, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments as of March 31, 2015 and June 30, 2014.

The Company has categorized its other financial instruments, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

#### **Cash, cash equivalents and marketable securities:**

Financial assets recorded on the condensed consolidated balance sheets as of March 31, 2015 and June 30, 2014 are categorized based on the inputs to the valuation techniques as follows (in thousands):

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

*Level 2* Financial assets whose value are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.

*Level 3* Financial assets whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset.

**Table of Contents**

	(\$ in thousands)			
<b>March 31, 2015</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
Money Market Funds	\$ 11,859	\$	\$	\$ 11,859
Marketable Securities:				
U.S. Treasury Bonds	13,702			13,702
U.S. Government Sponsored Agencies	46,395			46,395
Corporate Debt Securities	30,032			30,032
Total	\$ 101,988	\$	\$	\$ 101,988

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

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

**Convertible Notes**

The fair value of the Convertible Notes, which differs from their carrying values, is influenced by interest rates, the Company's stock price and stock price volatility and is determined by prices for the Convertible Notes observed in market trading which are Level 2 inputs. The estimated fair value of the Convertible Notes as of March 31, 2015 was \$99.6 million.

**6. Stockholders Equity**

At the Annual Stockholder Meeting on December 3, 2014, the Company's stockholders approved the amendment and restatement of the Company's Certificate of Incorporation to increase the maximum number of shares of the Company's stock authorized up to 165,000,000 shares of stock consisting of 155,000,000 shares of common stock and 10,000,000 shares of preferred stock. Previously the Company's Certificate of Incorporation authorized up to 145,000,000 shares of stock consisting of 135,000,000 shares of common stock and 10,000,000 shares of preferred stock.

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

**Table of Contents****Accumulated Other Comprehensive Income**

The components of accumulated other comprehensive income were as follows:

	Currency Translation Adjustments	Net Unrealized (Losses) Gains on Available-for-Sale Securities	Accumulated Other Comprehensive Income
Balance, July 1, 2014	\$ 261,924	\$ (87)	\$ 261,837
Other comprehensive (loss) income before reclassifications	(511,335)	15,972	(495,363)
Amounts reclassified from accumulated other comprehensive income (loss) <sup>(a)</sup>		(10,203)	(10,203)
Net current-period other comprehensive (loss) income	(511,335)	5,769	(505,566)
Balance, March 31, 2015	\$ (249,411)	\$ 5,682	\$ (243,729)
Balance, July 1, 2013	\$ 161,830	\$	\$ 161,830
Other comprehensive income before reclassifications	123,236	15,077	138,313
Amounts reclassified from accumulated other comprehensive income <sup>(a)</sup>		(4,193)	(4,193)
Net current-period other comprehensive income	123,236	10,884	134,120
Balance, March 31, 2014	\$ 285,066	\$ 10,884	\$ 295,950

<sup>(a)</sup> For the nine-months ended March 31, 2015 and 2014, \$10,203 and \$4,193 was reclassified from accumulated other comprehensive income to interest and other income, respectively.

All components of accumulated other comprehensive income are net of tax, except currency translation adjustments, which exclude income taxes related to indefinite investments in foreign subsidiaries.

**7. Stock Incentive Plan**

At the Annual Stockholder Meeting on December 3, 2014, the Company's stockholders approved the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the "Plan"). The Plan replaced the Company's 2006 Stock Incentive Plan (the "2006 Plan"), which terminated on December 3, 2014. The Plan was established to promote the interests of the Company, by providing eligible persons with the opportunity to acquire a proprietary interest in the Company as an incentive to remain with the organization and to align the employee's interest with our stockholders. The approval authorized

Edgar Filing: IMMUNOMEDICS INC - Form 10-Q

issuance of 9,000,000 shares plus the number of unallocated share available for issuance as of the effective date under the 2006 Plan that were not subject to outstanding awards.

As under the 2006 Plan, option awards under the Plan are generally granted with an exercise price equal to the market price of the Plan, the Company's common stock at the date of

**Table of Contents**

grant; those option awards generally vest based on four years of continuous service and have seven year contractual terms. Option awards that are granted to non-employee Board members under the annual option grant program are granted with an exercise price equal to the market price of the Company's common stock at the date of grant, are vested immediately and have seven year contractual terms. At March 31, 2015, there were 18,434,788 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (6,176,555 shares) and which were available to be issued for future grants (12,258,233 shares).

The weighted average fair value at the date of grant for options granted during the nine-month periods ended March 31, 2015 and 2014 were \$1.61 and \$1.94 per share, respectively. The Company uses historical data to estimate employee forfeitures for employees, executive officers and outside directors. The expected term of options granted represents the period of time that options granted are expected to be outstanding and the expected stock price volatility is based on the Company's daily stock trading history. The weighted average of the expected option term increased to 5.07 years for the nine-month period ended March 31, 2015 from 3.47 years for the nine-month period ended March 31, 2014 as a result of the issuance of short-term options to the former chief financial officer in the prior year. 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. The lower risk-free interest rate results from the short-term rate for the stock options granted to the former chief financial officer for the nine-month period ended March 31, 2014.

Information concerning options for the nine-month period ended March 31, 2015 is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding, July 1, 2014	5,308,617	\$ 3.41		
Granted	694,923	\$ 3.57		
Exercised	(178,625)	\$ 3.03		
Cancelled or forfeited	(399,750)	\$ 4.54		
Outstanding, March 31, 2015	5,425,165	\$ 3.34	3.24	\$ 3,817,459
Exercisable, March 31, 2015	4,105,123	\$ 3.18	2.42	\$ 3,441,461

A summary of the Company's non-vested restricted and performance stock units at July 1, 2014, and changes during the nine-month period ended March 31, 2015 are presented below:

Outstanding Non-Vested Restricted and Performance Stock Units	Number of Awards
Non-vested at July 1, 2014	788,364
Restricted Units Granted	277,313
Vested	
Exercised	(314,287)

Non-vested at March 31, 2015	751,390
------------------------------	---------

The Company has 2,071,432 non-vested options, restricted and performance stock units outstanding as of March 31, 2015. As of March 31, 2015, there was \$3.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is being recognized over a weighted-average period of 2.6 years. The Company recorded \$0.6 million and \$2.1 million for total stock-based compensation

---

**Table of Contents**

expense for employees, executive officers and non-employee Board members for the three and nine-month periods ended March 31, 2015, respectively, as compared to \$0.9 million and \$2.4 million for the three and nine-month periods ended March 31, 2014, respectively.

Each non-employee Board member who continues to serve shall receive on the date of the annual stockholders meeting an annual grant of non-qualified stock options and restricted stock units, each equal in value to \$45 thousand. The Company recorded \$44 thousand and \$135 thousand for stock-based compensation expense for these non-employee Board members restricted stock units for the three and nine-month periods ended March 31, 2015, respectively, as compared to \$44 thousand and \$159 thousand for the three and nine-month periods ended March 31, 2014, respectively.

On August 14, 2014, the Company awarded an additional 226,657 restricted stock units to certain executive officers of the Company at the market price on that date (\$3.32 per share). These restricted stock units will vest over a four-year period. As of March 31, 2015, there was \$1.4 million of total unrecognized compensation costs related to non-vested share-based compensation arrangements granted under the Plan for these executive officers, excluding performance stock units. The cost is being recognized over a weighted-average period of 2.5 years. The Company recorded \$0.2 million and \$0.6 million for stock-based compensation expense for these executive officers for the three and nine-month periods ended March 31, 2015, as compared to \$0.2 million and \$0.5 million for the three and nine-month periods ended March 31, 2014, respectively.

On August 16, 2013, the Company also awarded certain executive officers Performance Units of up to 389,864 units of restricted stock units which are subject to attainment of certain performance milestones as well as certain continued service requirements. All or a portion of the Performance Units vest based upon the level of achievement of the milestones set forth in each agreement, which is expected to be achieved within five years of the grant date. The Performance Units that vest based upon attainment of the Performance Milestone will be exercised based on a percentage basis on the attainment of anniversary dates. As of March 31, 2015, 116,959 of the total Performance Units were vested based on the achievement of certain performance milestones, which are currently outstanding. The remaining 272,905 Performance Units are available if the remaining performances are achieved within five years of grant date. The Company recorded \$0.1 million and \$0.3 for the stock-based compensation for the three and nine-month periods ended March 31, 2015, as compared to \$0.5 million and \$1.3 million for the stock-based compensation for the three and nine-month periods ended March 31, 2014, respectively. There is \$0.5 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of March 31, 2015. That cost is being recognized over a weighted-average period of 2.2 years. The unrecognized compensation cost is subject to modification on a quarterly basis based on review of performance probability and requisite achievement periods.

**8. Geographic Segments**

Immunomedics manages its operations as one line of business of researching, developing, manufacturing and marketing biopharmaceutical products, particularly antibody-based products for cancer, autoimmune and other serious diseases, and it currently reports as a single industry segment. Immunomedics conducts its research and development activities primarily in the United States. Immunomedics markets and sells LeukoScan® throughout Europe and in certain other countries outside the United States.

**Table of Contents**

The following table presents financial information based on the geographic location of the facilities of Immunomedics as of and for the three and nine-months ended March 31, 2015 and 2014 (\$ in thousands):

	<b>As of and for the three-months ended March 31, 2015</b>		
	United States	Europe	Total
Total assets	\$ 110,600	\$ 1,234	\$ 111,834
Property and equipment, net	2,056	9	2,065
Revenues	489	694	1,183
(Loss) before taxes	(11,762)	(23)	(11,785)

	<b>As of and for the three-months ended March 31, 2014</b>		
	United States	Europe	Total
Total assets	\$ 24,074	\$ 2,179	\$ 26,253
Property and equipment, net	1,980		1,980
Revenues	242	912	1,154
(Loss) income before taxes	(9,586)	53	(9,533)

	<b>Nine-months ended March 31, 2015</b>		
	United States	Europe	Total
Revenues	\$ 1,110	\$ 2,147	\$ 3,257
(Loss) income before taxes	(35,733)	79	(35,654)

	<b>Nine-months ended March 31, 2014</b>		
	United States	Europe	Total
Revenues	\$ 5,453	\$ 2,402	\$ 7,855
(Loss) before taxes	(23,588)	(68)	(23,656)

**9. 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 Scientific Officer, Ms. Cynthia L. Sullivan, the President and Chief Executive Officer, who is the wife of Dr. David M. Goldenberg, and certain companies with which the Company does business, including the Center for Molecular Medicine and

Immunology ( CMMI ), and the Company s majority-owned subsidiary IBC.

The Company incurred legal expenses on behalf of CMMI for patent related matters for the three and nine-month period ended March 31, 2015 of \$8 thousand and \$30 thousand, respectively, as compared to \$10 thousand and \$23 thousand for the three and nine-month periods ended March 31, 2014, 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. On occasion, CMMI engages in research contracts on behalf of Immunomedics, Inc. However, for the three and nine-month periods ended March 31, 2015 and 2014 there were no research related activities charged to the Company

**Table of Contents**

For the three-month and nine-month periods ended March 31, 2015, Dr. Goldenberg received approximately \$21 thousand and \$63 thousand, respectively, and approximately \$20 thousand and \$59 thousand for the three-month and nine-month periods ended March 31, 2014, respectively, in compensation for his services to IBC.

**10. License and Collaboration Agreements**  
**Takeda Pharmaceutical/Nycomed GmbH**

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

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

On October 3, 2013, Takeda-Nycomed delivered notice of termination of the Nycomed Agreement subsequent to the Company's filing of arbitration proceedings concerning delays in Takeda-Nycomed's development of veltuzumab, which the Company argued was a material breach of the Agreement. In response to the Company's claim for damages for the delays, Takeda-Nycomed made certain counterclaims against the Company. The Company responded by filing its own Statement of Defense on November 12, 2013, denying Takeda and Takeda-Nycomed's allegations and contesting Takeda or Takeda-Nycomed's rights to any relief. An arbitrator was appointed later that month.

On December 16, 2014, the Company was notified that the arbitrator awarded no money to either party and the award was in full settlement of all claims and counterclaims submitted to arbitration. All rights to veltuzumab have reverted back to the Company as a result of the termination.

**UCB, S.A.**

On May 9, 2006, the Company entered into an agreement with UCB, S.A. referred to herein as UCB, providing UCB an exclusive worldwide license to develop, manufacture, market and sell epratuzumab for the treatment of all non-cancer indications referred to herein as the UCB Agreement. Under the terms of the UCB Agreement, the Company received from UCB a non-refundable cash payment totaling \$38.0 million. On December 27, 2011, the Company entered into the Amendment Agreement with UCB referred to herein as the Amendment Agreement. The Amendment Agreement provided UCB the right to sublicense epratuzumab, subject to obtaining the Company's prior consent, to a third party for the United States and certain other territories. As of March 31, 2015, UCB has not executed a sublicense agreement with a third-party.



---

**Table of Contents**

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

Collectively, pursuant to the UCB Agreement and the Amendment Agreement the Company is entitled to receive (i) up to \$145.0 million in cash payments and \$20.0 million in equity investments in regulatory milestone payments and (ii) up to \$260.0 million related to the achievement of specified product sales milestones. The Company is also entitled to product royalties ranging from a mid-teen to mid-twenty percentage of aggregate annual net sales under the UCB Agreement and Amendment Agreement during the product royalty term, (subject to reduction in certain circumstances). No development milestone, commercialization milestone or royalty payments were achieved through March 31, 2015. There can be no assurance that the development or commercialization milestones or royalty payment thresholds under the UCB Agreement and Amendment Agreement will be met and therefore there can be no assurance that the Company will receive such future payments.

The Agreement commenced on May 9, 2006 and shall terminate in accordance with the terms thereof or by mutual written consent, unless UCB decides to cease all development and commercialization of epratuzumab pursuant to the Agreement. Either the Company or UCB has the right to terminate the Agreement by notice in writing to the other party upon or after any material breach of the Agreement by the other party, if the other party has not cured the breach within 60 days after written notice to cure has been given, with certain exceptions. Upon termination of the Agreement, among other things, all rights and licenses granted by the Company to UCB shall terminate, all rights of UCB under the Immunomedics Patent Rights, as defined in the Agreement and Immunomedics Know-How (as defined in the Agreement) shall revert to the Company, and UCB shall cease all use of the Immunomedics Patent Rights and Immunomedics Know-How. Further, all regulatory filings and Approvals (as defined in the Agreement) and any other documents relating to or necessary to further develop and commercialize the Licensed Compound (as defined in the Agreement) and Licensed Products (as defined in the Agreement), including, without limitation, all sublicenses granted by UCB, and all of UCB's right, title and interest therein and thereto, shall be assigned to the Company at the Company's option. No additional amounts shall be payable on events occurring after the effective date of termination.

**The Bayer Group (formerly Algeta ASA)**

In January 2013, the Company entered into a collaboration agreement, referred to herein as the Collaboration Agreement, with Algeta ASA, referred to herein as Algeta, for the development of epratuzumab to be conjugated with Algeta's proprietary thorium-227 alpha-pharmaceutical payload. On August 2, 2013, an amendment to the Collaboration Agreement was entered into between the two companies modifying certain delivery and supply parameters. Under the terms of the Collaboration Agreement, as amended, the Company is required to manufacture and supply clinical-grade epratuzumab to Algeta, which has rights to evaluate the potential of a Targeted Thorium Conjugate (TTC), linking thorium-227 to epratuzumab, for the treatment of patients with cancer. Algeta will fund all non-clinical and clinical development costs up to the end of Phase 1 clinical testing. Upon successful completion of Phase 1 testing, the parties shall negotiate terms for a license agreement at Algeta's request. The Company and Algeta agreed to certain parameters in the Collaboration Agreement. Under the terms of the Collaboration Agreement, as amended, Immunomedics received an upfront cash payment and other payments



---

**Table of Contents**

which have been recognized upon the Company fulfilling its obligations under the Collaboration Agreement. For the nine-month period ended March 31, 2014, the Company recognized \$4.6 million of revenue under this arrangement, which was included in license fee and other revenues, while the related costs of \$1.2 million was included in cost of license fee and other revenue. No such revenue was recognized for the three-month period ended March 31, 2014. For the three and nine-month periods ended March 31, 2015, the Company has recognized revenue of \$0.3 million under this arrangement. The Bayer Group, referred to herein as Bayer, has acquired all of the shares and voting rights in Algeta ASA and the program with Immunomedics has been formally transferred to Bayer (Algeta).

**11. Commitments and Contingencies*****Employment Contracts***

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

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

Under the terms of the Goldenberg Agreement, the Company makes a minimum quarterly payment of \$37.5 thousand to Dr. Goldenberg during each of the fiscal years during the Goldenberg Agreement, as an advance against the amounts due as additional incentive compensation, royalty payments and dispositions of undeveloped assets. For the three and nine-month periods ended March 31, 2015 and 2014, no additional incentive payments were made to Dr. Goldenberg.

On July 1, 2014, the Company and Cynthia L. Sullivan entered into the Fifth Amended and Restated Employment Agreement pertaining to Ms. Sullivan's service as the Company's President and Chief Executive Officer. The Amended Sullivan Agreement shall terminate on July 1, 2017. Ms. Sullivan's annual base salary under the agreement is \$0.6 million, which shall be reviewed annually for appropriate increases by the Board of Directors or the Compensation Committee (increased by 3.5% for the 2015 fiscal year). Ms. Sullivan is also eligible to participate in the Company's incentive compensation plan in place for its senior level executives. Ms. Sullivan's annual bonus target is 50% of her base salary, subject to achievement of performance goals, with a potential payout from 0 to 150% of the target amount. Ms. Sullivan will also be eligible to receive equity compensation awards under the Company's 2014 Long-Term Incentive Plan, or any such successor equity compensation plan as may be in place from time to time.



---

**Table of Contents*****Legal Matters***

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

***Shareholder complaints:***

Two separate shareholder derivative complaints have been filed against the Company. First, on March 24, 2014, a complaint styled *Kops v. Goldenberg, et al.*, was filed in the Superior Court of New Jersey, Chancery Division, General Equity Part, Morris County. Second, on April 18, 2014, a complaint styled *Breitman v. Sullivan, et al.*, was filed in the United States District Court for the District of New Jersey. The complaints allege, among other things, that the Company and certain directors and officers breached their fiduciary duties for disseminating false and misleading information relating to the termination of the Nycomed Agreement. In particular, the complaints allege that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaints allege that the breaches in fiduciary duties by the directors and officers caused damages to the Company and stockholders, including a decline in value of the Company's common stock, increased investigatory and litigation costs, and exposure to civil liability as a result of a pending securities fraud class action suit. Plaintiffs bring the derivative actions to recover damages against the directors and officers for the benefit of the Company, and to require the Company to reform and improve its corporate governance and internal procedures. On February 13, 2015, the *Kops* matter was dismissed without prejudice pursuant to a stipulation entered into by the parties. The *Breitman* matter is presently stayed pending the outcome of a motion to dismiss in a related putative class action lawsuit, described below. The defendants believe that the allegations in the derivative complaints are without merit and intend to defend the lawsuits vigorously; however, there can be no assurance regarding the ultimate outcome of these lawsuits.

A putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, was filed on February 27, 2014, in the United States District Court for the District of New Jersey. The lawsuit alleges that the Company and certain of its current and former officers and directors failed to disclose and/or made material misstatements in the Company's public filings relating to the termination of the Nycomed Agreement. In particular, the complaint alleges that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On June 24, 2014 the District Court entered an order appointing John Neff as lead plaintiff and The Rosen Law Firm, P.A. as lead counsel. Lead plaintiff and lead counsel thereafter filed an Amended Class Action Complaint on August 8, 2014. The defendants believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously. Defendants moved to dismiss the complaint on September 22, 2014. On January 29, 2015 the United States District Court for the District of New Jersey granted the Company's motion to dismiss the complaint in its entirety. The Court's opinion concluded that Immunomedics had no duty to disclose issues raised with Takeda-Nycomed prior to the termination of the Nycomed Agreement. The Court granted Plaintiffs thirty days from the date of the opinion in order to file an amended complaint. On February 27, 2015 a second amended complaint was filed by the plaintiff alleging failure to disclose information related to the status of the agreement. The Company filed a motion to dismiss the second amended complaint on April 13, 2015. The defendants continue to believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously.

**Table of Contents**

Immunomedics is also a party to various claims and litigation arising in the normal course of business, which includes some or all of certain of its patents. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to its consolidated results of operations in any one accounting period.

---

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Cautionary Note Regarding Forward-Looking Statements**

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

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

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report or in any document incorporated by reference might not occur. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Quarterly Report or the date of the document incorporated by reference in this Quarterly Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable law. All subsequent forward-looking statements attributable to Immunomedics, Inc. (Immunomedics, the Company, we, our or us), or any person authorized to act on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

**Overview**

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. Our advanced proprietary technologies allow us to create humanized antibodies that can be used either alone in unlabeled or naked form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins. Using these technologies, we have built a pipeline of nine



---

**Table of Contents**

clinical-stage product candidates. We have an ongoing collaboration with UCB, S. A. (UCB), to whom we licensed epratuzumab for the treatment of all non-cancer indications worldwide. UCB expects Phase 3 data in systemic lupus erythematosus in the first half of 2015. We are exploring epratuzumab in oncology in collaboration with independent cancer study groups. Our most advanced candidate, to which we retain worldwide rights for all indications, is <sup>90</sup>Y-clivatuzumab tetraxetan. We initiated a Phase 3 registration trial in January 2014 in patients with advanced pancreatic cancer. Our portfolio of wholly-owned product candidates also includes antibody-drug conjugates, (ADCs) that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxic effects that are usually found with conventional administration of these chemotherapeutic agents. Our most advanced ADCs are sacituzumab govitecan (IMMU-132) and labetuzumab govitecan (IMMU-130), which have completed patient enrollment in Phase 2 trials for certain solid tumors and metastatic colorectal cancer, respectively. We also have a number of other product candidates that target solid tumors and hematologic malignancies, as well as other diseases, in various stages of clinical and pre-clinical development. These include bispecific antibodies targeting cancers and infectious diseases as T-cell redirecting immunotherapies, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies, created using its patented DOCK-AND-LOCK<sup>®</sup> protein conjugation technology. We believe that our portfolio of intellectual property provides commercially reasonable protection for our product candidates and technologies.

The development and commercialization of successful therapeutic products is subject to numerous risks and uncertainties including, without limitation, the following:

the type of therapeutic compound under investigation and nature of the disease in connection with which the compound is being studied;

our ability, as well as the ability of our partners, to conduct and complete clinical trials on a timely basis;

the time required for us to comply with all applicable federal, state and foreign legal requirements, including, without limitation, our receipt of the necessary approvals of the U.S. Food and Drug Administration, or FDA, if at all;

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

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

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

**Research and Development**

As of March 31, 2015, we employed 17 professionals in our research and development departments and 22 professionals in our pre-clinical and clinical research departments. In addition to salaries and benefits, the other costs associated with research and development include the costs associated with producing biopharmaceutical compounds, laboratory equipment and supplies, the costs of conducting clinical trials, legal fees and expenses associated with

pursuing patent protection, as well as facilities costs.

At any one time our scientists are engaged in the research and development of multiple therapeutic compounds. Because we do not track expenses on the basis of each individual compound under investigation, but rather aggregate research and development costs for accounting purposes, it is not possible for investors to analyze and compare the expenses

## **Table of Contents**

associated with unsuccessful research and development efforts for any particular fiscal period, with those associated with compounds that are determined to be worthy of further development. This may make it more difficult for investors to evaluate our business and future prospects.

## **Clinical Pipeline Update**

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

### **Epratuzumab**

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

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

The IntreALL Inter-European study group is conducting a large, multicenter, international trial combining epratuzumab with chemotherapy in pediatric patients with relapsed ALL. This Phase 3 study, which is partially funded by the European Commission, assesses the efficacy and safety of this combination therapy using event-free survival as the surrogate for survival, the primary endpoint.

For adult patients with ALL, there is one ongoing clinical trial. The CheprALL study, sponsored by the French GRAALL study group, is a multicenter Phase 2 trial of epratuzumab combined with chemotherapy also in adult patients with relapsed ALL.

Although certain patents to the epratuzumab protein sequence expired in 2014 in the U.S. or will expire in 2015 overseas, other issued patents to therapeutic use of epratuzumab extend to 2018-2023 for cancer and 2020 for autoimmune disease. The method of preparing concentrated epratuzumab for subcutaneous administration is covered by another patent family with a 2032 expiration.

### ***Yttrium-90-Labeled Clivatuzumab Tetraxetan***

The Phase 3 PANCRIT-1 registration trial of yttrium-90-labeled clivatuzumab tetraxetan continues to enroll patients with metastatic pancreatic cancer who have received at least two prior therapies, one of which must have been a gemcitabine-containing regimen. This study is evaluating the safety and efficiency, as measured by overall survival,

of the radiolabeled antibody plus low-dose gemcitabine and best supportive care compared to placebo plus low-dose gemcitabine and best supportive care. Repeated treatments with this combination have been found to offer a survival benefit in the same late-stage setting in an earlier Phase 1b study.

**Table of Contents**

Due to the complexity of regulatory processes in different European countries, clinical site initiations for PANCRIT-1 are taking longer than we had originally anticipated. As a result, we now expect patient enrollment to be completed in calendar year 2016. We are working closely with our Clinical Research Organization to ramp up additional site openings, focusing on territories where we have the ability to have multiple sites to be opened at a single point in time.

**Antibody-Drug Conjugates (ADCs)**

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

**Sacituzumab Govitecan (IMMU-132)**

Sacituzumab govitecan has received Fast Track designation from FDA for the treatment of patients with triple-negative breast cancer (TNBC) who have failed prior therapies for metastatic disease and for patients with small-cell lung cancer (SCLC). This ADC has also been designated an orphan drug by FDA for the treatment of patients with SCLC and pancreatic cancer in the U.S. and by the European Medicines Agency, or EMA, for the treatment of pancreatic cancer in the European Union.

Currently, clinical development for sacituzumab govitecan involves the expansion of the number of patients with select types of solid cancers including TNBC, SCLC, non-small-cell lung cancer (NSCLC), and colorectal cancer (CRC). Results from this multicenter study were updated in an oral presentation at the 2015 Annual Meeting of the American Association for Cancer Research.

For patients with TNBC, 26% showed an objective response to sacituzumab govitecan, with 2 having a complete disappearance of their tumors, or complete response, and 10 showing a 30% or better tumor reduction, which qualified them as partial responders in accordance with the rules set by the Response Evaluation Criteria In Solid Tumors (RECIST 1.1). Including patients with responses between less than 30% tumor shrinkage and less than 20% tumor increase, which are considered stable disease, the disease control rate was 74%. At present, 21 of these patients are continuing therapy.

<b>Cancer Types (N*)</b>	<b>Objective Response**</b>	<b>Disease Control</b>
Triple-Negative Breast (46)	(2+10) (26%)	34 (74%)
Non-Small Cell Lung (19)	6 (32%)	14 (74%)
Small Cell Lung (20)	6 (30%)	11 (55%)
Esophageal (16)	2 (13%)	9 (56%)

\* N represents the number of patients that are evaluable at this time for treatment response.

\*\* Except with triple-negative breast cancer (2 patients with complete response), all objective responses are partial responses.

In lung cancer, the objective response rates were 32% and 30% for NSCLC and SCLC, respectively, and disease control rates were 74% and 55%, respectively. For the 18 patients with advanced cancer of the esophagus enrolled into the study, 16 were assessable for response, having an objective response rate of 13% and a disease control rate of 56%.

---

**Table of Contents**

Also reported were results on 29 patients with CRC in early assessments of survival. The median length of time living without the disease getting worse from the beginning of their sacituzumab govitecan treatments was 3.9 months. The median length of survival from the start of treatment was 18.0 months.

Sacituzumab govitecan is well tolerated by patients. At the optimal doses of 8 and 10 mg/kg, only 7% of patients required having dosing delayed due to adverse reactions, while dose reductions were experienced in only 15-16% of patients. Grades 3 and 4 adverse events occurring in more than 5% of patients include fatigue (5%), neutropenia (24%), and anemia (6%). Irinotecan, the parent drug of SN-38, shows an increased incidence of severe diarrhea (38%), neutropenia (31%), and neutropenic fever (8%). Further, despite repeated injections, no patient produced any antibody against sacituzumab govitecan.

Results from the Phase 1 portion of this study have been published in *Clinical Cancer Research*.

Certain patents relating to the protein sequence of the hRS7 antibody used in sacituzumab govitecan have a 2017 expiration in the U.S. and 2023 overseas. Other patents relating to use of hRS7 for cancer therapy, including the SN-38 conjugated form of hRS7 used in sacituzumab govitecan, extend to 2023.

*Labetuzumab Govitecan (IMMU-130)*

Our second investigational solid-tumor ADC involves our anti-CEACAM5 antibody labetuzumab, conjugated to SN-38. The agent is currently being studied in patients with mCRC who had received at least one prior irinotecan-containing regimen and had an elevated blood titer of carcinoembryonic antigen (CEA). Several dosing schedules were evaluated in three Phase 1 studies. Treatment responses from 26 patients were presented at the 2014 Annual Meeting of the American Society of Clinical Oncology. Labetuzumab govitecan showed therapeutic activity in all three trials, but a more frequent dosing schedule, with administrations of the ADC once or twice-weekly for two weeks followed by a week off, appeared to be more active in patients with mCRC than when administered every other week.

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

With more frequent dosing, a higher rate of disease control of 70% or more was observed, and one patient treated twice weekly achieved a PR.

In the expanded Phase 2 study, patients are being treated in 3-week cycles, receiving labetuzumab govitecan either once or twice weekly for the first two weeks followed by one week of rest. This study has completed patient enrollment with patient follow-up continuing.

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

Certain patents relating to the hMN-14 antibody used in labetuzumab govitecan expire in 2014-2016. Other patents relating to use of hMN-14 for cancer therapy, including the SN-38 conjugated form of hMN-14 used in labetuzumab govitecan, extend to 2023.

*Milatuzumab-Doxorubicin*

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

## **Table of Contents**

### ***Early-Stage Programs***

We have additional potential products for the treatment of cancer and autoimmune diseases including veltuzumab, our anti-CD20 antibody, milatuzumab, our anti-CD74 antibody and IMMU-114, a humanized anti-HLA-DR antibody.

#### ***Veltuzumab***

Veltuzumab is being evaluated in a Phase 2 study in combination with <sup>90</sup>Y-epratuzumab tetraxetan in patients with aggressive NHL, funded by a grant from the Small Business Innovation Research, or SBIR, program of the National Cancer Institute, or NCI. Patient enrollment into this trial has now been completed, with patient follow-up continuing.

In autoimmune diseases, we are studying the subcutaneous formulation of veltuzumab in patients with immune thrombocytopenia (ITP) in a Phase 1/2 trial. This trial has completed patient accrual and patients will be followed for up to 5 years.

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

#### ***Milatuzumab***

Milatuzumab is a humanized monoclonal antibody targeting tumors that express the CD74 antigen, which is present on a variety of hematological tumors and even on some solid cancers, with restricted expression by normal tissues. It has received orphan drug designation from FDA for the treatment of patients with multiple myeloma or CLL. Milatuzumab is the first anti-CD74 antibody that has entered into human testing and we have completed initial Phase 1 studies in patients with relapsed multiple myeloma, NHL or CLL.

Milatuzumab is being evaluated as a treatment of graft-versus-host disease. A Phase I clinical trial in this indication is now closed to patient enrollment. The anti-CD74 antibody is also being studied subcutaneously in a Phase 1b study in patients with active SLE. The SLE study is supported by a three-year research grant from the Department of Defense with a potential funding of \$1.6 million.

#### ***Yttrium-90-Labeled Epratuzumab Tetraxetan***

<sup>90</sup>Y-epratuzumab tetraxetan is our radiolabeled anti-CD22 investigational product for patients with NHL or ALL. As noted above, the radiolabeled antibody is currently being studied in a combination with veltuzumab in a Phase 2 clinical trial for the therapy of patients with aggressive NHL, supported by a NCI-SBIR grant.

In ALL, a team from the University of Nantes, Nantes, France, is sponsoring a Phase 1/2 study to evaluate the safety and efficacy of <sup>90</sup>Y-epratuzumab tetraxetan in patients with relapsed or refractory ALL. Results from the Phase 1 portion of this study have been published online in February, 2015 in *Lancet Haematol*.

#### ***IMMU-114***

IMMU-114 is a novel humanized antibody directed against an immune response target, HLA-DR, under development for the treatment of patients with B-cell cancers. HLA-DR is a receptor located on the cell surface whose role is to present foreign objects to the immune system for the purpose of eliciting an immune response. Increased presence of HLA-DR in hematologic cancers has made it a prime target for antibody therapy. The anti-HLA-DR antibody is being

evaluated as a subcutaneously administered monotherapy for patients with NHL or CLL in a Phase 1 study.

## **Table of Contents**

### ***Critical Accounting Policies***

For a description of our significant accounting policies, see Notes to Unaudited Condensed Consolidated Financial Statements Note 2 *Summary of Significant Accounting Policies*. Of these policies, the following are considered critical to an understanding of the Company's Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments; (i) Marketable securities, (ii) Revenue recognition, (iii) Stock-based compensation, (iv) Research and development costs and (v) Reimbursement of research and development costs.

### **Government Regulation**

#### *Regulatory Compliance*

Our research and development activities, including testing in laboratory animals and in humans, our manufacture of antibodies, as well as the design, manufacturing, safety, efficacy, handling, labeling, storage, record-keeping, advertising, promotion and marketing of the product candidates that we are developing and our marketed products, are all subject to stringent regulation, primarily by the FDA in the U.S. under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and the Public Health Service Act, or PHSA, and its implementing regulations, and by comparable authorities under similar laws and regulations in other countries. If for any reason we do not comply with applicable requirements, such noncompliance can result in various adverse consequences, including one or more delays in approval of, or even the refusal to approve, product licenses or other applications, the suspension or termination of clinical investigations, the revocation of approvals previously granted, as well as fines, criminal prosecution, recall or seizure of products, injunctions against shipping products and total or partial suspension of production and/or refusal to allow us to enter into governmental supply contracts.

#### *Product Approval*

In the United States, our product candidates are regulated as biologic pharmaceuticals, or biologics. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulations;

submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin and must be updated annually;

approval by an independent Institutional Review Board, or IRB, the ethics committee at each clinical site before the trial is initiated.

performance of adequate and well-controlled clinical trials to establish the safety, purity and potency of the proposed biologic, and the safety and efficacy of the proposed drug for each indication;

Edgar Filing: IMMUNOMEDICS INC - Form 10-Q

preparation of and submission to the FDA of a Biologics License Application, or BLA, for a new biologic, after completion of all pivotal clinical trials;

satisfactory completion of an FDA Advisory Committee review, if applicable;

a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

## Table of Contents

satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with current Good Manufacturing Practice, or cGMP, regulations; and

FDA review and approval of a BLA for a new biologic, prior to any commercial marketing or sale of the product in the United States.

Preclinical tests assess the potential safety and efficacy of a product candidate in animal models. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB before the trials may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a pharmaceutical, including a biologic, is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

Phase 1 studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

Phase 2 includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the product.

Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval.

The FDA may place clinical trials on hold at any point in this process if, among other reasons, it concludes that clinical subjects are being exposed to an unacceptable health risk. Trials may also be terminated by IRBs, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing authorization.

The results of the preclinical and clinical testing, along with information regarding the manufacturing of the product and proposed product labeling, are evaluated and, if determined appropriate, submitted to the FDA through a BLA. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Once the BLA submission has been accepted for filing, the FDA's standard goal is to review applications within ten months of the filing date or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. FDA offers

certain

---

**Table of Contents**

programs, such as Fast Track designation, designed to expedite the development and review of applications for products intended for the treatment of a serious or life-threatening disease or condition. If Fast Track designation is obtained, the FDA may initiate review of sections of a BLA before the application is complete, and the product may be eligible for accelerated approval. However, receipt of Fast Track designation for a product candidate does not ensure that a product will be developed or approved on an expedited basis, and such designation may be rescinded if the product candidate is found to no longer meet the qualifying criteria.

The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

After the FDA evaluates the BLA and conducts inspections of manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The FDA could approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated pathway establishes legal authority for FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. In March 2015, the FDA approved Novartis's Zarxio as a biosimilar product to Amgen's Neupogen. The approval, the first biosimilar product approved for distribution in the United States, could usher in lower prices for biologic products from increased competition.

*Post-Approval Requirements*

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA and certain state agencies, including requirements for record-keeping, reporting of adverse experiences with the biologic, submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products, establishment registration, compliance with cGMP standards (including investigation and correction of any deviations from cGMP), and certain state chain of distribution pedigree requirements. Additionally, any significant change in the approved product or in how it is



---

**Table of Contents**

manufactured, including changes in formulation or the site of manufacture, generally require prior FDA approval. The packaging and labeling of all products developed by us are also subject to FDA approval and ongoing regulation. Noncompliance with any regulatory requirements can result in, among other things, issuance of warning letters, civil and criminal penalties, seizures, and injunctive action. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

*Orphan Drug Act*

To date, we have successfully obtained Orphan Drug designation by the FDA under the Orphan Drug Act of 1983 for epratuzumab for non-Hodgkin lymphoma, yttrium-90-labeled clivatuzumab tetraxetan for pancreatic cancer, sacituzumab govitecan for small-cell lung and pancreatic cancers, labetuzumab for ovarian, pancreatic and small-cell lung cancers, and milatuzumab for multiple myeloma and chronic lymphocytic leukemia. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or where the manufacturer of the approved product cannot assure sufficient quantities. As a result, there can be no assurance that our competitors will not receive approval of drugs or biologics that have a different active ingredient for treatment of the diseases for which our products and product candidates are targeted.

*Foreign Regulation*

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates being developed, and products being marketed outside of the United States. We must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of our products in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required by the FDA for BLA licensure. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, we are subject to post-approval regulatory requirements, such as those regarding product manufacturing, marketing, or distribution.

*Other Regulatory Considerations*

We are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, The Clean Air Act, New Jersey Department of Environmental Protection and other current and potential future federal, state, or local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and various radioactive compounds. We believe that our procedures comply with the standards prescribed by state and federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.



**Table of Contents**

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our products and product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy, and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies, based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating compliance of healthcare providers and manufacturers with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary

## **Table of Contents**

penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for knowing failures ), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and submit reports to the government by March 31, 2014 and June 30, 2014, and the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

We are subject to the U.S. Foreign Corrupt Practices Act, which prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. Under this act, it is illegal to pay, offer to pay, or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other laws and regulations.

### *Pricing Controls*

The levels of revenues and profitability of biopharmaceutical companies may be affected by the continuing efforts of government and third party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing reimbursement or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the U. S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

### *Third Party Coverage and Reimbursement*

In addition, in the U.S. and elsewhere, sales of therapeutic and other pharmaceutical products are dependent in part on the availability of coverage and reimbursement to the consumer from third party payers, such as government and private insurance plans. Third party payers are increasingly challenging the prices charged for medical products and services. We cannot assure you that any of our products will be considered cost effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.



---

**Table of Contents****Results of Operations**

Our results for any interim period, such as those described in the following analysis, are not necessarily indicative of the results for the entire fiscal year or any other future period.

***Three-Month Period Ended March 31, 2015 Compared to 2014****Revenues*

Revenues for both three-month periods ended March 31, 2015 and 2014 were \$1.2 million. Product sales for the three-month periods ended March 31, 2015 were \$0.7 million as compared to \$0.9 million for the same period in 2014, representing a decrease of \$0.2 million or 22% due to unfavorable fluctuations in the currency rates and minimum sales volume decline of LeukoScan in Europe. License fee and other revenues were \$0.3 million for the three-month period ended March 2015 as compared to no revenue in the same period in 2014. This increase was due to the Bayer (Algeta) annual payment of \$250 thousand as per the Collaboration Agreement.

*Costs and Expenses*

Total costs and expenses for the three-month period ended March 31, 2015 were \$12.3 million, as compared to \$10.7 million for the same period in 2014, representing an increase of \$1.6 million or 15%. Research and development expenses for the three-month period ended March 31, 2015 were \$10.4 million as compared to \$8.1 million for the same period in 2014, representing an increase of \$2.3 million or 28%. The increase in research and development expenses resulted primarily from \$1.5 million of higher clinical trial expenses, driven by an increase of \$0.8 million for the Phase 3 clinical trial for clivatuzumab tetraxetan and increased product development expenses related to the antibody-drug conjugates clinical trials. This growth of research and development spending is expected to continue with the increased costs associated with the Phase 3 clinical trial as well as the expanding antibody-drug conjugates clinical trials.

Cost of goods sold was approximately the same for the three-months ended March 31, 2015 and 2014. Gross profit margins were 90% for the third quarter of both fiscal 2015 and fiscal 2014. General and administrative costs were \$1.6 million and \$2.2 million for the three-month periods ended March 31, 2015 and 2014, respectively, with the decline due primarily to reduced legal and professional expenses. Sales and marketing expenses for the three-month period ended March 31, 2015 were \$0.3 million as compared to \$0.2 million for the same period in 2014.

*Interest Expense*

Interest expense for the three-month period ended March 31, 2015 was \$0.7 million. This related to the issuance in February 2015 of \$100.0 million of 4.75% Convertible Senior Notes, due in February 2020 and included amortization of debt issuance costs of \$0.1 million. There was no interest expense for the three-month period ended March 31, 2014.

*Net Loss Attributable to Immunomedics, Inc. Stockholders*

Net Loss Attributable to Immunomedics, Inc. stockholders for the three-month period ended March 31, 2015 was \$11.8 million or \$0.13 per share, as compared to a net loss of \$9.5 million or \$0.11 per share, for the same period in 2014 representing an increase of \$2.3 million, or 24%. The increase in the net loss attributable to Immunomedics, Inc. stockholders over the same period in 2014 resulted primarily from increased research and development expenses and interest expense.



---

**Table of Contents*****Nine-Month Period Ended March 31, 2015 Compared to 2014******Revenues***

Revenues for the nine-month period ended March 31, 2015 were \$3.3 million as compared to \$7.9 million for the same period in 2014, representing a decrease of \$4.6 million, or 58%. License and other revenues were \$0.3 million for the nine-month period ended March 31, 2015 compared to \$4.6 million for the same period in the previous year. The license and other revenue in the 2014 period resulted from revenue earned upon fulfilling the Company's obligations under the Algeta ASA Service Agreement, as amended. Product sales for the nine-month period ended March 31, 2015 were \$2.2 million as compared to \$2.4 million for the same period in 2014, representing a decrease of \$0.2 million, or 8%, due to unfavorable fluctuations in the currency rates in Europe. Research and development revenues for both nine-month periods ended March 31, 2015 and 2014 were \$0.8 million.

***Costs and Expenses***

Total costs and expenses for the nine-month period ended March 31, 2015 were \$38.3 million as compared to \$31.5 million for the same period in 2014, representing an increase of \$6.8 million, or 22%. Research and development expenses for the nine-month period ended March 31, 2015 were \$30.1 million as compared to \$23.2 million for the same period in 2014, representing an increase of \$6.9 million, or 30%. This increase was primarily due to \$4.2 million higher Phase 3 clinical trial expenses for clivatuzumab tetraxetan and increased product development expenses related to the antibody-drug conjugates clinical trials and increased general and administrative expenses. This growth of research and development spending is expected to continue with the increased costs associated with the Phase 3 clinical trial as well as the expanding antibody-drug conjugates clinical trials.

Cost of goods sold for each of the nine-month periods ended March 31, 2015 and 2014 was \$0.2 million and \$0.3 million, respectively. Gross profit margins were 90% and 89%, respectively, for the first nine-months of fiscal 2015 and fiscal 2014. Cost of license fee and other revenues of \$1.2 million resulted from the recognition of manufacturing costs related to the Bayer (Algeta) Service Agreement which was completed during the nine-month period ended March 31, 2014. Sales and marketing expenses decreased from \$0.9 million for the nine-month period ended March 31, 2014 to \$0.7 million for the nine-month period ended March 31, 2015. This decrease was primarily due to the increased European regulatory fees required for the sale of the LeukoScan product in Europe in the previous year. General and administrative costs were \$7.2 million for the nine-month period ended March 31, 2015 and \$6.0 million for the same period in 2014 representing an increase of \$1.2 million or 20%. This increase is primarily attributable to approximately \$1.2 million of increased legal and professional fees, (principally increased legal fees regarding the arbitration proceedings with Takeda-Nycomed).

***Interest Expense***

Interest expense for the nine-month period ended March 31, 2015 was \$0.7 million, which related to the issuance in February 2015 of \$100.0 million of 4.75% Convertible Senior Notes, due in February 2020 and included amortization of debt issuance costs of \$0.1 million. There was no interest expense for the nine-month period ended March 31, 2014.

***Net Loss Attributable to Immunomedics, Inc. Stockholders***

Net Loss Attributable to Immunomedics, Inc. stockholders for the nine-month period ended March 31, 2015 was \$35.6 million or \$0.38 per share, as compared to net loss of \$23.6 million



---

**Table of Contents**

or \$0.28 per share, for the same period in 2014, representing an increased net loss of \$12.0 million. The increase in net loss attributable to Immunomedics, Inc. resulted primarily due to research and development costs related to clinical trials, increased legal and professional fees, interest expense and the decrease in other revenues received in the prior period that related to the Collaboration Agreement.

**Liquidity and Capital Resources****Discussion of Cash Flows**

*Cash flows from operations.* Net cash used in operating activities for the nine-month period ended March 31, 2015 was \$30.4 million compared to \$21.4 million net cash used in operating activities for the nine months ended March 31, 2014. The increase in the current fiscal year's cash flow used in operations is primarily due to a higher net loss of \$12.0 million partially offset by \$2.5 million of realized deferred revenue in fiscal 2014 and \$1.9 million increase in accounts payable and accrued expenses primarily as a result of higher clinical trial expenses.

*Cash flows from investing.* Net cash used in investing activities for the nine-months ended March 31, 2015 was \$56.1 million compared to \$16.4 million of net cash used in investing activities for the nine-months ended March 31, 2014. The increase in cash used in investing activities for fiscal 2015 is primarily due to \$62.2 million of increased purchases of marketable securities in the current period, partially offset by \$22.7 million of increased maturities or sales of these securities during fiscal year 2015.

*Cash flows from financing.* Net cash provided by financing activities for the nine-month period ended March 31, 2015 was \$96.3 million as compared to \$1.4 million for the corresponding period in the previous year. The increase in cash flows from financing is due to the approximately \$96.3 million of net cash proceeds, received from the issuance of \$100 million of 4.75% convertible senior notes in February 2015.

**Working Capital and Cash Requirements**

At March 31, 2015, we had working capital of \$100.6 million, which was approximately \$62.3 million higher than the working capital of \$38.3 million at June 30, 2014. Our cash, cash equivalents and marketable securities amounted to \$106.2 million at March 31, 2015, representing an increase of \$64.4 million from \$41.8 million at June 30, 2014. Working capital increased primarily from the issuance of the \$100 million convertible senior notes in February 2015. Partially offsetting this increase was our use of \$30.4 million of cash in operations.

Our budgeted cash requirements for the fiscal year ending 2015 (June 30, 2015) are expected to be approximately \$42.0 million, which includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, as well as for expenses for the ongoing Phase 2 expansion ADC clinical trials (sacituzumab govitecan and labetuzumab govitecan). Based on our projected cash flow projections, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months.

We currently estimate that for fiscal year 2016 the net cash flow needs will be in the range of \$44.0 to \$46.0 million, not including the interest costs of \$4.8 million for fiscal year 2016 from the outstanding Convertible Senior Notes as issued in February 2015. Future financial demands include ongoing operating expenses, Phase 3 and Phase 2 clinical trials and further development of various clinical trial programs in fiscal 2016 and 2017. The Company will continue to require additional funding in order to fund our operations and programs.



## **Table of Contents**

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

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our currently available financial resources. These financial resources may not be adequate to sustain our operations, and we will be required to finance future cash needs through strategic licensing or collaboration agreements, the sale of additional equity and/or debt securities. However, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainty with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit our ability to operate our business.

Actual results could differ materially from our expectations as a result of a number of risks and uncertainties, including the risks described in Item 1A Risk Factors, Factors That May Affect Our Business and Results of Operations, and elsewhere in this Form 10-Q. Our working capital and working capital requirements are affected by numerous factors and such factors may have a negative impact on our liquidity. Principal among these are the success of product commercialization and marketing products, the technological advantages and pricing of our products, the impact of the regulatory requirements applicable to us, and access to capital markets that can provide us with the resources, when necessary, to fund our strategic priorities.

## **Effects of Inflation**

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

**Table of Contents**

**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.

**Table of Contents**

**ITEM 4. CONTROLS AND PROCEDURES**

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

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

---

**Table of Contents****PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

In the ordinary course of business, the Company may be subject to legal proceedings and claims. At this time, the Company is not a party to any legal proceedings, claims or assessments that, in management's opinion, would have a material adverse effect on the Company's business, financial condition or results of operations.

***Shareholder complaints:***

Two separate shareholder derivative complaints have been filed against the Company. First, on March 24, 2014, a complaint styled *Kops v. Goldenberg, et al.*, was filed in the Superior Court of New Jersey, Chancery Division, General Equity Part, Morris County. Second, on April 18, 2014, a complaint styled *Breitman v. Sullivan, et al.*, was filed in the United States District Court for the District of New Jersey. The complaints allege, among other things, that the Company and certain directors and officers breached their fiduciary duties for disseminating false and misleading information relating to the termination of the Nycomed Agreement. In particular, the complaints allege that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaints allege that the breaches in fiduciary duties by the directors and officers caused damages to the Company and stockholders, including a decline in value of the Company's common stock, increased investigatory and litigation costs, and exposure to civil liability as a result of a pending securities fraud class action suit. Plaintiffs bring the derivative actions to recover damages against the directors and officers for the benefit of the Company, and to require the Company to reform and improve its corporate governance and internal procedures. On February 13, 2015, the *Kops* matter was dismissed without prejudice pursuant to a stipulation entered into by the parties. The *Breitman* matter is presently stayed pending the outcome of a related putative class action lawsuit, described below. The defendants believe that the allegations in the derivative complaints are without merit and intend to defend the lawsuits vigorously; however, there can be no assurance regarding the ultimate outcome of these lawsuits.

A putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, was filed on February 27, 2014 in the United States District Court for the District of New Jersey. The lawsuit alleges that the Company and certain of its current and former officers and directors failed to disclose and/or made material misstatements in the Company's public filings relating to the termination of the Nycomed Agreement. In particular, the complaint alleges that defendants failed to make timely disclosure concerning a dispute concerning a delay in the development of veltuzumab. On October 9, 2013, the Company announced that the Nycomed Agreement was terminated. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. On June 24, 2014, the District Court entered an order appointing John Neff as lead plaintiff and The Rosen Firm, P.A. as lead counsel. Lead plaintiff and lead counsel thereafter filed an Amended Class Action Complaint on August 8, 2014. Defendants moved to dismiss the complaint on September 22, 2014. On January 29, 2015 the United States District Court for the District of New Jersey granted the Company's motion to dismiss the complaint in its entirety. The Court's opinion concluded that Immunomedics had no duty to disclose issues raised with Takeda-Nycomed prior to the termination of the Nycomed Agreement. The Court granted Plaintiffs thirty days from the date of the opinion in order to file an amended complaint. On February 27, 2015 a second amended complaint was filed by the plaintiff alleging failure to disclose information related to the status of the agreement. The Company filed a motion to dismiss the second amended complaint on April 13, 2015. The defendants continue to believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously.



**Table of Contents**

Immunomedics is also a party to various claims and litigation arising in the normal course of business, which includes some or all of certain of its patents. While it is not possible to determine the outcome of these matters, the Company believes that the resolution of all such matters will not have a material adverse effect on its consolidated financial position or liquidity, but could possibly be material to its consolidated results of operations in any one accounting period.

**Table of Contents**

**Item 1A. RISK FACTORS**

**Factors That May Affect Our Business and Results of Operations**

Our business is subject to certain risks and uncertainties, each of which could materially and adversely affect our business, financial condition, cash flows and results of operations.

***Risks Relating to Our Business, Operations and Product Development***

***We have a long history of operating losses and it is likely that our operating expenses will continue to exceed our revenues for the foreseeable future.***

We have incurred significant operating losses since our formation in 1982. As of March 31, 2015, we had an accumulated deficit of approximately \$297.1 million. We continue to spend our cash resources to fund our research and development programs and, subject to adequate funding, we expect these expenses to increase for the foreseeable future. Our only significant sources of revenue in recent years have been derived from our existing licensing agreement with UCB and the collaboration agreement with Bayer (Algeta). The timing of when we are able to record licensing fee revenue from such agreements has varied historically and may result in quarterly or annual profits or losses that are not necessarily reflective of our business operations or related cash flows. There can be no assurance that we will be profitable in future quarters or other periods. Additionally, the only product sales we have earned to date have come from the limited sales of our diagnostic imaging product for which our patent protection has recently expired (which may leave us vulnerable to increased competition, for example, from generic manufacturers). In addition, we have made the strategic decision to de-emphasize sales of our diagnostic product and focus on our therapeutic pipeline. We have never had product sales of any therapeutic product. Although we may have net income from time to time based on the timing and amount of proceeds received under collaborative agreements, we expect to experience significant operating losses as we invest further in our research and development activities while simultaneously attempting to develop and commercialize our other therapeutic product candidates. If we are unable to develop commercially viable therapeutic products or to license them to third parties, it is likely that we will never achieve significant revenues or become profitable, either of which would jeopardize our ability to continue as a going concern.

***We have significant future capital needs and may be unable to raise capital when needed, which could force us to delay or reduce our clinical development efforts.***

We believe we have adequate cash at our current expected spending level to fund our clinical development programs through the next twelve months. However, we will require additional financial resources after we utilize our current liquid assets in order to continue our clinical development programs as is currently forecasted beyond fiscal year 2016. We are actively pursuing various financing alternatives as market conditions permit through licensing and collaborative agreements or additional potential equity or debt financings, if necessary. We continue to evaluate various programs to raise additional capital and to seek additional revenues from the licensing of our proprietary technologies. At the present time, we are unable to determine whether any of these future activities will be successful and, if so, the terms and timing of any definitive agreements. If we are unable to raise additional capital funding in the near term, we can implement certain planned discretionary spending reductions, including the reduced funding of our clinical trial programs in order for us to continue our operations at least through the next twelve months.

**Table of Contents**

***Our most advanced therapeutic product candidates are still only in the clinical development stage, and will require us to raise capital in the future in order to fund further expensive and time-consuming studies before they can even be submitted for final regulatory approval.***

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

Clinical trials involve the administration of a product candidate to patients who are already extremely ill, making patient enrollment often difficult and expensive. Moreover, even in ideal circumstances where the patients can be enrolled and then followed for the several months or more required to complete the study, the trials can be suspended, terminated, delayed or otherwise fail for any number of reasons, including:

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

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

we or our collaboration partner(s) may experience delays in obtaining, or be unable to obtain, agreement for the conduct of our clinical trials from FDA, institutional review boards (IRBs) or other reviewing entities at clinical sites selected for participation in our clinical trials;

while underway, the continuation of clinical trials may be delayed, suspended or terminated due to modifications to the clinical trial's protocols based on interim results obtained or changes required or conditions imposed by the FDA, an IRB, a data and safety monitoring board, or DSMB, or any other regulatory authority;

our third-party contractors may fail to meet their contractual obligations to us in a timely manner;

FDA or other regulatory authorities may impose a clinical hold, for example based on an inspection of the clinical trial operations or trial sites;

we or our collaboration partner(s) may suspend or cease trials in our or their sole discretion;

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

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

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, sacituzumab govitecan and yttrium 90-labeled clivatuzumab tetraxetan, could severely harm our business and results of operations.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, the Company may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between the company and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

---

**Table of Contents**

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

Progression of our drug products through the clinical development process is dependent upon our trials indicating our drugs have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the trial protocols. Failure to achieve either of these could result in delays in our trials or require the performance of additional unplanned trials. This could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

***Should the clinical development process be successfully completed, our ability to derive revenues from the sale of therapeutics will depend upon our first obtaining FDA as well as foreign regulatory approvals, all of which are subject to a number of unique risks and uncertainties.***

Even if we are able to demonstrate the safety and efficacy of our product candidates in clinical trials, if we fail to gain timely approval to commercialize our product candidates from the FDA and other foreign regulatory authorities, we will be unable to generate the revenues we will need to build our business. These approvals may not be granted on a timely basis, if at all, and even if and when they are granted, they may not cover all the indications for which we seek approval. For example, while we may develop a product candidate with the intention of addressing a large, unmet medical need, the FDA may only approve the use of the drug for indications affecting a relatively small number of patients, thus greatly reducing the market size and our potential revenues. The approvals may also contain significant limitations in the form of warnings, precautions or contraindications with respect to conditions of use, which could further narrow the size of the market. In certain countries, even if the health regulatory authorities approve a drug, it cannot be marketed until pricing for the drug is also approved. Finally, even after approval can be obtained, we may be required to recall or withdraw a product as a result of newly discovered safety or efficacy concerns, either of which would have a materially adverse effect on our business and results of operations.

***In order to fund future operations, we will need to raise significant amounts of additional capital. Because it can be difficult for a small-cap company like ours to raise equity capital on acceptable terms and given the continued weakness of the economy, we cannot assure you that we will be able to obtain the necessary capital when we need it, or on acceptable terms, if at all.***

Even if our technologies and product candidates are superior, if we lack the capital needed to bring our future products to market, we will never be successful. We have obtained the capital necessary to fund our research and development programs to date primarily from the following sources:

Upfront payments, milestone payments and payments for limited amounts of our antibodies received from licensing partners;

Proceeds from the public and private sale of our equity or debt securities; and

Limited product sales of LeukoScan<sup>®</sup>, licenses, grants and interest income from our investments. Our budgeted cash requirements in fiscal year 2015 are expected to be approximately \$42.0 million, which includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, as well as expenses for the ongoing Phase 2 expansion ADC clinical trials (sacituzumab govitecan and labetuzumab govitecan). For



**Table of Contents**

the nine-month period ended March 31, 2015, we utilized cash aggregating \$30.4 million in operations. As of March 31, 2015, we have \$106.2 million of cash, cash equivalents and marketable securities. Based on our expected cash flow projections, we believe we have sufficient funds to continue our operations and research and development programs for at least the next twelve months. We currently estimate that for fiscal year 2016 the net cash flow needs will be in the range of \$44.0 to \$46.0 million, not including the interest costs of \$4.8 million for fiscal year 2016 from the outstanding Convertible Senior Notes as issued in February 2015. Future financial demands include ongoing operating expenses, the Phase 3 and Phase 2 clinical trials and further development of various clinical trial programs in fiscal 2016 and 2017.

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

Over the long term, we expect research and development activities to continue to expand and we do not believe we will have adequate cash to continue to complete development of product candidates in line with our pipeline included in our long term corporate strategy. Our capital requirements are dependent on numerous factors, including:

The rate at which we progress our research programs and the number of product candidates we have in pre-clinical and clinical development at any one time;

The cost of conducting clinical trials involving patients in the U.S., Europe and possibly elsewhere;

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

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

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

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

The ability of the holders of our 4.75% senior convertible notes due 2020 to convert their notes to Immunomedics common stock; and

Our ability to enter into licensing and other collaborative agreements to help offset some of these costs. There may be additional cash requirements for many reasons, including, but not limited to, changes in our research and development plans, the need for unexpected capital expenditures or costs associated with any acquisitions of other businesses, assets or technologies that we may choose to undertake. If we deplete our existing capital resources, we

will be required to either obtain additional capital quickly, or else significantly reduce our operating expenses and capital expenditures, either of which could have a material adverse effect on us.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources. These financial resources may not be adequate to sustain our operations and we will be required to finance future cash needs through strategic collaboration agreements, the sale of additional equity or debt securities. However, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years, which has resulted in uncertainties with respect to availability of capital and hence the timing to meet an entity's liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also

---

**Table of Contents**

may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result; and if we raise funds by incurring additional debt financing, the terms of the debt may involve future cash payment obligations and/or conversion to equity as well as restrictions that may limit our ability to operate our business.

***If we, or our collaboration partners, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partners, to sell products and conduct clinical trials will be impaired.***

Our ability to conduct our pre-clinical and clinical research and development programs depends, in large part, upon our ability to manufacture our proprietary compounds in accordance with FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in significant quantities, and we may not be able to do so in the quantities required to commercialize these products. Any interruption in manufacturing at this site, whether by natural acts or otherwise, could significantly and adversely affect our operations, and delay our research and development programs.

We and our collaboration partners also depend on third parties to provide certain raw materials, manufacturing and processing services. All manufacturers of pharmaceutical products must comply with current Good Manufacturing Practice regulations, ( cGMPs ), required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections. If our manufacturing facility or those facilities of our partners and our respective contract manufacturers or processors do not comply with applicable cGMPs and other regulatory requirements, we may be subject to product liability claims, we may be unable to meet clinical demand for our products, and we could suffer delays in the progress of clinical trials for products under development.

***We are dependent upon UCB for the final development and commercialization of epratuzumab for the treatment of non-cancer indications worldwide, and they may not be successful.***

We have licensed the exclusive worldwide rights for the treatment of non-cancer indications to one of our most advanced therapeutic compounds, epratuzumab to UCB. As a result, UCB is solely responsible, and we are depending upon them, for completing the clinical development of these compounds, obtaining all necessary regulatory approvals, and then commercializing and manufacturing the compounds for sale. If they do not fully perform their responsibilities under our agreements, or if the clinical trials to be conducted or regulatory approvals to be obtained are not initiated, are unsuccessful or are terminated by them for any other reason, our ability to commercialize this product candidate in the future, as well as other product candidates we have in development which are closely related to them, would be severely jeopardized. In such event, it is likely we would never receive any additional milestone payments or royalties that we are eligible to receive under our agreement with UCB, and our ability to fund the development and testing of our other product candidates would be adversely affected.

***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.***



## **Table of Contents**

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

We expect to rely at least in part on third party collaborators to perform a number of activities relating to the development and commercialization of our product candidates, including the manufacturing of product materials, the design and conduct of clinical trials for our product candidates, and potentially the obtaining of regulatory approvals and marketing and distribution of any successfully developed products. Our collaborative partners may also have or acquire rights to control aspects of our product development and clinical programs. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate. In addition, if any of these collaborative partners withdraw support for our programs or product candidates or otherwise impair their development, our business could be negatively affected. To the extent we undertake any of these activities internally, our expenses may increase.

In addition, our success depends on the performance of our collaborators of their responsibilities under these arrangements. Some potential collaborators may not perform their obligations in a timely fashion or in a manner satisfactory to us. Because such agreements may be exclusive, we may not be able to enter into a collaboration agreement with any other company covering the same product field during the applicable collaborative period. In addition, our collaborators' competitors may not wish to do business with us at all due to our relationship with our collaborators. If we are unable to enter into additional product discovery and development collaborations, our ability to sustain or expand our business will be significantly diminished.

***Our future success will depend upon our ability to first obtain and then adequately protect our patent and other intellectual property rights, as well as avoiding the infringement of the rights of others.***

Our future success will be highly dependent upon our ability to first obtain and then defend the patent and other intellectual property rights necessary for the commercialization of our product candidates. We have filed numerous patent applications on the technologies and processes that we use in the U.S. and certain foreign countries. Although we have obtained a number of issued U.S. patents to date, the patent applications owned or licensed by us may not result in additional patents being issued. Moreover, these patents may not afford us the protection we need against competitors with similar technologies or products. A number of jurisdictions where we have sought, or may in future choose to seek, intellectual property protection, have intellectual property laws and patent offices which are still developing. Accordingly, we may have difficulty obtaining intellectual property protection in these markets, and any intellectual property protections which we do obtain may be less protective than in the U. S., which could have an adverse effect on our operations and financial prospects.

The successful development of therapeutic products frequently requires the application of multiple technologies that may be subject to the patent or other intellectual property rights of third parties. Although we believe it is likely we will need to license technologies and processes from third parties in the ordinary course of our business, we are not currently aware of any material conflict involving our technologies and processes with any valid patents or other intellectual property rights owned or licensed by others. In the event that a third party was to claim such a conflict existed, they could sue us for damages as well as seek to prevent us from



---

**Table of Contents**

commercializing our product candidates. It is possible that a third party could successfully claim that our products infringe on their intellectual property rights. Uncertainties resulting from the litigation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Any patent litigation or other proceeding, even if resolved in our favor, would require significant financial resources and management time.

Some of our competitors may be able to sustain these costs more effectively than we can because of their substantially greater financial and managerial resources. If a patent litigation or other proceeding is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products without a license from the other party, in addition to being held liable for significant damages. We may not be able to obtain any such license on commercially acceptable terms, if at all.

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws, nondisclosure and confidentiality agreements and licensing arrangements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or otherwise gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

***Expiry of our intellectual property rights could lead to increased competition***

Even where we are able to obtain and then defend patent and other intellectual property rights necessary for research, development and commercialization of our product candidates, such intellectual property rights will be for a limited term. Where patents which we own or license expire, the technology the subject of the patent may be utilized by third parties in research and development or competing products (for example, generic versions of a patented product may be manufactured by third parties once the patent expires). While we endeavor to maintain robust intellectual property protection, as our existing issued patents expire it may materially and adversely affect our competitive position.

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

The biotechnology industry is highly competitive, particularly in the area of diagnostic and therapeutic oncology and autoimmune disease products. In recent years, there have been extensive technological innovations achieved in short periods of time, and it is possible that future technological changes and discoveries by others could result in our products and product candidates quickly becoming uncompetitive or obsolete. A number of companies, including Biogen Idec, Roche, GlaxoSmithKline, Seattle Genetics, ImmunoGen, Merck Serono, Genmab, Amgen, Bristol-Myers Squibb, Bayer Healthcare Pharmaceuticals, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic autoimmune and oncology products. For example, Human Genome Sciences, a wholly owned subsidiary of GlaxoSmithKline, has received approval from the FDA for belimumab, their human monoclonal antibody against B-lymphocyte stimulator, or BlyS, for the therapy of patients with SLE. Many of these companies have significantly greater financial, technical and marketing resources than we do. In addition, many of these companies have more established positions in the pharmaceutical industry and are therefore better equipped to develop, commercialize and market oncology and autoimmune disease products. Even some smaller competitors may obtain a significant competitive advantage over us if they are able to discover or otherwise acquire patentable inventions, form collaborative arrangements or merge with larger pharmaceutical companies. Further, even if we are able to successfully develop and commercialize products, other manufacturers operating in emerging markets may also have a competitive advantage over us with respect to competing products due to their ability to manufacture with

a lower cost base.

**Table of Contents**

We expect to face increasing competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in the field of antibody-based technologies and they are increasingly aware of the commercial value of their findings. As a result, they are demanding greater patent and other proprietary rights, as well as licensing and future royalty revenues. It is possible that such competition could come from universities with which we have, or have previously had, collaborative research and development relationships, notwithstanding our efforts to protect our intellectual property in the course of such relationships.

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

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

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

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

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

We are heavily dependent upon the talents of Dr. David M. Goldenberg, our Chairman of the Board and Chief Scientific Officer, and Ms. Cynthia L. Sullivan, our President and Chief Executive Officer, as well as certain other key personnel. If Dr. Goldenberg, Ms. Sullivan or any of our other key personnel were to unexpectedly leave our Company, our business and results of operations could be materially and adversely affected. In addition, as our business grows we will need to continue to attract additional management and scientific personnel. Competition for qualified personnel in the biotechnology and pharmaceutical industries is intense and we may not be successful in our recruitment efforts. If we are unable to attract, motivate and retain qualified professionals, our operations could be materially and adversely affected.

***Certain potential for conflicts of interest, both real and perceived, exist which could result in expensive and time-consuming litigation.***

---

**Table of Contents**

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 and Chief Scientific Officer, Ms. Cynthia L. Sullivan, our President and Chief Executive Officer (who is also the wife of Dr. Goldenberg), and certain companies with which we do business, including the Center for Molecular Medicine and Immunology and the Garden State Cancer Center (which operates as the clinical arm of CMMI to facilitate the translation of CMMI's research efforts in the treatment of patients), collectively defined as CMMI. For example, Dr. Goldenberg is the President and a Trustee of CMMI, a not-for-profit cancer research center that we used to conduct certain research activities. Dr. Goldenberg's employment agreement with us permits him to devote more of his time working for CMMI than for us, and other key personnel of our company also have research collaborations with CMMI. Dr. Goldenberg is also a minority stockholder, director and officer of our majority-owned subsidiary, IBC Pharmaceuticals, Inc. Dr. Goldenberg is the primary inventor of new intellectual property for Immunomedics and IBC and is largely responsible for allocating ownership between the two companies. Dr. Goldenberg also has primary responsibility for monitoring the market for incidences of potential infringement of the Company's intellectual property by third parties.

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

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

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

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

During the last few years, we have generated revenues from awards made to us by the National Institutes of Health and the Department of Defense to partially fund some of our programs. We cannot rely on grants or additional contracts as a continuing source of funds. Funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. It is possible that Congress or the government agencies that administer these government research programs will continue to scale



---

**Table of Contents**

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. Where funding is obtained from government agencies or research bodies, our intellectual property rights in the research or technology funded by the grant are typically subject to certain licenses to such agencies or bodies, which could have an impact on our utilization of such intellectual property in future.

***We face a number of risks relating to the maintenance of our information systems and our use of information relating to clinical trials.***

In managing our operations, we rely on computer systems and electronic communications, including systems relating to record keeping, financial information, sourcing, and back-up and the internet ( Information Systems ). Our Information Systems include the electronic storage of financial, operational, research, patient and other data. Our Information Systems may be subject to interruption or damage from a variety of causes, including power outages, computer and communications failures, system capacity constraints, catastrophic events (such as fires, tornadoes and other natural disasters), cyber risks, computer viruses and security breaches. If our Information Systems cease to function properly, are damaged or are subject to unauthorized access, we may suffer interruptions in our operations, be required to make significant investments to fix or replace systems and/or be subject to fines, penalties, lawsuits, or government action. The realization of any of these risks could have a material adverse effect on our business, financial condition and results of operations. Our clinical trials information and patient data (which may include personally identifiable information) is part of our Information Systems and is therefore subject to all of the risks set forth above, notwithstanding our efforts to code and protect such information.

**Risks Related to Government Regulation of our Industry*****Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products and profitability. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA), which includes a number of health care reform provisions and requires most U.S. citizens to have health insurance. The new law, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, and establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance also have been added, which may require modification of business practices with health care practitioners.



**Table of Contents**

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our future products, and we could be adversely affected by current and future health care reforms.

***Our industry and we are subject to intense regulation from the U.S. Government and such other governments and quasi-official regulatory bodies where our products are and product candidates may be sold.***

Both before and after regulatory approval to market a particular product candidate, including our biologic product candidates, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements, including, without limitation, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, requirements and good clinical practice requirements for any clinical trials that we conduct post-approval. As a result, we are subject to a number of governmental and other regulatory risks, which include:

Clinical development is a long, expensive and uncertain process; delay and failure can occur at any stage of our clinical trials;

Our clinical trials are dependent on patient enrollment and regulatory approvals; we do not know whether our planned trials will begin on time, or at all, or will be completed on schedule, or at all;

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

We rely on third parties, such as consultants, contract research organizations, medical institutions, and clinical investigators, to conduct clinical trials for our drug candidates and if we or any of our third-party contractors fail to comply with applicable regulatory requirements, such as current good clinical practice, or cGCP, requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials;

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

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

We have not received regulatory approval in the U.S. or any foreign jurisdiction for the commercial sale of any of our biologic product candidates;

Even if one or more of our product candidates does obtain approval, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate;

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities;

**Table of Contents**

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions;

Although several of our product candidates have received orphan drug designation in the U.S. and the E.U. for particular indications, we may not receive orphan drug exclusivity for any or all of those product candidates or indications upon approval, and even if we do obtain orphan drug exclusivity, that exclusivity may not effectively protect the product from competition;

Even if one or more of our product candidates is approved in the U.S., it may not obtain the 12 years of exclusivity from biosimilars for which innovator biologics are eligible, and even if it does obtain such exclusivity, that exclusivity may not effectively protect the product from competition;

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates, and if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained; and

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

In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency and privacy and security laws, including, without limitation:

the federal Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare or Medicaid programs. This statute has been applied to pharmaceutical manufacturer marketing practices, educational programs, pricing policies and relationships with healthcare providers. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;

---

**Table of Contents**

federal sunshine requirements imposed by PPACA on drug manufacturers regarding any transfer of value made or distributed to physicians and teaching hospitals, and any ownership and investment interests held by such physicians and their immediate family members. Failure to submit the required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations; and

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require drug manufacturers to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and financial arrangements with physicians, could be subject to challenge under one or more of such laws. Any action against us, even if we successfully defend against it, could result in the commencement of civil and/or criminal proceedings, exclusion from governmental health care programs, substantial fines, penalties, and/or administrative remedies, any of which could have an adverse effect on our financial condition and results of operations.

**Risks Related to Our Securities*****Our common stock may be delisted from the NASDAQ Global Market, or NASDAQ.***

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

If our stock is delisted from NASDAQ, we will make every possible effort to have it listed on the Over the Counter Bulletin Board (the OTC Bulletin Board). If our common stock were to be traded on the OTC Bulletin Board, the Securities Exchange Act of 1934, as amended, and related SEC rules would impose additional sales practice requirements on broker-dealers that sell our securities. These rules may adversely affect the ability of stockholders to sell our common stock and otherwise negatively affect the liquidity, trading market and price of our common stock.

If our common stock would not be able to be traded on the OTC Bulletin Board, we would make every effort to have it available for trading on the National Quotation Bureau's Pink Sheets, or the Pink Sheets. The Pink Sheets market consists of security firms who act as market makers in the stocks, usually, of very small companies. The bid and asked prices are not quoted electronically, but are quoted daily in hard copy which is delivered to firms that subscribe. Stocks that trade in the Pink Sheets are usually not as liquid as those that trade in electronic markets and, often time, the difference between the bid and the asked prices are substantial. As a result, if our common stock were traded on the Pink Sheets, there would likely be a further negative affect on the liquidity, trading market and price of our common stock even compared to what we might suffer if we were traded on the OTC Bulletin Board.

---

**Table of Contents**

As a result of the above, we cannot assure you that our common stock will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the Pink Sheets; or if it is to be listed, whether or not there would be an interruption in the trading of our common stock. We believe that the listing of our stock on a recognized national trading market, such as NASDAQ, is an important part of our business and strategy. Such a listing helps our stockholders by providing a readily available trading market with current quotations. Without that, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock would likely decline. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded it by other parties. In that regard, listing on a recognized national trading market will also affect our ability to benefit from the use of its operations and expansion plans, including for use in licensing agreements, joint ventures, the development of strategic relationships and acquisitions, which are critical to our business and strategy and none of which is currently the subject of any agreement, arrangement or understanding, with respect to any future financing or strategic relationship it may undertake. The delisting from NASDAQ would result in negative publicity and would negatively impact our ability to raise capital in the future.

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

Delisting from NASDAQ may depress the price of our common stock such that we may become a penny stock. The SEC generally defines a penny stock as an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. We continue to be listed on NASDAQ.

Penny Stock rules require, among other things, that any broker engaging in a purchase or sale of our securities provide its customers with: (i) a risk disclosure document; (ii) disclosure of market quotations, if any; (iii) disclosure of the compensation of the broker and its salespersons in the transaction; and (iv) monthly account statements showing the market values of our securities held in the customers' accounts.

A broker would be required to provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained on the customers' confirmation. Generally, brokers are less willing to effect transactions in penny stocks due to these additional delivery requirements. These requirements may make it more difficult for stockholders to purchase or sell our common stock. Because the broker, not us, prepares this information, we would not be able to assure that such information is accurate, complete or current.

***Conversion of the 4.75% Notes will dilute the ownership interest of existing stockholders and could adversely affect the market price of our common stock.***

The conversion of some or all of the 4.75% Notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon such conversion and exercise could adversely affect prevailing market prices of our common stock. In addition, the existence of the 4.75% Notes may encourage short selling by market participants.

***Our indebtedness and debt service obligations may adversely affect our cash flow.***

As of March 31, 2015, our total consolidated indebtedness was \$107.1 million, including \$100 million of our obligations under our 4.75% Notes. We intend to fulfill our current debt

**Table of Contents**

service obligations, including repayment of the principal from our existing cash and investments, as well as the proceeds from potential licensing agreements and any additional financing from equity or debt transactions. However, our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow to meet these obligations, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive, or delaying or curtailing research and development programs. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

***We may add additional lease lines to finance capital expenditures and may obtain additional long-term debt and lines of credit. If we issue other debt securities in the future, our debt service obligations will increase further.***

Our indebtedness could have significant additional negative consequences, including, but not limited to:

requiring the dedication of a substantial portion of our existing cash and marketable securities balances and, if available, future cash flow from operations to service our indebtedness, thereby reducing the amount of our expected cash flow available for other purposes, including capital expenditures;

increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

placing us at a possible competitive disadvantage to less leveraged competitors and competitors that have better access to capital resources.

***We may not have the ability to raise funds necessary to purchase the notes upon a fundamental change and our future debt may contain limitations on our ability to repurchase the 4.75% Notes.***

Following a fundamental change as described in the indenture, holders of notes will have the right to require the Company to purchase their notes for cash. A fundamental change may also constitute an event of default or require prepayment under, and result in the acceleration of the maturity of, our other than existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change purchase price in cash with respect to any notes surrendered by holders for purchase upon a fundamental change. In addition, restrictions in the agreements governing our then-outstanding indebtedness, if any, may not allow us to purchase the notes upon a fundamental change. Our failure to purchase the notes upon a fundamental change when required would result in an event of default with respect to the notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated

after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and purchase the notes, which could have a material and adverse impact on our financial condition and results of operations.

---

**Table of Contents**

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

Sales of our common stock (including the issuance of shares upon conversion of convertible debt) in the public market could materially and adversely affect the market price of shares. We have outstanding \$100 million principal amount of 4.75% Senior Convertible Notes that convert to common stock at prices equivalent to \$5.11 (subject to adjustment for certain dilutive events). Our obligation to convert the 4.75% Notes upon demand by the holders may depress the price of our common stock and also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that we deem appropriate.

As of April 30, 2015 we had 93,464,463 shares of common stock outstanding, plus (1) \$100 million of principal amount of 4.75% Notes convertible into up to approximately 19,583,360 shares of common stock at the conversion rate of \$5.11 subject to adjustment as described in the indenture, (2) 5,410,478 options to purchase shares of common stock with a weighted-average exercise price of \$3.34 per share, (3) 751,390 restricted stock units to purchase shares of common stock as they are vested, (4) 12,253,233 options to purchase shares of common stock under the Plan and (5) warrants to purchase 1,000,000 shares of common stock with an exercise price of \$8.00. All of the remaining 22,537,076 shares of common stock are freely tradable without restriction.

***Our outstanding convertible notes, options and warrants may adversely affect our ability to consummate future equity-based financings due to the dilution potential to future investors.***

Due to the number of shares of common stock we are obligated to issue pursuant to outstanding convertible notes, options and warrants, potential investors may not purchase our future equity offerings at market price because of the potential dilution such investors may suffer as a result of the exercise of the outstanding convertible notes, options and warrants.

***Our outstanding 4.75% Notes may adversely affect our ability to consummate future equity-based financings due to the restrictive covenants contained in the Indenture pursuant to which the 4.75% Notes were issued.***

Holders of our 4.75% Notes have certain rights that may inhibit our ability to raise additional capital. Those rights include (a) full-ratchet anti-dilution protection in the event we sell securities at a price lower than the applicable conversion or exercise price of the 4.75% Notes and (b) the right to *pro rata* participation in any future financing.

***The market price of our common stock has fluctuated widely in the past, and is likely to continue to fluctuate widely based on a number of factors, many of which are beyond our control.***

The market price of our common stock has been, and is likely to continue to be, highly volatile. Furthermore, the stock market and the market for stocks of relatively small biopharmaceutical companies like ours have from time to time experienced, and likely will again experience, significant price and volume fluctuations that are unrelated to actual operating performance.

From time to time, stock market analysts publish research reports or otherwise comment upon our business and future prospects. Due to a number of factors, we may fail to meet the expectations of securities analysts or investors and our stock price would likely decline as a result. These factors include:

Announcements by us, our current collaboration partners, any future alliance partners or



**Table of Contents**

our competitors of pre-clinical studies and clinical trial results, regulatory developments, technological innovations or new therapeutic products, product sales, new products or product candidates and product development timelines;

The formation or termination of corporate alliances;

Developments in patent or other proprietary rights by us or our respective competitors, including litigation;

Developments or disputes concerning our patent or other proprietary rights, and the issuance of patents in our field of business to others;

Government regulatory action;

Period-to-period fluctuations in the results of our operations; and

Developments and market conditions for emerging growth companies and biopharmaceutical companies, in general.

In addition, Internet chat rooms have provided forums where investors make predictions about our business and prospects, oftentimes without any real basis in fact, that readers may trade on.

In the past, following periods of volatility in the market prices of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. If we face such litigation in the future, it would result in substantial costs and a diversion of management's attention and resources, which could negatively impact our business. For example, as described in this Quarterly Report on Form 10-Q, two separate shareholder derivative complaints have been filed against the Company. First, on March 24, 2014 a complaint styled *Kops v. Goldenberg, et al.*, was filed in the Superior Court of New Jersey, Chancery Division, General Equity Part, Morris County. Second, on April 8, 2014, a complaint styled *Breitman v. Sullivan, et al.*, was filed in the United States District Court for the District of New Jersey. In addition, a putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, was filed on February 27, 2014 in the United States District Court for the District of New Jersey. On January 29, 2015 the United States District Court for the District of New Jersey in a putative class action lawsuit, styled *Nasyrova v. Immunomedics, Inc.*, has granted the Company's motion to dismiss the complaint in its entirety. The Court granted Plaintiffs thirty days from the date of the opinion in order to file an amended complaint. On February 27, 2015 a second amended complaint was filed by the plaintiff alleging failure to disclose information related to the status of the agreement. The Company filed a motion to dismiss the second amended complaint on April 13, 2015. The defendants continue to believe that the allegations in the class action complaint are without merit and intend to defend the lawsuit vigorously. All three complaints are based on the allegation that we and certain of our current and former officers and directors failed to disclose and/or made material misstatements in the Company's public filings relating to the termination of an agreement between the Company and Nycomed GmbH (Nycomed). There can be no assurance that such litigation will be resolved in our favor, and we might be required to devote significant resources and management time defending the company from these claims, which could adversely affect our business, financial condition and results of operations.

At April 30, 2015, we had 93,464,463 shares of common stock outstanding, 6,161,868 additional shares reserved for the exercise of outstanding options and restricted stock units 12,253,233 shares available for future grant under our stock option plan and 1,000,000 shares of common stock reserved for issuance upon the exercise of outstanding warrants.

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

As of March 31, 2015, Dr. David M. Goldenberg, our Chairman and Chief Scientific 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,

---

**Table of Contents**

controlled the right to vote approximately 9% of our outstanding common stock and 7% of our fully diluted common stock. As a result of this voting power, Dr. Goldenberg has the ability to significantly influence the outcome of substantially all matters that may be put to a vote of our stockholders, including the election of our directors.

*There are limitations on the liability of our directors, and we may have to indemnify our officers and directors in certain instances.*

Our certificate of incorporation limits, to the maximum extent permitted under Delaware law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. Our bylaws provide that we will indemnify our officers and directors and may indemnify our employees and other agents to the fullest extent permitted by law. These provisions may be in some respects broader than the specific indemnification provisions under Delaware law. The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified and to obtain directors' and officers' insurance. Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify a director, officer, employee or agent made or threatened to be made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or was serving at the request of the corporation, against expenses actually and reasonably incurred in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Delaware law does not permit a corporation to eliminate a director's duty of care and the provisions of our certificate of incorporation have no effect on the availability of equitable remedies, such as injunction or rescission, for a director's breach of the duty of care.

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

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

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



**Table of Contents**

The Sarbanes-Oxley Act requires that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Among other things, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act ( Section 404 ). Compliance with Section 404 requires substantial accounting expense and significant management efforts. Our testing, or the subsequent review by our independent registered public accounting firm, may reveal deficiencies in our internal controls that would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, the NASDAQ GMS or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock.

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

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our product candidates and therefore we do not intend to pay cash dividends in the foreseeable future. Until such time as we determine to pay cash dividends on our common stock, our stockholders must rely on increases in the market price of our common stock for appreciation.

**Table of Contents**

**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.

**Table of Contents**

**SIGNATURES**

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

IMMUNOMEDICS, INC.

May 6, 2015

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

May 6, 2015

By: /s/ Peter P. Pfreunds Schuh  
Peter P. Pfreunds Schuh  
Vice President, Finance and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
4.1	Indenture, dated as of February 11, 2015, by and between Immunomedics, Inc., and Wells Fargo Bank, National Association, incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed with the Commission on February 12, 2015.
4.2	Form of 4.75% Convertible Senior Note due 2020 incorporated by reference from Exhibit 4.1 to the Registrant's Current Report on Form 8-K as filed with the Commission on February 12, 2015.
10.1	Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.2	Forms of Incentive Stock Option Notice and Incentive Stock Option Agreement under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.3	Forms of Nonqualified Stock Option Notice and Nonqualified Stock Option Agreement under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.4	Forms of Restricted Stock Units Notice and Restricted Stock Units Agreement (for Officers/Employees) under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.4 to the Registrant's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
10.5	Forms of Restricted Stock Units Notice and Restricted Stock Units Agreement (for Directors) under the Immunomedics, Inc. 2014 Long-Term Incentive Plan, incorporated by reference from Exhibit 99.5 to the Registrant's Registration Statement on Form S-8 as filed with the Commission on January 13, 2015.
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2015, formatted in XBRL (eXtensible Business Reporting Language) filed electronically herewith: (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and, (iv) the Notes to Unaudited Condensed Consolidated Financial Statements.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.
101.LAB	XBRL Taxonomy Extension Label Linkbase.

101.PRE XBRL Taxonomy Extension Presentation Linkbase.

\* Filed herewith.