

IMMUNOMEDICS INC  
Form 10-Q  
February 09, 2017  
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2016

or

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

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

Commission File Number: 0-12104

Immunomedics, Inc.

(Exact name of Registrant as specified in its charter)

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Delaware

61-1009366

(State or other jurisdiction of (I.R.S. Employer Identification No.)

incorporation or organization)

300 The American Road, Morris Plains, New Jersey 07950

(Address of principal executive offices) (Zip Code)

(973) 605-8200

(Registrant's Telephone Number, Including Area Code)

Former Name, Former Address and Former Fiscal Year,

If Changed Since Last Report: Not Applicable

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

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

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

Large Accelerated Filer Accelerated Filer

Non-Accelerated Filer Smaller Reporting Company

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

The number of shares of the registrant's common stock outstanding as of February 6, 2017 was 106,079,504.

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## IMMUNOMEDICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	December 31, 2016	June 30, 2016
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 5,011,316	\$ 13,203,625
Marketable securities	41,602,301	37,424,221
Accounts receivable, net of allowance for doubtful accounts of \$28,727 at December 31, 2016 and \$74,546 at June 30, 2016	187,954	513,992
Inventory	737,931	350,524
Other receivables	4,952	236,768
Prepaid expenses	1,042,100	1,038,155
Other current assets	230,000	183,820
Total current assets	48,816,554	52,951,105
Property and equipment, net of accumulated depreciation of \$29,100,002 and \$28,637,606 at December 31, 2016 and June 30, 2016, respectively	4,277,895	3,969,163
Other long-term assets	30,000	30,000
Total Assets	\$ 53,124,449	\$ 56,950,268
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 14,099,368	\$ 15,188,189
Warrant liability	14,543,343	—
Deferred revenues	218,261	235,372
Total current liabilities	28,860,972	15,423,561
Convertible senior notes – net of unamortized debt issuance costs of \$2,280,694 at December 31, 2016 and \$2,645,602 at June 30, 2016	97,719,309	97,354,398
Other liabilities	1,726,404	1,699,276
Commitments and Contingencies (Note 12)	—	—
Stockholders' Deficit:		
Preferred stock, \$.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at December 31, 2016 and June 30, 2016	—	—
Common stock, \$.01 par value; authorized 155,000,000 shares; issued 106,026,321 shares and outstanding 105,991,596 shares at December 31, 2016; issued 95,867,298 shares and outstanding 95,832,573 shares at June 30, 2016	1,060,262	958,672
Capital contributed in excess of par	334,187,988	311,320,651
Treasury stock, at cost: 34,725 shares at December 31, 2016 and at June 30, 2016	(458,370)	(458,370)
Accumulated deficit	(409,150,186)	(368,504,954)
Accumulated other comprehensive loss	(79,366)	(132,226)

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Total Immunomedics, Inc. stockholders' deficit	(74,439,672)	(56,816,227)
Noncontrolling interest in subsidiary	(742,564)	(710,740)
Total stockholders' deficit	(75,182,236)	(57,526,967)
Total Liabilities and Stockholders' Deficit	\$ 53,124,449	\$ 56,950,268

See accompanying notes to unaudited condensed consolidated financial statements

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## IMMUNOMEDICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF

## COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended December 31,		Six months ended December 31,	
	2016	2015	2016	2015
Revenues:				
Product sales	\$ 316,968	\$ 589,947	\$ 914,482	\$ 1,171,195
License fee and other revenues	10,007	25,403	25,114	36,228
Research and development	57,195	55,754	186,380	194,559
Total revenues	384,170	671,104	1,125,976	1,401,982
Costs and Expenses:				
Costs of goods sold	46,762	64,519	301,867	122,783
Research and development	12,748,026	14,261,676	27,273,890	27,174,806
Sales and marketing	185,075	386,696	400,931	530,217
General and administrative	2,763,956	1,655,841	3,455,540	3,380,135
Total costs and expenses	15,743,819	16,368,732	31,432,228	31,207,941
Operating loss	(15,359,649)	(15,697,628)	(30,306,252)	(29,805,959)
Changes in fair market value of warrant liability	(7,230,340)	—	(7,230,340)	—
Interest expense	(1,369,956)	(1,369,956)	(2,739,911)	(2,739,911)
Interest and other income, net	69,756	83,762	154,962	175,720
Other financing expenses	(346,568)	—	(346,568)	—
Foreign currency transaction gain (loss), net	(211,406)	6,950	(208,947)	(3,511)
Loss before income tax	(24,448,163)	(16,976,872)	(40,677,056)	(32,373,661)
Income tax benefit	—	3,204,250	—	3,185,000
Net loss	(24,448,163)	(13,772,622)	(40,677,056)	(29,188,661)
Less: Net loss attributable to noncontrolling interest	(779)	(26,572)	(31,824)	(48,789)
Net loss attributable to Immunomedics, Inc. stockholders	\$ (24,447,384)	\$ (13,746,050)	\$ (40,645,232)	\$ (29,139,872)
Loss per common share attributable to Immunomedics, Inc. stockholders (basic and diluted):	\$ (0.23)	\$ (0.15)	\$ (0.41)	\$ (0.31)
Weighted average shares used to calculate loss per common share (basic and diluted)	104,657,280	94,664,758	100,270,504	94,630,292
Other comprehensive income (loss), net of tax:				



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Foreign currency translation adjustments	73,708	(54,739)	110,816	(37,271)
Unrealized loss on securities available for sale	(25,347)	(112,964)	(57,956)	(79,267)
Other comprehensive income (loss), net of tax:	48,361	(167,703)	52,860	(116,538)
Comprehensive loss	(24,399,802)	(13,940,325)	(40,624,196)	(29,305,199)
Less comprehensive loss attributable to noncontrolling interest	(779)	(26,572)	(31,824)	(48,789)
Comprehensive loss attributable to Immunomedics, Inc. stockholders	\$ (24,399,023)	\$ (13,913,753)	\$ (40,592,372)	\$ (29,256,410)

See accompanying notes to unaudited condensed consolidated financial statements

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## IMMUNOMEDICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (40,677,056)	\$ (29,188,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Changes in fair value of warrant liability	7,230,340	—
Depreciation and amortization	459,402	336,127
Amortization of deferred revenue	(25,114)	(2,152)
Amortization of bond premiums	159,469	381,107
Amortization of debt issuance costs	364,911	364,911
Amortization of deferred rent	27,128	49,758
(Loss) gain on sale of marketable securities	15,040	(1,844)
(Decrease) increase in allowance for doubtful accounts	(45,819)	13,298
Non-cash expense related to stock compensation	1,445,806	1,965,816
Other	346,568	—
Changes in operating assets and liabilities	(809,080)	4,258,184
Net cash used in operating activities	(31,508,405)	(21,823,456)
Cash flows from investing activities:		
Proceeds from sales/maturities of marketable securities	24,750,000	26,128,088
Purchases of marketable securities	(29,160,546)	(2,749,117)
Purchases of property and equipment	(730,627)	(1,230,726)
Net cash (used in) provided by investing activities	(5,141,173)	22,148,245
Cash flows from financing activities:		
Sale of common stock and warrants, net of related expenses	28,578,473	—
Exercise of stock options	105,133	158,079
Tax withholding payments for stock compensation	(194,050)	(185,499)
Net cash provided by (used in) financing activities	28,489,556	(27,420)
Effect of changes in exchange rates on cash and cash equivalents	(32,287)	(33,937)
Net (decrease) increase in cash and cash equivalents	(8,192,309)	263,432
Cash and cash equivalents - beginning of period	13,203,625	13,452,775
Cash and cash equivalents - end of period	\$ 5,011,316	\$ 13,716,207
Supplemental disclosure of cash flow information:		
Interest paid	\$ 2,375,000	\$ 2,427,778

See accompanying notes to unaudited condensed consolidated financial statements.



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IMMUNOMEDICS, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

Reference is made to the Annual Report on Form 10-K of Immunomedics, Inc., a Delaware corporation (“Immunomedics,” the “Company,” “we,” “our” or “us”), for the fiscal year ended June 30, 2016, 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® product in territories where regulatory approvals have previously been granted in Europe, Canada and in other markets outside the U.S. LeukoScan® is indicated for diagnostic imaging for determining the location and extent of infection and inflammation in bone of patients with suspected osteomyelitis, including patients with diabetic foot ulcers.

The Company has two foreign subsidiaries, Immunomedics B.V. in the Netherlands and Immunomedics GmbH in Rodermark, 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 six-month periods ended December 31, 2016 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2017, 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 or its’ collaborators may be unable to secure regulatory approval of and market its drug candidates; the Company’s dependence upon pharmaceutical and biotechnology collaborations; the levels and timing of payments under the Company’s collaborative agreements, if any; uncertainties about the Company’s ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development or regulatory approval of competing products; the Company’s ability to protect its proprietary technologies; patent-infringement claims; and risks of new, changing and competitive

technologies and regulations in the United States and internationally.

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Since its inception in 1982, Immunomedics' principal sources of funds have been the private and public sale of equity and debt securities, and revenues from licensing agreements, including up-front and milestone payments, funding of development programs, and other forms of funding from collaborations. As of December 31, 2016 the Company had \$46.6 million in cash, cash equivalents and marketable securities. During fiscal 2017, the Company plans to continue its Phase 2 clinical trials of sacituzumab govitecan ("IMMU-132") in patients with metastatic triple negative breast cancer ("TNBC"), metastatic non-small-cell lung cancer ("NSCLC"), small-cell lung cancer ("SCLC"), and metastatic urothelial cancers ("UC"). The Company also plans to continue, without interruption, the preparation and initiation of the Phase 3 confirmatory clinical trial in TNBC, and the large-scale manufacture of IMMU-132. These activities are necessary to support the planned submission of a BLA to FDA for accelerated approval of IMMU-132 in metastatic TNBC. The Company anticipates that it can also continue its other operations and research and development programs at a reduced spending level. Based on the Company's cash flow projections, it believes its cash and marketable securities balance as of December 31, 2016, are sufficient to continue its planned operations and research and development programs, as described above, for at least the next twelve months.

The Company will require additional funding to complete its clinical trials currently underway or planned, continue research and new development programs, and continue operations. The Company continues to pursue potential strategic licensing or collaboration agreements as a possible source of financing to fund its business plan. These business arrangements may be with new or existing partners and may include the Company's clinical development programs as well as any of its intellectual property estate. Other potential sources of funding include equity and potential debt financing.

Additionally, on November 16, 2016, venBio Select Advisor LLC and Behzad Aghazadeh (collectively, "venBio"), filed with the SEC a preliminary proxy statement on Schedule 14A for the purpose of electing four individuals nominated by venBio as directors of the Company at its 2016 annual meeting of stockholders, scheduled to be held on February 16, 2017. On December 6, 2016, venBio filed with the SEC its definitive proxy statement. If a settlement with venBio is not reached prior to the 2016 annual meeting, it is possible that the venBio nominees could constitute a majority of the Company's board of directors following the 2016 annual meeting. The Company's business, operating results or financial condition could be harmed by this proxy contest because, among other things: responding to the proxy contest is costly and time-consuming, is a significant distraction for its board of directors, management and employees, and diverts the attention of its board of directors and senior management from the pursuit of its business strategy, which could adversely affect its results of operations and financial condition. Until the Company can generate significant cash through strategic licensing or collaboration agreements, it expects to continue to fund its operations with its current financial resources. These financial resources will not be adequate to sustain the Company's operations at the current level of activity. Having insufficient funds will require the Company to further 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. Consequently, if the Company cannot obtain sufficient funding through strategic licensing or collaborations, it could be required to finance future cash needs through the sale of additional equity and/or debt securities in capital markets. However, there can be no assurance that the Company will be able to raise the additional capital needed to complete its pipeline of research and development programs on commercially acceptable terms, if at all. 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. The Company's existing debt may also negatively impact the Company's ability to raise additional capital. If the Company is unable to raise capital on acceptable terms, its ability to continue its business would be materially and adversely affected.

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### 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, 2016. The Company adheres to the same accounting policies in preparation of its interim financial statements.

#### Principles of Consolidation and Presentation

The condensed consolidated financial statements include the accounts of Immunomedics and its subsidiaries. Noncontrolling interests in consolidated subsidiaries in the condensed consolidated balance sheets represent minority stockholders' proportionate share of the 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, 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, 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 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 of raw materials, work-in-process and the finished product of LeukoScan®, is stated at the lower of cost (which approximates first-in, first-out) or market, and includes materials, labor and manufacturing overhead.

#### 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





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determined using vendor specific objective evidence, if it exists; otherwise third-party evidence or the Company's best estimate of selling price is used for each deliverable.

Payments received under contracts to fund certain research activities are recognized as revenue in the period in which the research activities are performed. Payments received in advance that are related to future performance are deferred and recognized as revenue when the research projects are performed. Upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement are recorded as deferred revenue and recognized over the estimated service period. The Company estimates the period of continuing involvement based on the best evidential matter available at each reporting period. If the estimated service period is subsequently modified, the period over which the upfront fee is recognized is modified accordingly on a prospective basis.

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

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

### Research and Development Costs

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

### Reimbursement of Research & Development Costs

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

### Stock-Based Compensation

The Company utilizes stock-based compensation in the form 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.

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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 six-month periods ended December 31, 2016 and 2015:

	Six Months Ended December 31,	
	2016	2015
Expected dividend yield	0%	0%
Expected option term (years)	5.05	5.03
Expected stock price volatility	62%	56%
Risk-free interest rate	1.16% - 1.91%	1.28% - 1.64%

The Company uses historical data to estimate forfeitures. The expected term of options granted represents the period of time that options granted are expected to be outstanding. Expected stock price volatility was calculated based on the Company's daily stock trading history. The risk-free rate for periods within the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

## Common Stock Warrants

In connection with a public offering in October 2016, the Company issued warrants and recorded them as liability due to certain net cash settlement provisions. The warrants were recorded at fair value using the Black-Scholes valuation model. The Black-Scholes valuation model takes into account, as of the valuation date, factors including the current exercise price, the term of the warrant, the current price of the underlying stock and its expected volatility, expected dividends on the stock, and the risk-free interest rate for the term of the warrant. These warrants are subject to re-measurement at each balance sheet date until the warrants are exercised or expired, and any change in fair value is recognized as "change in the fair value of warrant liability" in the consolidated statements of operations.

## 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

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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 December 31, 2016.

At June 30, 2016, the Company has available net operating loss carry forwards for federal income tax reporting purposes of approximately \$288.7 million and for state income tax reporting purposes of approximately \$108.5 million, which expire at various dates between fiscal 2017 and 2036. 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 as defined in Section 382 of the Internal Revenue Code. The Company's net operating loss carry forwards available to offset future federal taxable income arising before such ownership changes may be limited. Similarly, the Company may be restricted in using its research credit carry forwards arising before such ownership changes to offset future federal income tax expense.

The Company's U.S. operations reported net losses for the three and six-month periods ended December 31, 2016 and 2015, resulting in tax benefits that were fully offset by valuation allowances. The foreign jurisdictions during the three and six-month periods ended December 31, 2016 reported a net loss, resulting in a tax benefit that was fully offset by a valuation allowance. Income taxes provided for profitable foreign jurisdictions during the three-month period ended September 30, 2015 were reversed as a result of the net loss for the six-month period ended December 31, 2015 with respect to such jurisdictions.

During the three and six-month periods ended December 31, 2015, the Company sold certain State of New Jersey State Net Operating Losses ("NOL") and Research and Development ("R&D") tax credits through the New Jersey Economic Development Authority Technology Business Tax Certificate Transfer Program. Pursuant to such sale, during the three and six-month periods ended December 31, 2015, the Company recorded a tax benefit of \$3.2 million as a result of its sale of approximately \$35.9 million of New Jersey State NOL and \$1.3 million of New Jersey R&D tax credits. There was no such sale during the current fiscal year.

The Company has no liability for uncertain tax positions as of December 31, 2016.

### 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 six-month periods ended December 31, 2016 and 2015. The common stock equivalents excluded from the diluted per share calculation are 30,900,783 and 27,902,219 shares at December 31, 2016 and 2015, respectively.

### Net Comprehensive Loss

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

### Recently Issued Accounting Pronouncements

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows: Clarification of Certain Cash Receipts and Cash Payments", which eliminates the diversity in practice related to the classification of



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certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. ASU 2016-15 is effective for annual and interim reporting periods beginning after December 15, 2017 and early adoption is permitted. ASU 2016-15 provides for retrospective application for all periods presented. The Company is assessing ASU 2016-15's impact and will adopt it when effective.

In March 2016, the FASB issued ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting" which simplified several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Public companies will be required to adopt this standard in annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted in any interim or annual period provided that the entire standard is adopted. The Company does not expect ASU 2016-09 to have a material impact on the consolidated financial statement presentation.

In February 2016, the FASB issued ASU 2016-02, "Leases". This standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by lease terms of more than 12 months. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early application is permitted. The Company is assessing ASU 2016-02's impact and will adopt it when effective.

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.

On May 28, 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In August 2015, with the issuance of ASU 2015-14, the FASB amended the effective date of this ASU to fiscal years beginning after December 15, 2017, and early adoption is permitted only for fiscal years beginning after December 15, 2016. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is assessing ASU 2014-09's impact and will adopt it when effective.

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## 3. Marketable Securities

Marketable securities at December 31, 2016 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	\$ 9,700	\$ 1	\$ (5)	\$ 9,696
Certificate of Deposits	5,362	1	—	5,363
U.S. Government Sponsored Agencies	9,309	1	(3)	9,307
Corporate Debt Securities	9,737	—	(11)	9,726
Commercial Paper	7,512	—	(2)	7,510
	\$ 41,620	\$ 3	\$ (21)	\$ 41,602

Maturities of debt securities classified as available-for-sale were as follows at December 31, 2016 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	\$ 41,602	\$ 41,748
Due after one year through five years	—	—
	\$ 41,602	\$ 41,748

Marketable securities at June 30, 2016 consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	\$ 5,059	\$ 6	\$ —	\$ 5,065
Certificate of Deposits	3,000	3	—	3,003
U.S. Government Sponsored Agencies	14,311	31	—	14,342
Corporate Debt Securities	15,014	2	(2)	15,014
	\$ 37,384	\$ 42	\$ (2)	\$ 37,424

Maturities of debt securities classified as available-for-sale were as follows at June 30, 2016 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	\$ 37,424	\$ 37,601
Due after one year through five years	—	—
	\$ 37,424	\$ 37,601

#### 4. Convertible Senior Notes

In February 2015, the Company issued \$100.0 million of Convertible Senior Notes (net proceeds of approximately \$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 Senior 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, are amortized over the term of the Convertible Senior Notes. The Convertible Senior Notes are senior unsecured obligations of the Company. Interest at



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4.75% is payable semiannually on February 15 and August 15 of each year. The effective interest rate on the Convertible Senior Note was 5.48% for the period from the date of issuance through December 31, 2016.

The Convertible Senior 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 Senior 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 Senior Notes), holders may require Immunomedics to purchase for cash all or part of the Convertible Senior Notes at a purchase price equal to 100% of the principal amount of the Convertible Senior 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 Senior 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, selling or disposing of assets, or issuing or repurchasing its other securities, provided that such event is not deemed to be a fundamental change (as defined in the indenture governing the Convertible Senior Notes). The indenture contains customary terms and covenants and events of default.

If an event of default with respect to the Convertible Senior Notes occurs, holders may, upon satisfaction of certain conditions, accelerate the principal amount of the Convertible Senior Notes plus premium, if any, and accrued and unpaid interest, if any. In addition, the principal amount of the Convertible Senior 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 Senior Notes was \$1.4 million and \$2.7 million for three and six-month periods ended December 31, 2016 and 2015. Included in interest expense is the amortization of debt issuance costs of \$0.2 million and \$0.4 million for the three and six-month periods ended December 31, 2016 and 2015.

## 5. Warrant Liability

Due to certain net cash settlement provisions, the warrants issued in connection with a public offering in October 2016, do not meet the criteria for classification as equity and are recorded as a liability. The Company recognized these warrants as a liability at their fair value and re-measures them at fair value on each reporting date.

The Company uses Level 2 inputs for its valuation methodology for the warrant liability. The estimated fair value was determined using a Black-Scholes valuation model based on various assumptions. The warrant liability is adjusted to reflect estimated fair value at each period end, with any changes in the fair value being recorded in changes in fair value of warrant liability.

The estimated fair value of the warrant liability was approximately \$14.5 million and \$7.3 million, as of December 31, 2016 and October 11, 2016 (date of issuance), respectively. The change in fair value of the warrant liability for the three and six months December 31, 2016 was approximately \$7.2 million.



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## 6. 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, warrant liability and Convertible Senior 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 December 31, 2016 and June 30, 2016.

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.

Financial instruments recorded on the condensed consolidated balance sheets as of December 31, 2016 and June 30, 2016 are categorized based on the inputs to the valuation techniques as follows (in thousands):

- Level 1 – Financial instruments 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 instruments 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 instruments 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.

Cash equivalents and marketable securities:

	(\$ in thousands)			Total
	Level 1	Level 2	Level 3	
December 31, 2016				
Money Market Funds Note (a)	\$ 3,761	\$ —	\$ —	\$ 3,761
Marketable Securities:				
U.S. Treasury Bonds	9,696	—	—	9,696
Certificate of Deposits	5,363	—	—	5,363
U.S. Government Sponsored Agencies	9,307	—	—	9,307
Corporate Debt Securities	9,726	—	—	9,726
Commercial Paper	7,510	—	—	7,510
Total	\$ 45,363	\$ —	\$ —	\$ 45,363

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June 30, 2016	(\$ in thousands)			Total
	Level 1	Level 2	Level 3	
Money Market Funds Note (a)	\$ 10,012	\$ —	\$ —	\$ 10,012
Marketable Securities:				
U.S. Treasury Bonds	5,065	—	—	5,065
Certificate of Deposits	3,003	—	—	3,003
U.S. Government Sponsored Agencies	14,342	—	—	14,342
Corporate Debt Securities	15,014	—	—	15,014
Total	\$ 47,436	\$ —	\$ —	\$ 47,436

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

## Convertible Senior Notes

The carrying amounts and estimated fair values (Level 2) of debt instruments are as follows (in thousands):

	As of December 31, 2016		As of June 30, 2016	
	Carrying Amount	Estimated Fair Value	Carrying Amount	Estimated Fair Value
Convertible Senior Notes	\$ 97,719	\$ 93,877	\$ 97,354	\$ 71,359

The fair value of the Convertible Senior 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 Senior Notes observed in market trading which are Level 2 inputs.

## Warrant Liability

The Company has determined its warrant liability to be a Level 2 fair value measurement and used the Black Scholes valuation model to calculate the fair value as of October 11, 2016 and December 31, 2016:

At the measurement dates, the Company estimated the fair value for the warrants based on Black-Scholes valuation model and using the following assumptions:

	October 11, 2016	December 31, 2016
Risk-free interest rate	0.87%	1.20%
Expected remaining term	2.0 years	1.78 years
Expected volatility	75.00%	77.87%

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Dividend yield                      0%                      0%

The following table sets forth the changes in the fair value for the warrant liability during the six-month period ended December 31, 2016 (in thousands):

	Level 2
Fair value – July 1, 2016	\$ —
Additions, pursuant to October 11, 2016 public offering	7,313
Change in fair value	7,230
Fair value – December 31, 2016	\$ 14,543

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## 7. Stockholders' Deficit

## Common stock

On October 11, 2016, the Company completed an underwritten public offering of 10 million shares of its common stock and accompanying warrants to purchase 10 million shares of common stock at a purchase price of \$3.00 per unit, comprising of one share and one warrant. The Company received gross and net proceeds of \$30.0 million and approximately \$28.6 million, respectively after deducting the underwriting discounts and commissions and estimated expenses related to the offering payable. The warrants will be exercisable six months following the date of issuance, will expire on the second anniversary of the date of issuance and have an exercise price of \$3.75. The shares of common stock were sold pursuant to an effective shelf registration statement filed with the Securities and Exchange Commission. The warrants under certain situations require cash settlement by the Company.

## 8. Accumulated Other Comprehensive (Loss) Income

The components of accumulated other comprehensive loss were as follows (in thousands):

	Currency Translation Adjustments	Net Unrealized Gains (Losses) on Available for-Sale Securities	Accumulated Other Comprehensive (Loss) Income
Balance, July 1, 2016	\$ (172)	\$ 40	\$ (132)
Other comprehensive loss before reclassifications	111	(73)	38
Amounts reclassified from accumulated other comprehensive income (a)	—	15	15
Net current-period other comprehensive income	111	(58)	53
Balance, December 31, 2016	\$ (61)	\$ (18)	\$ (79)
Balance, July 1, 2015	\$ (173)	\$ 12	\$ (161)
Other comprehensive loss before reclassifications	(37)	(78)	(115)
Amounts reclassified from accumulated other comprehensive loss (a)	—	(2)	(2)
Net current-period other comprehensive loss	(37)	(80)	(117)
Balance, December 31, 2015	\$ (210)	\$ (68)	\$ (278)

(a) For the six-month periods ended December 31, 2016 and 2015, a \$15 thousand loss and a \$2 thousand gain were reclassified from accumulated other comprehensive loss to interest and other income, respectively.

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

## 9. Stock Incentive Plan

The Company has a stock incentive plan, the Immunomedics, Inc. 2014 Long-Term Incentive Plan (the "Plan"), that includes a discretionary grant program, a stock issuance program and an automatic grant program. The plan was

established to promote the interests of the Company, by providing eligible persons with the opportunity to acquire a proprietary interest in the Company as an incentive to remain with the organization and to align the employee's interest with our stockholders.

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Under the Plan option awards are generally granted with an exercise price equal to the closing price of the Company's common stock on the date of grant. Those option awards generally vest based on four years of continuous service and have seven year contractual terms. Option awards that are granted to non-employee Board members under the annual option grant program are granted with an exercise price equal to the closing price of the Company's common stock on the date of grant, are vested immediately and have seven year contractual terms. At December 31, 2016, there were 15,645,708 shares of common stock reserved for possible future issuance under the Plan, both currently outstanding (5,991,336 shares) and those available to be issued for future grants (9,654,372 shares).

The weighted average fair value at the date of grant for options granted during the six-month periods ended December 31, 2016 and 2015 were \$1.76 and \$1.00 per share, respectively. The Company uses historical data to estimate employee forfeitures for employees, executive officers and outside directors. The expected term of options granted represents the period of time that options granted are expected to be outstanding and the expected stock price volatility is based on the Company's daily stock trading history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

Information concerning options for the six-month period ended December 31, 2016 is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in 000's)
Outstanding, July 1, 2016	4,015,895	\$ 3.42		
Granted	239,032	\$ 3.31		
Exercised	(54,621)	\$ 1.92		
Cancelled or forfeited	(196,288)	\$ 4.25		
Outstanding, December 31, 2016	4,004,018	\$ 3.39	3.66	\$ 1,925
Exercisable, December 31, 2016	2,804,409	\$ 3.57	2.81	\$ 917

A summary of the Company's non-vested restricted and performance stock units at December 31, 2016, and changes during the six-month period ended December 31, 2016 are presented below:

Outstanding Non-Vested Restricted and Performance Stock Units	Number of Awards	Weighted-Average per Share of Market Value on Grant Date
Non-vested at July 1, 2016	2,066,041	\$ 2.57
Restricted Units Granted(a)	106,061	\$ 3.30
Vested/Exercised	(170,315)	\$ 2.99
Cancelled	(14,469)	\$ 3.11
Non-vested at December 31, 2016	1,987,318	\$ 2.57

(a) For the six-month period ended December 31, 2016, 106,061 restricted stock units were awarded to the Company's President and Chief Executive Officer.



The Company has 3,186,927 non-vested options, restricted stock units and performance stock units outstanding as of December 31, 2016. As of December 31, 2016, there was \$4.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That

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cost is being recognized over a weighted-average period of 2.10 years. The Company recorded \$0.7 million and \$1.4 million for total stock-based compensation expense for employees, executive officers and non-employee Board members for the three and six-month periods ended December 31, 2016, respectively as compared to \$1.1 million and \$2.0 million for the three and six-month periods ended December 31, 2015, respectively.

On August 20, 2015, the Company awarded an additional 214,205 restricted stock units to certain executive officers of the Company at the closing price on that date (\$1.76 per share). These restricted stock units will vest over a four year period. As of December 31, 2016, there was \$1.0 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 2.47 years. The Company recorded \$0.1 million and \$0.3 million for stock-based compensation expense for restricted stock units for the three and six-month periods ended December 31, 2016, respectively, and \$0.2 million and \$0.3 million for the three and six-month periods ended December 31, 2015, respectively.

As part of the Amended and Restated Employment Agreement with Dr. Goldenberg which became effective July 1, 2015, (see Note 11), Dr. Goldenberg received a grant of 1,500,000 Restricted Stock Units, which shall vest, if at all, after the three (3) year period commencing on the grant date of July 14, 2015, provided the applicable milestones based on achievement of certain market conditions (stock prices) are met and conditioned upon Dr. Goldenberg's continued employment through the vesting period, subject to the terms and conditions of the Restricted Stock Units Notice and the Restricted Stock Units Agreement and such other terms and conditions as set forth in the grant agreement. The Company recorded \$0.3 million and \$0.6 million for the stock-based compensation for the three and six-month periods ended December 31, 2016, respectively, and \$0.3 million and \$0.5 million for the three and six-month periods ended December 31, 2015, respectively. There is \$1.7 million of total unrecognized compensation cost related to these non-vested Restricted Stock Units granted as of December 31, 2016. That cost is being recognized over a remaining weighted-average period of 1.53 years.

During fiscal year 2014 the Company awarded certain executive officers Performance Units (as such term is defined in the Plan) 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 exercisable based on a percentage basis on the attainment of anniversary dates. During the six-month period ended December 31, 2016, the Company awarded 9,746 of these restricted stock units to the executive officers as a result of achieving certain continued service requirements. In fiscal years 2016 and 2015, 136,453 units and 116,959 units were awarded from achieving the four performance milestones, respectively. As of December 31, 2016, all four of the performance milestones have been achieved and there are 126,706 Performance Units available that are based on certain continued service requirements that began on each performance milestone vesting date. The Company recorded \$47 thousand and \$0.1 million for the stock-based compensation for the three and six-month periods ended December 31, 2016, respectively, as compared to \$0.1 million and \$0.2 million for the three and six-months ended December 31, 2015, respectively. There is \$0.1 million of total unrecognized compensation cost related to these non-vested Performance Units granted as of December 31, 2016. That cost is being recognized over a weighted-average period of 1.0 years. The unrecognized compensation cost is based on continued service requirements.

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## 10. Geographic Segments

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

The following table presents financial information based on the geographic location of the facilities of Immunomedics as of and for the three-month ended December 31, 2016 and 2015, respectively (\$ in thousands):

	As of and for the three months ended December 31, 2016		
	United		
	States	Europe	Total
Total assets	\$ 51,747	\$ 1,377	\$ 53,124
Property and equipment, net	4,195	83	4,278
Revenues	67	317	384
Loss before taxes	(24,334)	(114)	(24,448)

	As of and for the three months ended December 31, 2015		
	United		
	States	Europe	Total
Total assets	\$ 80,833	\$ 1,131	\$ 81,964
Property and equipment, net	3,109	28	3,137
Revenues	81	590	671
Loss before taxes	(16,761)	(216)	(16,977)

	As of and for the six months ended December 31, 2016		
	United		
	States	Europe	Total
Revenues	\$ 212	\$ 914	\$ 1,126
Loss before taxes	(40,433)	(244)	(40,677)

	As of and for the six months ended December 31, 2015		
	United		
	States	Europe	Total
Revenues	\$ 231	\$ 1,171	\$ 1,402

Loss before income tax expense	(32,188)	(186)	(32,374)
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#### 11.Related Party Transactions

Certain of the Company’s affiliates, including members of its senior management and 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 Company’s Chairman, Chief Scientific Officer and Chief Patent 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”), which has ceased operations, and IBC Pharmaceuticals, Inc., a majority-owned subsidiary.

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The Company incurred \$1 thousand and \$4 thousand of legal expenses on behalf of CMMI for patent related matters for each of the three and six-month periods ended December 31, 2016, as compared to \$5 thousand and \$14 thousand for the three and six-month periods ended December 31, 2015, respectively. The Company has first rights to license those patents, and may decide whether or not to support them.

For the three and six-month periods ended December 31, 2016, Dr. Goldenberg received approximately \$10 thousand and \$20 thousand, respectively, in compensation for his services to IBC. For the three and six-month periods ended December 31, 2015, such compensation was approximately \$22 thousand and \$44 thousand, respectively.

### 12. Collaboration Agreement

The Bayer Group (formerly Algeta ASA)

In fiscal 2013 the Company entered into a collaboration agreement, referred to herein as the Collaboration Agreement, with Algeta ASA (subsequently acquired by The Bayer Group “Bayer”), for the development of epratuzumab to be conjugated with Algeta’s proprietary thorium-227 alpha-pharmaceutical payload. Under the terms of the Collaboration Agreement, the Company manufactured and supplied clinical-grade epratuzumab to Bayer, 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. Bayer has the right to terminate the Collaboration Agreement with three months prior written notice, subject to certain provisions. Bayer 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 Bayer’s request. The Company and Bayer have 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 aggregating \$6.0 million, which have been recognized in prior periods upon the Company fulfilling its obligations under the Collaboration Agreement.

For the year ended June 30, 2015, the Company recognized \$1.0 million in license and other revenue for the completion of the clinical development milestone as described in the Collaboration Agreement, which required the shipment of sufficient quantities of clinical grade material to Bayer to complete their Phase 1 clinical trial. In addition, in January 2016 and 2015, the Company recorded revenue of \$0.3 million representing an anniversary payment under the agreement. The contract provides for the Company to receive one more similar payment of \$0.3 million, representing “anniversary payment” over the 2017 fiscal year.

### 13. Commitments and Contingencies

Employment Contracts

Dr. David M. Golderberg

Effective July 1, 2015, the Company entered into the Amended and Restated Employment Agreement with Dr. Goldenberg pertaining to Dr. Goldenberg’s service to the Company as the Company’s Chairman of the Board, Chief Scientific Officer and Chief Patent Officer (the “Amended and Restated Goldenberg Agreement”).

The Amended and Restated Goldenberg Agreement will continue, unless earlier terminated by the parties, until July 1, 2020. Dr. Goldenberg’s current annual base salary under the Amended and Restated Goldenberg Agreement is \$0.6 million, which shall be reviewed annually for appropriate increases by the Board or the Compensation Committee. Dr. Goldenberg is also eligible to participate in the Company’s



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incentive compensation plan in place for its senior level executives. Dr. Goldenberg's annual bonus target is 50% of his base salary, subject to achievement of performance goals established by the Compensation Committee, with a potential payout from 0 to 150% of the target amount. For the 2016 fiscal year, the strategic goal to out-license sacituzumab govitecan was not met. Taking into account the importance to the Company of out-licensing sacituzumab govitecan, the Compensation Committee determined that although certain individual performance goals were met, the Company's overall strategic plan had not been accomplished and, therefore, that any cash incentive payment that Dr. Goldenberg was eligible for, based on his performance during 2016, would not be granted. Dr. Goldenberg will also be eligible to receive equity compensation awards under the Plan, or any such successor equity compensation plan as may be in place from time to time, at the discretion of the Compensation Committee.

In lieu of any annual performance equity or equity-based grants throughout the term of the Amended and Restated Goldenberg Agreement, Dr. Goldenberg received a grant of 1,500,000 Restricted Stock Units (as such term is defined in the Plan), which shall vest, if at all, after the three 3 year period commencing on the grant date of July 14, 2015, provided the applicable milestones based on achievement of certain market conditions (stock prices) are met and conditioned upon Dr. Goldenberg's continued employment through the vesting period, subject to the terms and conditions of the Restricted Stock Units Notice and the Restricted Stock Units Agreement and such other terms and conditions as set forth in the grant agreement.

Dr. Goldenberg is also eligible to receive certain additional incentive compensation during the agreement term. For any fiscal year in which the Company records an annual net loss, Dr. Goldenberg shall receive a sum equal to 0.75% of the consideration the Company receives from any licensing agreement, sale of intellectual property or similar transaction with any third party, with certain exceptions as defined in the Goldenberg Agreement. For any fiscal year in which the Company records net income, Dr. Goldenberg shall receive a sum equal to 1.50% of the Company's Annual Net Revenue as defined in the Goldenberg Agreement for each such fiscal year, and thereafter throughout the non-competition period, as described in the Agreement.

Dr. Goldenberg is also eligible to receive royalty payments on royalties received by the Company. For each fiscal year the Company shall pay Dr. Goldenberg a sum equal to a percentage of the annual royalties the Company receives on each of the products for which Dr. Goldenberg is an Inventor, and all products using, related to or derived from products for which Dr. Goldenberg is an Inventor. The percentage of royalties that the Company will pay to Dr. Goldenberg on each patented product will be determined based on the percentage of royalties that the Company must pay to external third parties.

Dr. Goldenberg is also eligible to receive minimum payments of \$150 thousand during each of the fiscal years, payable in equal quarterly payments, as an advance against the amounts due as additional incentive compensation, royalty payments and dispositions of undeveloped assets. In the event the Company completes a disposition of the Company's undeveloped assets for which Dr. Goldenberg was an Inventor, the Company will pay Dr. Goldenberg a sum equal to at least twenty percent or more of the consideration the Company receives from each disposition. The Company's obligation to compensate Dr. Goldenberg upon dispositions of undeveloped assets applies to all dispositions of such assets completed within the contract term or within three years thereafter. For the 2016, 2015 and 2014 fiscal years, Dr. Goldenberg received the minimum payment under the employment agreement. Dr. Goldenberg also is compensated by IBC Pharmaceuticals as discussed in greater detail below.

Cynthia L. Sullivan

Effective July 1, 2014, the Company entered into the Fifth Amended and Restated Employment Agreement with Cynthia L. Sullivan pertaining to Ms. Sullivan's service to the Company as the Company's





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President and Chief Executive Officer (the “Amended Sullivan Agreement”), which terminates on June 30, 2017. Ms. Sullivan’s current annual base salary under the Amended Sullivan Agreement is \$0.7 million, which is reviewed annually for appropriate increases by the Board or the Compensation Committee. 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. For the 2016 fiscal year, the strategic goal to out-license sacituzumab govitecan was not met. Taking into account the importance to the Company of out-licensing sacituzumab govitecan, the Compensation Committee determined that although certain individual performance goals were met, the Company’s overall strategic plan had not been accomplished and, that any cash incentive payment that Ms. Sullivan was eligible for, based on her performance during 2016, would not be granted. Ms. Sullivan is also eligible to receive equity compensation awards under the Plan, or any such successor equity compensation plan as may be in place from time to time. The Board of Directors of the Company has determined not to renew the Amended Sullivan Agreement, and Ms. Sullivan will step down upon the Company’s filing for Accelerated Approval of IMMU-132 to the Food and Drug Administration, which is expected to occur in mid-2017. Accordingly, the Governance and Nominating Committee of the Board has initiated a search for a new Chief Executive Officer, with the assistance of a leading, independent, executive search firm.

## Change of Control Agreements

Certain executives have Change of Control Agreements, whereby if a majority of a new board of directors is constituted by newly elected board members not endorsed by the Company’s current Board of Directors, and if, subsequent to such a change, there is a significant change in the responsibilities or employment status of these executives, then severance provisions included in their Change of Control Agreements could be triggered. These severance provisions could result in accelerated vesting of equity compensation and significant, unbudgeted, cash severance payments.

## Legal Matters

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

### Patent litigation:

Immunomedics filed a first amended complaint on October 22, 2015 and a second amended complaint on January 14, 2016 in the United States District Court for the District of New Jersey, against Roger Williams Medical Center (“RWMC”), Richard P. Junghans, M.D., Ph.D. and Steven C. Katz, M.D. The second amended complaint alleges that RWMC and Dr. Junghans breached a Material Transfer Agreement (“MTA”) through which it provided to them a monoclonal antibody known as MN-14 and related materials. Defendants are alleged to have breached the MTA and to have been negligent by, among other things, using the materials beyond the agreed-upon Research Project, sharing confidential information, failing to provide Immunomedics with a right of first refusal, failing to notify Immunomedics of intended publications prior to publishing, and refusing to return the materials upon request. Immunomedics also asserts defendants’ claims of conversion, tortious interference, unjust enrichment, and infringement of three patents owned by Immunomedics. On January 28, 2016, defendants filed an Answer to the Second Amended Complaint. On October 12, 2016, Immunomedics filed a Third Amended Complaint, and further added as defendants Sorrento Therapeutics, Inc. and its subsidiaries TNK Therapeutics, Inc., BDL Products, Inc., and CARgenix Holdings, LLC. Defendants Junghans, Katz, and RWMC subsequently moved to dismiss for failure to state a claim on November 14, 2016, but this motion was denied on January 4, 2017. On December 2, 2016, Sorrento, TNK, BDL, and CARgenix moved to dismiss for lack of personal jurisdiction over them in New Jersey. The court granted this motion on January 25, 2017. On January 20, 2017, the court held a Markman hearing to construe the claims in the patents in suit. A decision on claim construction is currently



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pending and is expected to issue shortly. Immunomedics and defendants are currently engaged in fact discovery and the exchange of patent disclosures.

Stockholder complaints:

Class Action Stockholder Federal Securities Cases

Two purported class action cases have been filed in the United States District Court for the District of New Jersey; namely, *Fergus v. Immunomedics, Inc., et al.*, No. 2:16-cv-03335, filed June 9, 2016; and *Becker v. Immunomedics, Inc., et al.*, No. 2:16-cv-03374, filed June 10, 2016. These cases arise from the same alleged facts and circumstances, and seek class certification on behalf of purchasers of our common stock between April 20, 2016 and June 2, 2016 (with respect to the Fergus matter) and between April 20, 2016 and June 3, 2016 (with respect to the Becker matter). These cases concern the Company's statements in press releases, investor conference calls, and SEC filings beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 American Society of Clinical Oncology ("ASCO") conference in Chicago, Illinois. The complaints allege that these statements were false and misleading in light of June 2, 2016 reports that ASCO had cancelled the presentation because it contained previously reported information. The complaints further allege that these statements resulted in artificially inflated prices for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. An order of voluntary dismissal without prejudice was entered on November 10, 2016 in the Becker matter. As of the date hereof, service of the initiating papers in the Fergus matter has not been made on the Company.

Stockholder Derivative Action in the Superior Court of New Jersey

On October 3, 2016, plaintiff commenced an action captioned *Rosenfeld v. Goldenberg, et al.*, No. L-2200-16, alleging the same underlying facts and circumstances as in the pending federal securities class action, the Fergus matter. Specifically, this action concerns the Company's statements in press releases, investor conference calls, and SEC filings beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 ASCO conference in Chicago, Illinois. The complaint alleges that these statements were false and misleading in light of the June 2, 2016 reports that ASCO had cancelled the presentation because it contained previously reported information. The complaint further alleges that these statements resulted in artificially inflated prices for our common stock, and that certain directors and officers of the Company breached their fiduciary duties to the Company. In addition to monetary damages, the complaint seeks to require the Company to reform its corporate governance and internal procedures. As of the date hereof, service of the initiating papers has not been made on the Company.

Class Action Stockholder Claim in the Court of Chancery of the State of Delaware

On December 13, 2016, plaintiff commenced an action captioned *Desanctis v. Goldenberg, C.A. No. 12981-VCL* (Del. Ch. Ct.), alleging that the Company's Board of Directors failed to comply with Delaware law and breached their fiduciary duties when it rescheduled the Immunomedics 2016 Annual Meeting of Stockholders from December 14, 2016 to February 16, 2017. On December 22, 2016, the Delaware Court of Chancery refused to schedule an expedited hearing in the action and concluded that plaintiff failed to carry his burden of demonstrating that he had pleaded a colorable claim and that there was a threat of irreparable harm. The Court further stated that the Complaint failed to demonstrate that the Board's actions were unreasonable when it rescheduled the Annual Meeting in response to the proxy contest initiated by venBio Select Advisor LLC.



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### Other matters:

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.

### Proxy Contest

On November 16, 2016, venBio Select Advisor LLC and Behzad Aghazadeh (collectively, “venBio”), filed with the SEC a preliminary proxy statement on Schedule 14A for the purpose of electing four individuals nominated by venBio as directors of the Company at the Company’s 2016 annual meeting of stockholders, scheduled to be held on February 16, 2017. On December 6, 2016, venBio filed with the SEC its definitive proxy statement. If a settlement with venBio is not reached prior to the 2016 annual meeting, it is possible that the venBio nominees could constitute a majority of the Company’s board of directors following the 2016 annual meeting. Responding to the proxy contest is costly and time-consuming and will result, regardless of the outcome, in significant additional costs. The expenses for legal and advisory fees and administrative and associated costs incurred in connection with responding to proxy contests and any related litigation will be substantial. In addition, as a result of the proxy contest, the Company may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would require the Company to incur significant additional costs.

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

Words such as “may,” “anticipate,” “estimate,” “expects,” “projects,” “intends,” “plans,” “believes” and words and terms of similar substance used in 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: the risk that we may be unable to obtain additional capital through strategic collaborations, licensing, issuance of convertible debt securities or equity financing in order to continue our research and development activities and secure regulatory approval of and market our drug candidates; 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



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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; 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 other stockholder litigation; 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 to any person authorized to act on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

### Overview

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune disorders 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 eight clinical-stage product candidates.

Our portfolio of investigational products includes antibody-drug conjugates (“ADCs”) that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxicities 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 are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer (“CRC”), respectively. Sacituzumab govitecan has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (“FDA”) for the treatment of patients with triple-negative breast cancer (“TNBC”) who have failed at least two prior therapies for metastatic disease.

We have a research collaboration with Bayer to study epratuzumab as a thorium-227-labeled antibody. We have other ongoing collaborations in oncology in collaboration with independent cancer study groups.

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 combination therapies involving our ADCs, 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 our patented DOCK-AND-LOCK® (“DNL®”) 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





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and uncertainties including, without limitation, the following:

- we may be unable to obtain additional capital through strategic collaborations, licensing, issuance of convertible debt securities or equity financing in order to continue our research and secure regulatory approval of and market our drug;
- 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 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 December 31, 2016, we employed 9 professionals in our research and development departments and 27 professionals in our pre-clinical and clinical research departments. In addition to salaries and benefits, the other costs associated with research and development include the costs associated with producing biopharmaceutical compounds, laboratory equipment and supplies, the costs of conducting clinical trials, legal fees and expenses associated with pursuing patent protection, as well as facilities costs.

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

## Clinical Pipeline Update

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

### Antibody-Drug Conjugates (ADCs)

We have two product candidates from our proprietary ADC program that are in clinical development, focusing on the treatment of patients with metastatic solid tumors. The first ADC program, sacituzumab govitecan is an anti-TROP-2-SN-38 ADC currently being evaluated in patients with a variety of solid tumors. Labetuzumab govitecan is an anti-CEACAM5-SN-38 ADC currently in development for the treatment of metastatic CRC.

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## Sacituzumab Govitecan or IMMU-132

Sacituzumab govitecan has been studied in over 410 diverse cancer patients, with the dose of 10 mg/kg given on days 1 and 8 of repeated 21-day cycles being the established dose regimen. Sacituzumab govitecan has received Breakthrough Therapy Designation from the FDA for the treatment of patients with TNBC who have failed at least two prior therapies for metastatic disease. The FDA has also granted this ADC Fast Track designation for the treatment of patients with TNBC and for patients with small-cell lung cancer (“SCLC”), or non-small-cell lung cancer (“NSCLC”). Sacituzumab govitecan has also been designated an orphan drug by the FDA for the treatment of patients with SCLC or pancreatic cancer in the U.S. and by the European Medicines Agency (“EMA”) for the treatment of patients with pancreatic cancer in the European Union.

Currently, clinical development for sacituzumab govitecan focuses on a number of select types of solid cancers including TNBC, SCLC, NSCLC, urothelial cancer (“UC”) and certain other cancers. In a Phase 2 study in heavily-pretreated patients with metastatic TNBC, sacituzumab govitecan, as reported by our clinical investigator at the 2017 Investor R&D Day (“R&D Day”), produced tumor shrinkage from baseline measurements in 81% of 85 assessable patients. These patients experienced two complete and 23 partial responses, while an additional three patients with initial partial responses are awaiting confirmation. The clinical benefit rate (complete and partial remissions, and patients with stable disease) at six months or later computed to 44%. The median duration of response for those with objective responses was almost 11 months, while the median overall survival (“OS”) for all 85 patients has been extended to almost 19 months. It was emphasized that these are interim results, since 20 patients are continuing treatment; a final outcome must await analysis of all patients enrolled.

The major toxicity (grade >3) has been neutropenia (39%) in this and most cancer patient cohorts, which has been manageable by dose reduction, dose delays, or giving a hematopoietic cytokine. Diarrhea, which is the major side effect with irinotecan, the parent drug from which SN-38 is derived, has been much less, such as a grade >3 of 13%.

These results will be part of a Biologics License Application (“BLA”) submission for the accelerated approval of sacituzumab govitecan. In December 2016, we achieved the goal of enrolling 100 TNBC patients, as requested by FDA for this BLA filing. In addition, the FDA also requires a confirmatory Phase 3 trial to be underway at the time of BLA submission. We plan to launch the confirmatory study in the first quarter of this calendar year. Depending upon whether the Company enters into a potential partnership for sacituzumab govitecan prior to that time, we may need to contribute financially toward the development of this program. The Company would require additional funding in order to complete this Phase 3 clinical trial. Details of this trial can be obtained from [clinicaltrials.gov](http://clinicaltrials.gov) website using the identifier NCT02574455.

In addition to TNBC, we are making progress with sacituzumab govitecan across the other three advanced indications. In patients with UC, especially metastatic urinary bladder cancer, we reported on 27 assessable patients, at the R&D Day, from more than 40 patients enrolled. The objective response rate was 33%, including one complete and eight partial remissions. The duration of objective response was a median of 7.5 months, with one patient with a partial response approaching 17 months. The clinical benefit rate at six months or later was 59%, but 10 patients are still under therapy. Overall, 70% of the patients showed tumor shrinkage from baseline with sacituzumab govitecan therapy. The median progression-free survival (“PFS”) and OS on an intention-to-treat (“ITT”) basis were seven and almost 16 months, respectively. The safety profile was similar to the findings in patients with TNBC.

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Interim results in patients with lung cancers were also presented at the R&D Day. In over 50 patients with metastatic NSCLC enrolled, about one-fifth of evaluable patients had a partial response. Overall, 64% of patients had tumor shrinkage from baseline measurements when given sacituzumab govitecan. These patients had a median of three prior therapies. Importantly, patients with either nonsquamous or squamous pathology responded, as well as patients who failed a prior immune checkpoint inhibitor treatment. The clinical benefit rate at four months or later was 43%. The median duration of response was eight months, but two patients remain under therapy and responsive for over 20 months. Median PFS and OS on an ITT basis were five and over nine months, respectively.

In patients with metastatic SCLC who had a median of two prior therapies, 16% experienced a confirmed partial response, with an additional nine patients showing tumor shrinkage >20%. Overall, 60% of patients showed tumor shrinkage from baseline. The clinical benefit rate at 4 months or later was 40%. The median duration of partial responses and stable disease was about five months (two patients extending out to 21 months), while the median PFS and OS on an ITT basis were almost four months and seven months, respectively.

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 2033.

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 metastatic CRC who had received at least one prior irinotecan-containing regimen and had an elevated blood titer of carcinoembryonic antigen. Several dosing schedules were evaluated in three Phase 1 studies. 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 metastatic CRC than when administered every other week.

In the expanded Phase 2 study patients were being treated in 3-week cycles, receiving labetuzumab govitecan at 8 or 10 mg/kg once-weekly or twice a week at 4 or 6 mg/kg for the first two weeks followed by one week of rest. Updated results were presented at the April 2016 AACR Annual Meeting.

Since there was no significant difference in safety and efficacy between the two once-weekly dosing schedules, for patient's convenience, the once-a-week dose of 10 mg/kg was chosen for future studies in metastatic CRC patients. Although certain patents relating to labetuzumab used in labetuzumab govitecan expired in 2014 in the U.S. and in 2015 overseas and others expired in 2016, other patents relating to use labetuzumab for cancer therapy, including the SN-38 conjugated form of labetuzumab used in labetuzumab govitecan, extend to 2033.

Epratuzumab

As a result of UCB's termination of the Licensing Agreement for epratuzumab, all rights to the anti-CD22 antibody revert to us and the parties have begun the process of transitioning all materials back to us. The 5-year warrant to purchase one million shares of our common stock (granted as part of the Agreement with UCB as amended December 27, 2011), par value \$0.01 per share, at an exercise price of \$8.00 per share expired on December 27, 2016.

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We have a research collaboration with Bayer to study epratuzumab as a thorium-227 labeled antibody. We also have other collaborations ongoing in oncology with independent study groups. The IntreALL Inter-European study group is conducting a large, randomized, Phase 3 trial combining epratuzumab with chemotherapy in children with relapsed acute lymphoblastic leukemia (“ALL”) at clinical sites in Australia, Europe, and Israel. 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. and 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 expiration in the United States in 2032.

### Early-Stage Programs

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

#### 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 and other 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 non-Hodgkin lymphoma (“NHL”) or chronic lymphocytic leukemia (“CLL”) in a Phase 1 study. Results from this study were presented at the December 2015 Annual Meeting of the American Society of Hematology and updated at the 2016 Pan Pacific Lymphoma Symposium. IMMU-114 showed early evidence of efficacy in both NHL and CLL and was well tolerated by patients, with only local skin reactions at the injection sites, which were all mild to moderate and transient.

#### Milatuzumab

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. It has received orphan drug designation from FDA for the treatment of patients with multiple myeloma or CLL.

The anti-CD74 antibody is also being studied subcutaneously in a Phase 1b study in patients with active systemic lupus erythematosus supported by a three-year research grant from the Department of Defense with a potential funding of \$2 million. First results from the open-label study were presented at a poster session during the 2016 annual European League Against Rheumatism Congress. Based on early encouraging results, the study has been expanded into a double-blind, placebo-controlled 30-patient trial to confirm the activity of milatuzumab in this population and have received approval from the Department of Defense for an increased budget to support the expansion.

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### Veltuzumab

Veltuzumab is a humanized monoclonal antibody targeting CD20 receptors on B lymphocytes currently under development for the treatment of NHL and autoimmune diseases. The Office of Orphan Products Development of the FDA has granted orphan status for the use of veltuzumab for the treatment of patients with immune thrombocytopenia (“ITP”). We have studied the subcutaneous formulation of veltuzumab in patients with ITP in a Phase 1/2 trial, which was designed to evaluate different dosing schedules. This trial has completed patient accrual and patients are being followed for up to five years. In oncology, we have completed a National Cancer Institute-funded Phase 2 study in patients with aggressive NHL in combination with 90Y-epratuzumab tetraxetan.

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

### Thorium-227-Labeled Epratuzumab Tetraxetan

Targeted Thorium Conjugates (“TTCs”) represent a new technology directing the power of the alpha-particle selectively towards tumor cells. The high linear energy transfer of the alpha particle generated by decay of the radionuclide thorium-227 induces double-strand DNA breaks causing cell death in targeted tumor cells.

Our corporate partner, Bayer, is currently enrolling patients with relapsed or refractory CD22-positive NHL into a Phase 1 clinical trial evaluating epratuzumab labeled with thorium-227. This study is focusing on patients with diffuse large B-cell lymphoma and potentially follicular lymphomas who have been previously treated with, or are not considered candidates for available therapies. An overview of the TTC platform and the CD22 TTC program was provided in an oral presentation by Bayer at the 2016 AACR Annual Meeting.

### Yttrium-90-Labeled Epratuzumab Tetraxetan

90Y-epratuzumab tetraxetan is our radiolabeled anti-CD22 investigational product for patients with ALL. A team from the University of Nantes, Nantes, France, is starting 2 new trials with the radiolabeled antibody. The first study is randomized Phase 2 trial evaluating the safety and efficacy of 90Y-epratuzumab tetraxetan in adult patients with CD22 positive relapsed or refractory ALL. The second trial is evaluating the feasibility of a reduced conditioning regimen FB2A2 preceding a fractionated radio-immunotherapy with 90Y-epratuzumab tetraxetan before allogeneic stem cell transplantation for patients with CD22 positive ALL in a Phase 1/2 open-label, prospective trial.

### 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) Revenue recognition, (ii) Stock-based compensation and (iii) Research and development costs.

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### 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 (“FDCA”) and its implementing regulations, and the Public Health Service Act (“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 (“GLP”) regulations;
- submission to the FDA of an Investigational New Drug Application (“IND”) which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board (“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;
- preparation of and submission to the FDA of a Biologics License Application (“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;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities to assess compliance with current Good Manufacturing Practice (“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 (“cGCPs”), which

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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 programs, such as Breakthrough Therapy designation and 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. For Breakthrough Therapy designation, preliminary clinical evidence of the product indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If Breakthrough Therapy or 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 accelerate approval. However, receipt of Breakthrough Therapy or 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.

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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 ("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 ("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 more biosimilar products and lower prices for biologic products from increased competition. Indeed, on February 9, 2016, the Arthritis Advisory Committee of the FCA recommended for approval Pfizer's Inflectra as a biosimilar product to Johnson & Johnson's Remicade.



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### Expedited Review and Approval

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced review staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the BLA within six months, compared to ten months under standard review. In February 2016, sacituzumab govitecan was granted Breakthrough Therapy designation from the FDA for the treatment of patients with TNBC who have failed at least two prior therapies for metastatic disease.

### 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 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 NHL, yttrium-90-labeled clivatuzumab tetraxetan for pancreatic cancer, IMMU-132 for SCLC and pancreatic cancer, labetuzumab for ovarian, pancreatic and SCLCs, milatuzumab for multiple myeloma and CLL, and veltuzumab for ITP and pemphigus. 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



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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.

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



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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 (“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 Affordable Care Act (“ACA”) imposes, among other things, 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 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 (“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.

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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.

Results of Operations

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

Three-Month Period Ended December 31, 2016 Compared to 2015

Revenues

Revenue for the three-month periods ended December 31, 2016 and 2015 was \$0.4 million and \$0.7 million, respectively. Product sales for the three-month period ended December 31, 2016 were \$0.3 million, a decrease of \$0.3 million, or approximately 50%, compared to \$0.6 million for the same period in 2015, resulting from a \$0.3 million decrease in sales of LeukoScan® in the current period due to a delay in obtaining regulatory approval for new LeukoScan® inventory. Research and development revenues for the three-month periods ended December 31, 2016 and 2015 were \$0.1 million.

Costs and Expenses

Total costs and expenses for the three-month period ended December 31, 2016 were \$15.7 million, compared to \$16.4 million for the same period in 2015, a decrease of \$0.7 million, or approximately 4%. Research and development expenses for the three-month period ended December 31, 2016 were \$12.7 million, compared to \$14.3 million for the same period in 2015, a decrease of \$1.6 million, or approximately 11%. The decrease in research and development expense was due primarily to a \$4.6 million decrease in expenses related the Phase 3 PANCRIT-1 clinical trial, (which was terminated during the third quarter of fiscal 2016), and \$0.6 million of lower manufacturing material purchases than the prior year. These reductions were partially offset by a \$3.7 million increase in product development expenses related to manufacturing of the antibody drug-conjugate sacituzumab govitecan (IMMU-132).

Cost of goods sold for the three-month period ended December 31, 2016 was \$47 thousand compared to \$65 thousand for the same period in 2015. Gross profit margin was 85% and 89%, for the three-month periods ended December 31, 2016 and 2015, respectively. Sales and marketing expenses were \$0.2 million and \$0.4 million, for the three-month periods ended December 31, 2016 and 2015, respectively. The decrease in sales and marketing expenses was due primarily to changes in the commercial operations in Europe in 2015. General and administrative expenses were \$2.8 million and \$1.7 million for the three month periods ended December 31, 2016 and 2015, respectively, an increase of \$1.1 million, or approximately 65%. The increase in general and administrative expenses was due primarily to a \$0.5 million increase in legal fees and a \$0.9 million increase in professional fees (associated with the proxy contest commenced by venBio Select Advisor LLC), partially offset by lower employee related costs.

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Change in Fair Value of Warrant Liability

The Company recognized a \$7.2 million non-cash expense during the three-month period ended December 31, 2016 reflecting the corresponding increase in the fair value of the warrant liability at December 31, 2016 resulting from the increase of the common stock price from the issuance date of October 11, 2016.

Interest Expense

Interest expense for both three-month periods ended December 31, 2016 and 2015 was \$1.4 million, relating to the \$100.0 million of 4.75% Convertible Senior Notes due in February 2020 and included amortization of debt issuance costs of \$0.2 million for each of the three-month periods ended December 31, 2016 and 2015.

Other Financing Expense

Other financing expense of \$0.3 million for the three-month period ended December 31, 2016 relates to expenses incurred in connection with the public offering we consummated on October 11, 2016 public offering, that were attributable to the warrant liability.

Foreign Currency Transaction (Loss) Gain

Foreign currency transaction loss amounted to \$0.2 million for the three-month period ended December 31, 2016 as compared to a gain of \$7 thousand for the same period in 2015, primarily as a result of fluctuations in currency between the U.S dollar and the euro.

Income Tax Benefit

There was no income tax benefit for the three-month period ended December 31, 2016 compared to an income tax benefit of \$3.2 million for the same period in 2015. The income tax benefit for the three-month period December 31, 2015 related to the sale of a portion of our New Jersey State Tax NOL's and R&D tax credits in 2015. No NOL's or R&D tax credits were sold during the three-month period ended December 31, 2016.

Net Loss Attributable to Immunomedics, Inc. Stockholders

Net loss attributable to Immunomedics, Inc. common stockholders for the three-month period ended December 31, 2016 was \$24.4 million, or \$0.23 per share of common stock, compared to a net loss of \$13.7 million, or \$0.15 per share of common stock, for the same period in 2015. The \$10.7 million increase in net loss in the current period was due primarily to the increase in the fair value of the warrant liability of \$7.2 million, the receipt of proceeds from the non-recurring \$3.2 million NOL and R&D tax credit sale in 2015, and the \$1.1 million increase in general and administrative expenses primarily attributable to the proxy contest commenced by venBio Select Advisor LLC, partially offset by a \$1.5 million decrease in research and development expenses.

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Six-Month Period Ended December 31, 2016 Compared to 2015

Revenues

Revenue for the six-month period ended December 31, 2016 was \$1.1 million, compared to \$1.4 million for the same period in 2015. Product sales were \$0.9 million and \$1.2 million for the six-month periods ended December 31, 2016 and 2015, respectively, a decrease of \$0.3 million, or approximately 25% due primarily to a delay in obtaining regulatory approval for new LeukoScan® inventory during the six-month period ended December 31, 2016. Research and development revenues for the six-month periods ended December 31, 2016 and 2015 were \$0.2 million.

Costs and Expenses

Total costs and expenses for the six-month period ended December 31, 2016 were \$31.4 million, compared to \$31.2 million for the same period in 2015, an increase of \$0.2 million. Research and development expense for the six-month period ended December 31, 2016 was \$27.3 million, compared to \$27.2 million for the six-month period ended December 31, 2015. An \$8.4 million increase in product development expense from manufacturing the antibody drug-conjugate sacituzumab govitecan (IMMU-132), was offset, partially, by a \$7.7 million reduction from the closure of the Phase 3 PANCRIT-1 clinical trial.

Cost of goods sold for the six-month period ended December 31, 2016 was \$0.3 million compared to \$0.1 million for the same period in 2015. During the first six months of fiscal year 2017, cost of goods sold included a \$0.2 million write down relating to LeukoScan® work-in-process inventories that were deemed to be unsaleable due to a manufacturing process deviation. Gross profit margin was 67% and 89%, for the six-month periods ended December 31, 2016 and 2015, respectively. Sales and marketing expenses were \$0.4 million and \$0.5 million, for the six-month periods ended December 31, 2016 and 2015, respectively. General and administrative expenses were \$3.5 million and \$3.4 million for the six-month periods ended December 31, 2016 and 2015, respectively, reflecting an \$0.8 million increase in legal fees and a \$0.9 million increase in professional fees (associated with the proxy contest commenced by venBio Select Advisor LLC), as compared to the same period in the prior year offset by approximately \$1.5 million of adjustments for deferred unearned executive bonuses compared to the same period in the prior year.

Change in Fair Value of Warrant Liability

The Company recognized a \$7.2 million non-cash expense during the six-month period ended December 31, 2016 reflecting the corresponding increase in the fair value of the warrant liability at December 31, 2016 resulting from the increase of the common stock price from the issuance date of October 11, 2016.

Interest Expense

Interest expense for both six-month periods ended December 31, 2016 and 2015 was \$2.7 million, relating to the \$100.0 million of 4.75% Convertible Senior Notes due in February 2020 and included amortization of debt issuance costs of \$0.4 million for each of the three-month periods ended December 31, 2016 and 2015.

Other Financing Expense

Other financing expense of \$0.3 million for the three-month period ended December 31, 2016 relates to expenses incurred in connection with the public offering we consummated on October 11, 2016 public offering, that were attributable to the warrant liability.





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### Foreign Currency Transaction Loss

Foreign currency transaction loss amounted to \$0.2 million and \$4 thousand for the six-month periods ended December 31, 2016 and 2015, respectively, primarily as a result of fluctuations in currency between the U.S dollar and the euro.

### Income Tax Benefit

There was no income tax benefit for the six-month period ended December 31, 2016, compared to an income tax benefit of \$3.2 million for the same period in 2015. The income tax benefit relates to the sale of a portion of our New Jersey State Tax NOL's and R&D tax credits in 2015. No NOL's or R&D tax credits were sold during the six-month period ended December 31, 2016.

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

Net loss attributable to Immunomedics, Inc. common stockholders for the six-month period ended December 31, 2016 was \$40.7 million, or \$0.41 per share of common stock, compared to a net loss of \$29.1 million, or \$0.31 per share of common stock, for the same period in 2015. The \$11.6 million increase in net loss in the current period was due primarily to the increase in the fair value of the warrant liability of \$7.2 million and the receipt of proceeds from the non-recurring \$3.2 million NOL and R&D tax credit sale in 2015.

### Liquidity and Capital Resources

#### Discussion of Cash Flows

Cash flows from operating activities. Net cash used in operating activities for the six-month period ended December 31, 2016 was \$31.5 million compared to \$21.8 million for the six-month period ended December 31, 2015, an increase of \$9.7 million, or 46%. The increase was due primarily to the increase in our net loss of \$11.5 million for the current period, of which \$7.2 million relates to the non-cash expense for the change in fair market value of warrant liability and movements in operating assets and liabilities.

Cash flows from investing activities. Net cash used in investing activities for the six-months ended December 31, 2016 was \$5.1 million. For the same period in the prior year, \$22.1 million of net cash was provided by investing activities, an increase of \$27.2 million, or 123%. This change in cash flows resulted primarily from a \$26.4 million increase in the purchases of marketable securities, the proceeds received from the sale of 10 million shares of common stock on October 11, 2016.

Cash flows from financing activities. Net cash provided by financing activities for the six-month period ended December 31, 2016 was approximately \$28.5 million, compared to \$27 thousand net cash used in financing activities for the six-months ended December 31, 2015. The increase was the result of the approximately \$28.6 million of net cash proceeds received from the sale by the Company of 10,000,000 shares of common stock at \$3.00 per share and accompanying warrants during the six-months ended December 31, 2016.

### Working Capital and Cash Requirements

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We had \$20.0 million working capital as of December 31, 2016, a decrease of \$17.5 million, compared to \$37.5 million as of June 30, 2016. The primary reason for the decline in working capital is the \$14.5 million of warrant liability reported as a current liability, as part of the Company's sale of common stock and warrants in October 2016. We had \$46.6 million cash, cash equivalents and marketable securities as

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of December 31, 2016, a decrease of \$4.0 million, compared to \$50.6 million as of June 30, 2016. The decrease in cash was due primarily to the use of \$31.5 million for operations and \$0.7 million for capital expenditures offset by the increase of approximately \$28.6 million in net proceeds from the Company's sale of common stock and warrants.

By raising additional capital during October, 2016, we are able to continue clinical and manufacturing activities for IMMU-132 development without interruption, while simultaneously continuing our out-licensing efforts. During fiscal 2017, we plan to continue our Phase 2 clinical trials of sacituzumab govitecan ("IMMU-132") in patients with metastatic triple negative breast cancer ("TNBC"), metastatic non-small-cell lung cancer ("NSCLC"), small-cell lung cancer ("SCLC"), and metastatic urothelial cancers. We also plan to continue, without interruption, the preparation and initiation of the Phase 3 confirmatory clinical trial in TNBC, and continue preparations for commercial manufacture of IMMU-132. These activities are necessary to support the planned submission of a BLA to FDA for accelerated approval of IMMU-132 in metastatic triple-negative breast cancer. Based on our cash flow projections, we believe our cash and marketable securities balances as of December 31, 2016, are sufficient to allow us to continue our planned operations and research and development programs, with reduced expenses for programs other than IMMU-132 for TNBC, for at least the next twelve months, with or without a partner for IMMU-132.

Although the Company has sufficient funding to continue IMMU-132 development, with or without a partner, with reduced expenses for programs other than IMMU-132 for TNBC, it is still our plan to initiate the Phase 3 trial in TNBC and continue development of IMMU-132 with a partner. To that end, we engaged Greenhill & Co., LLC to serve as a strategic advisor primarily to assist in our ongoing efforts to out-license IMMU-132. If we consummate a partnership before initiating the Phase 3 clinical trial in TNBC, based on our cash flow projections, we estimate that we would spend approximately \$42.0 million to \$44.0 million during fiscal 2017. There can be no assurance that we will close such a partnership transaction within such timeframe. In the event we do not close such a partnership transaction before initiating the Phase 3 confirmatory trial in TNBC, we would continue development of IMMU-132 while simultaneously seeking to consummate a partnership agreement. If we initiate the Phase 3 trial in TNBC and continue development of IMMU-132 before consummating a partnership transaction, based on our cash flow projections, we estimate that we would spend approximately \$56.0 million for all planned development activities at a reduced spending level during fiscal 2017.

We will require additional funding to complete our clinical trials currently underway or planned, continue the Phase 3 confirmatory study of IMMU-132 in TNBC, complete commercial manufacturing readiness of IMMU-132 for TNBC, continue research and new development programs, and continue operations. We continue to pursue potential strategic licensing or collaboration agreements as a possible source of financing to fund our business plan. These business arrangements may be with new or existing partners and may include our clinical development programs as well as any of our intellectual property estate. Other potential sources of funding include equity and potential debt financing.

Additionally, on November 16, 2016, venBio Select Advisor LLC and Behzad Aghazadeh (collectively, "venBio"), filed with the SEC a preliminary proxy statement on Schedule 14A for the purpose of electing four individuals nominated by venBio as directors of the Company at our 2016 annual meeting of stockholders, scheduled to be held on February 16, 2017. On December 6, 2016, venBio filed with the SEC its definitive proxy statement. If a settlement with venBio is not reached prior to the 2016 annual meeting, it is possible that the venBio nominees could constitute a majority of our board of directors following the 2016 annual meeting. Our business, operating results, including progress on developing our lead product candidate, IMMU-132, or our financial condition could be harmed by this proxy contest because, among other things: responding to the proxy contest is costly and time-consuming, is a significant distraction for our board of

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directors, management and employees, and diverts the attention of our board of directors and senior management from the pursuit of our business strategy, which could adversely affect our results of operations and financial condition.

Until we can generate significant cash through strategic licensing or collaboration agreements, we expect to continue to fund our operations with our current financial resources. These financial resources will not be adequate to sustain our operations at the current level of activity. Having insufficient funds will require the Company to further 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. Consequently, if we cannot obtain sufficient funding through strategic licensing or collaborations, we would be required to finance future cash needs through the sale of additional equity and/or debt securities in capital markets. However, there can be no assurance that we will be able to raise the additional capital needed to complete our pipeline of research and development programs on commercially acceptable terms, if at all. 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. If we are unable to raise capital on acceptable terms, our ability to continue our business would be materially and adversely affected. 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 our Annual Report on Form 10-K. 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.

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.

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



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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.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

#### Patent litigation:

Immunomedics filed a first amended complaint on October 22, 2015 and a second amended complaint on January 14, 2016 in the United States District Court for the District of New Jersey, against Roger Williams Medical Center (“RWMC”), Richard P. Junghans, M.D., Ph.D., and Steven C. Katz, M.D. The second amended complaint alleges that RWMC and Dr. Junghans breached a Material Transfer Agreement (“MTA”) through which it provided to them a monoclonal antibody known as MN-14 and related materials. Defendants are alleged to have breached the MTA and to have been negligent by, among other things, using the materials beyond the agreed-upon Research Project, sharing confidential information, failing to provide Immunomedics with a right of first refusal, failing to notify Immunomedics of intended publications prior to publishing, and refusing to return the materials upon request. Immunomedics also asserts defendants’ claims of conversion, tortious interference, unjust enrichment, and infringement of three patents owned by Immunomedics. On January 28, 2016, defendants filed an Answer to the Second Amended Complaint. On October 12, 2016, Immunomedics filed a Third Amended Complaint, and further added as defendants Sorrento Therapeutics, Inc. and its subsidiaries TNK Therapeutics, Inc., BDL Products, Inc., and CARgenix Holdings, LLC. Defendants Junghans, Katz, and RWMC subsequently moved to dismiss for failure to state a claim on November 14, 2016, but this motion was denied on January 4, 2017. On December 2, 2016, Sorrento, TNK, BDL, and CARgenix moved to dismiss for lack of personal jurisdiction over them in New Jersey. The court granted this motion on January 25, 2017. On January 20, 2017, the court held a Markman hearing to construe the claims in the patents in suit. A decision on claim construction is currently pending and is expected to issue shortly. Immunomedics and defendants are currently engaged in fact discovery and the exchange of patent disclosures.

#### Stockholder complaints:

#### Class Action Stockholder Federal Securities Cases

Two purported class action cases have been filed in the United States District Court for the District of New Jersey; namely, Fergus v. Immunomedics, Inc., et al., No. 2:16-cv-03335, filed June 9, 2016; and Becker v. Immunomedics, Inc., et al., No. 2:16-cv-03374, filed June 10, 2016. These cases arise from the same





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alleged facts and circumstances, and seek class certification on behalf of purchasers of our common stock between April 20, 2016 and June 2, 2016 (with respect to the Fergus matter) and between April 20, 2016 and June 3, 2016 (with respect to the Becker matter). These cases concern the Company's statements in press releases, investor conference calls, and SEC filings beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 American Society of Clinical Oncology ("ASCO") conference in Chicago, Illinois. The complaints allege that these statements were false and misleading in light of June 2, 2016 reports that ASCO had cancelled the presentation because it contained previously reported information. The complaints further allege that these statements resulted in artificially inflated prices for our common stock, and that the Company and certain of its officers are thus liable under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. An order of voluntarily dismissal without prejudice was entered on November 10, 2016 in the Becker matter. As of the date hereof, service of the initiating papers in the Fergus matter has not been made on the Company.

Stockholder Derivative Action in the Superior Court of New Jersey

On October 3, 2016, plaintiff commenced an action captioned *Rosenfeld v. Goldenberg, et al.*, No. L-2200-16, alleging the same underlying facts and circumstances as in the pending federal securities class action, the Fergus matter. Specifically, this action concerns the Company's statements in press releases, investor conference calls, and SEC filings beginning in April 2016 that the Company would present updated information regarding its IMMU-132 breast cancer drug at the 2016 ASCO conference in Chicago, Illinois. The complaint alleges that these statements were false and misleading in light of the June 2, 2016 reports that ASCO had cancelled the presentation because it contained previously reported information. The complaint further alleges that these statements resulted in artificially inflated prices for our common stock, and that certain directors and officers of the Company breached their fiduciary duties to the Company. In addition to monetary damages, the complaint seeks to require the Company to reform its corporate governance and internal procedures. As of the date hereof, service of the initiating papers has not been made on the Company.

Class Action Stockholder Claim in the Court of Chancery of the State of Delaware

On December 13, 2016, plaintiff commenced an action captioned *Desanctis v. Goldenberg, C.A. No. 12981-VCL* (Del. Ch. Ct.), alleging that the Company's Board of Directors failed to comply with Delaware law and breached their fiduciary duties when it rescheduled the Immunomedics 2016 Annual Meeting of Stockholders from December 14, 2016 to February 16, 2017. On December 22, 2016, the Delaware Court of Chancery refused to schedule an expedited hearing in the action and concluded that plaintiff failed to carry his burden of demonstrating that he had pleaded a colorable claim and that there was a threat of irreparable harm. The Court further stated that the Complaint failed to demonstrate that the Board's actions were unreasonable when it rescheduled the Annual Meeting in response to venBio Select Advisor LLC's proxy contest.

Other matters:

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

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Item 1A.RISK FACTORS

Factors That May Affect Our Business and Results of Operations

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

Risks Relating to Our Business, Operations and Product Development

Our business and the market price of our common stock could be negatively affected as a result of a proxy contest.

On November 16, 2016, venBio Select Advisor LLC and Behzad Aghazadeh (collectively, “venBio”), filed with the SEC a preliminary proxy statement on Schedule 14A for the purpose of electing four individuals nominated by venBio as directors of the Company at our 2016 annual meeting of stockholders, scheduled to be held on February 16, 2017. On December 6, 2016, venBio filed with the SEC its definitive proxy statement. If a settlement with venBio is not reached prior to the 2016 annual meeting, it is possible that the venBio nominees could constitute a majority of our board of directors following the 2016 annual meeting.

Our business, operating results or financial condition could be harmed by this proxy contest because, among other things:

- Responding to the proxy contest is costly and time-consuming, is a significant distraction for our board of directors, management and employees, and diverts the attention of our board of directors and senior management from the pursuit of our business strategy, which could adversely affect our results of operations and financial condition;
- Perceived uncertainties as to our future direction, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team, including our chief executive officer, may lead to the perception of a change in the direction of our business, instability or lack of continuity which may be exploited by our competitors, and may result in the loss of potential business opportunities and make it more difficult to attract and retain qualified personnel and business partners;
- The expenses for legal and advisory fees and administrative and associated costs incurred in connection with responding to proxy contests and any related litigation may be substantial; and
- We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors, management and employees and would require us to incur significant additional costs.

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In addition, if the venBio nominees, without the endorsement of the current Board of Directors, are elected and constitute a majority of the board of directors, our business, operating results or financial condition could be harmed a change of control.

The occurrence of any of the foregoing events could adversely affect our business. In addition, the market price of our common stock could be subject to significant fluctuation or otherwise be adversely affected by the uncertainties described above or the outcome of the proxy contest.

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

We have incurred significant operating losses since our formation in 1982. As of December 31, 2016, we had an accumulated deficit of approximately \$409.1 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 collaboration agreement with Bayer. 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 expired (which may leave us vulnerable to increased competition, for example, from biosimilar 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 or licensing 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.

Although we plan to initiate the Phase 3 trial in TNBC and continue development of IMMU-132 with a partner, we believe our funds available as of December 31, 2016, are sufficient to continue our Phase 2 clinical programs, and also continue, without interruption, the preparation and initiation of the Phase 3 confirmatory clinical trial in TNBC, and the large-scale manufacture of IMMU-132. These activities are necessary to support the planned submission of a BLA to FDA for accelerated approval of IMMU-132 in metastatic triple-negative breast cancer. We anticipate we can also continue our other operations and research and development programs, at a reduced spending level, with or without a partner for at least the next twelve months. If we were to initiate the Phase 3 trial in TNBC and continue development of IMMU-132 before consummating a partnership transaction, we estimate that we would spend approximately \$56.0 million for all planned activities assuming reduced spending levels in certain other areas throughout the organization during fiscal 2017.

We will require additional funding to complete our clinical trials currently underway or planned, continue the Phase 3 confirmatory study of IMMU-132 in TNBC, complete commercial manufacturing readiness of IMMU-132 for TNBC, continue research and new development programs, and continue operations. We continue to pursue potential strategic licensing or collaboration agreements as a possible source of financing to fund our business plan. These business arrangements may be with new or existing partners and may include our clinical development programs as well as any of our intellectual property estate. Other potential sources of funding include equity and potential debt financing.



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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. Our existing debt may also negatively impact our ability to raise additional capital in the future. If we do not receive sufficient funding in a timely manner, we will need to further delay or reduce our clinical development efforts.

Additionally, on November 16, 2016, venBio Select Advisor LLC and Behzad Aghazadeh (collectively, “venBio”), filed with the SEC a preliminary proxy statement on Schedule 14A for the purpose of electing four individuals nominated by venBio as directors of the Company at our 2016 annual meeting of stockholders, scheduled to be held on February 16, 2017. On December 6, 2016, venBio filed with the SEC its definitive proxy statement. If a settlement with venBio is not reached prior to the 2016 annual meeting, it is possible that the venBio nominees could constitute a majority of our board of directors following the 2016 annual meeting. Our business, operating results, including progress on developing our lead product candidate, IMMU-132, or our financial condition could be harmed by this proxy contest because, among other things: responding to the proxy contest is costly and time-consuming, is a significant distraction for our board of directors, management and employees, and diverts the attention of our board of directors and senior management from the pursuit of our business strategy, which could adversely affect our results of operations and financial condition.

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. A failure of a clinical trial could severely harm our business and results of operations.

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 or fail to meet the primary endpoint;
- 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 may experience delays in obtaining, or be unable to obtain, agreement for the conduct of our clinical trials from the FDA, 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 (“DSMB”), or any other regulatory authority;
- our third-party contractors may fail to meet their contractual obligations to us in a timely manner;
- the 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 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.



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Any substantial delay in successfully completing clinical trials for our product candidates, sacituzumab govitecan and labetuzumab govitecan, 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. The 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.

Our clinical trials may not adequately show that our drugs are safe or effective, or a failure to achieve the planned endpoints could result in termination of product development.

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 endpoints could result in delays in our trials; require the performance of additional unplanned trials or termination of any further development of the product for the intended indication.

These factors 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.

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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, 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®, licenses, grants and interest income from our investments

As of December 31, 2016 we had \$46.6 million cash, cash equivalents and marketable securities. During fiscal 2017, we plan to continue our Phase 2 clinical trials of sacituzumab govitecan (IMMU-132) in patients with metastatic triple negative breast cancer (TNBC), metastatic non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), and metastatic urothelial cancers, and also continue, without interruption, the preparation and initiation of the Phase 3 confirmatory clinical trial in TNBC, and the large-scale manufacture of IMMU-132. These activities are necessary to support the planned submission of a BLA to FDA for accelerated approval of IMMU-132 in metastatic triple-negative breast cancer. We also anticipate that we will continue our other operations and research and development programs, at a reduced spending level.

Although the Company has sufficient funding to continue IMMU-132 development, with or without a partner, with reduced expenses for programs other than IMMU-132, it is still our plan to initiate the Phase 3 trial in TNBC and continue development of IMMU-132 with a partner. To that end, we engaged Greenhill & Co., LLC to serve as a strategic advisor primarily to assist in our ongoing efforts to out-license IMMU-132. If we consummate a partnership before initiating the Phase 3 clinical trial in TNBC, based on our cash flow projections, we estimate that we would spend approximately \$42.0 million to \$44.0 million during fiscal 2017. In the event we do not close such a partnership transaction before initiating the Phase 3 confirmatory trial in TNBC, we would continue development of IMMU-132 while simultaneously seeking to consummate a partnership agreement. If we initiate the Phase 3 trial in TNBC and continue development of IMMU-132 before consummating a partnership transaction, based on our cash flow projections, we estimate that we would spend approximately \$56.0 million for all planned development activities at a reduced spending level during fiscal 2017.

We will require additional funding to complete our clinical trials currently underway or planned, continue the Phase 3 confirmatory study of IMMU-132 in TNBC, complete commercial manufacturing readiness of IMMU-132 for TNBC, continue research and new development programs, and continue operations. We continue to pursue potential strategic licensing or collaboration agreements as a possible source of financing to fund our business plan. These business arrangements may be with new or existing partners and may include our clinical development programs as well as any of our intellectual property estate. Other potential sources of funding include equity and potential debt 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



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with our pipeline included in our long term corporate strategy. Our capital requirements are dependent on numerous factors, including:

- the rate at which we progress our research programs and the number of product candidates we have in pre-clinical and clinical development at any one time;
- the cost of conducting clinical trials involving patients in the United States, Europe and possibly elsewhere;
- our need to establish the manufacturing capabilities necessary to produce the quantities of our product candidates we project we will need;
- the time and costs involved in obtaining FDA and foreign regulatory approvals;
- the cost of first obtaining, and then defending, our patent claims and other intellectual property rights;
- the ability and willingness of the holders of our 4.75% Convertible Senior Notes due 2020 (“Convertible Senior Notes”) to convert their Convertible Senior 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 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 through strategic licensing or collaboration agreements, we expect to continue to fund our operations with our current financial resources. These financial resources will not be adequate to sustain our operations. Consequently, if we cannot obtain sufficient funding through strategic licensing or collaborations, we could be required to finance future cash needs through the sale of additional equity and/or debt securities in capital markets. However, there can be no assurance that we will be able to raise the additional capital needed to complete our pipeline of research and development programs on commercially acceptable terms, if at all. 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. The Company’s existing debt will also negatively impact the Company’s ability to raise additional capital. If the Company is unable to raise capital on acceptable terms, its ability to continue its business would be materially and adversely affected. 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.

If we, or our collaboration partner, cannot successfully and efficiently manufacture the compounds that make up our products and product candidates, our ability, and the ability of our collaboration partner, 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 the FDA and other regulatory requirements. We have limited historical experience in manufacturing these compounds in

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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 partner also depend on third parties to provide certain raw materials, manufacturing and processing services. All manufacturers of pharmaceutical products must comply with current Good Manufacturing Practice regulations or cGMPs, required by the FDA and other regulatory agencies. Such regulations address, among other matters, controls in manufacturing processes, quality control and quality assurance requirements and the maintenance of proper records and documentation. The FDA and other regulatory agencies routinely inspect manufacturing facilities. The FDA generally will issue a notice on Form 483 if it finds issues with respect to its inspections. If our manufacturing facility or those facilities of our partner 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 may not successfully establish and maintain collaborative and licensing arrangements, which could adversely affect our ability to develop and commercialize our product candidates. Our future collaboration partners may not adequately perform their responsibilities under our agreement, which could adversely affect our development and commercialization program.

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

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

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



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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 United States 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 United States, 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 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, biosimilars 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.



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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, Celgene, Amgen, Bristol-Myers Squibb, Bayer Healthcare Pharmaceuticals, Pfizer, AstraZeneca and Eli Lilly, are engaged in the development of therapeutic oncology products. 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.

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

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the event of a successful product liability claim. Any successful claim in excess of our insurance coverage could materially and adversely affect our financial condition and operating results.

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

We are heavily dependent upon the talents of Dr. David M. Goldenberg, our Chairman of the Board, Chief Scientific Officer, and Chief Patent 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.

Certain members of our senior management and Board of Directors have relationships and agreements, both with us as well as among themselves and their respective affiliates, which create the potential for both real, as well as perceived, conflicts of interest. These include Dr. David M. Goldenberg, our Chairman, Chief Scientific Officer, and Chief Patent 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 operated 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 was the President and a Trustee of CMMI, a not-for-profit cancer research center that we used to conduct certain research activities. CMMI has ceased operations. 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 recent cancer therapeutics for solid cancers such as the ones we are developing can cost approximately in excess of \$12,500 a month, 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





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

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Risks Related to Government Regulation of our Industry

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

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our future products and profitability. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, “PPACA”), which includes a number of health care reform provisions and requires most United States 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.

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 United States 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 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 cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials;

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- if the clinical development process is completed successfully, our ability to derive revenues from the sale of therapeutics will depend on our first obtaining FDA or other comparable foreign regulatory approvals, each of which are subject to unique risks and uncertainties;
- there is no assurance that we will receive FDA or corollary foreign approval for any of our product candidates for any indication; we are subject to government regulation for the commercialization of our product candidates;
- we have not received regulatory approval in the United States 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;
- 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 FDA and other applicable United States 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 United States and the EU 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 United States, 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



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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;

- 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;
- 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

Conversion of the Convertible Senior 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 Convertible Senior 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 Convertible Senior Notes may encourage short selling by market participants.

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

As of December 31, 2016, our total consolidated indebtedness was \$128.3 million, including our obligations under our Convertible Senior Notes. We intend to fulfill our current debt 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 Convertible Senior 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.

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

As a result of the above, we cannot assure you that our common stock will be listed on a national securities exchange, a national quotation service, the OTC Bulletin Board or the Pink Sheets; or if it is to be listed, whether or not there would be an interruption in the trading of our common stock. We believe that the listing of our stock on a recognized national trading market, such as NASDAQ, is an important part of our business and strategy. Such a listing helps our stockholders by providing a readily available trading market with current quotations. Without that, stockholders may have a difficult time getting a quote for the sale or purchase of our stock, the sale or purchase of our stock would likely be made more difficult and the trading volume and liquidity of our stock would likely decline. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded it by other parties. In that regard, listing on a recognized national trading market will also affect our ability to benefit from the use of its operations and



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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.

We may add 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 ability to sell assets if deemed necessary;
- 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.



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

Following a fundamental change (which includes matters such as a change in control of the Company, approval by the Company's stockholders of a plan of dissolution or liquidation of the Company, and the cessation of listing of the Company's common stock on NASDAQ or The New York Stock Exchange, among others as further described in the indenture), holders of Convertible Senior Notes will have the right to require the Company to purchase their Convertible Senior 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 then-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 Convertible Senior 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 Convertible Senior Notes upon a fundamental change. Our failure to purchase the Convertible Senior Notes upon a fundamental change when required would result in an event of default with respect to the Convertible Senior 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 Convertible Senior Notes, which could have a material and adverse impact on our financial condition and results of operations.

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 Convertible Senior Notes that convert to common stock at prices equivalent to \$5.11 (subject to adjustment for certain dilutive events). Our obligation to convert the Convertible Senior 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 December 31, 2016 we had 106,026,321 shares of common stock issued, plus (1) \$100 million of principal amount of Convertible Senior 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) 4,004,018 options to purchase shares of common stock with a weighted average exercise price of \$3.39 per share, (3) 487,318 restricted stock units, (4) 9,654,372 for potential future grants of options to purchase shares of common stock under the Plan, (5) 1,500,000 of restricted stock units issued to Dr. Goldenberg as part of the Amended and Restated Employment Agreement and (6) warrants to purchase 10,000,000 shares of common stock with an exercise price of \$3.75. Of the 160,000,000 shares of common stock authorized under our Certificate of Incorporation, there are 3,744,611 shares of common stock that remain available for future issuance.

Our outstanding Convertible Senior 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 Senior 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 Senior Notes, options and warrants.

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

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

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

- Announcements by us, our current collaboration partner, any future alliance partners or our competitors of pre-clinical studies and clinical trial results, regulatory developments, technological innovations or new therapeutic products, product sales, new products or product candidates and product development timelines;
- The formation or termination of corporate alliances;
- Developments in patent or other proprietary rights by us or our respective competitors, including litigation;
- Developments or disputes concerning our patent or other proprietary rights, and the issuance of patents in our field of business to others;
- Government regulatory action;
- Period-to-period fluctuations in the results of our operations; and
- Developments and market conditions for emerging growth companies and biopharmaceutical companies, in general.

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

In the past, following periods of volatility in the market prices of the securities of companies in our industry, securities class action litigation has often been instituted against those companies. Please see Item 3 (“Legal Proceedings”) for a description of such litigation. 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.

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

As of December 31, 2016, Dr. David M. Goldenberg, our Chairman of the Board, Chief Scientific Officer and Chief Patent Officer, together with certain members of his family, including Ms. Cynthia L. Sullivan, our President and Chief Executive Officer, who is Dr. Goldenberg’s wife, and other affiliates, controlled the right to vote approximately 7% of our outstanding common stock and approximately 5% of our fully diluted common stock. As a result of this voting power, Dr. Goldenberg has the ability to significantly influence the outcome of substantially all matters that may be put to a vote of our stockholders, including the election of our directors.

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

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

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

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

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

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

firm, may reveal deficiencies in 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 Stock Market or other regulatory authorities that would require additional financial and management resources and could adversely affect the market price of our common stock.

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

We have never declared or paid dividends on our common stock. We intend to retain future earnings to develop and commercialize our 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 of their investment.

ITEM 6.EXHIBITS

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

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SIGNATURES

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

IMMUNOMEDICS, INC.

February 9, 2017 By: /s/ Cynthia L. Sullivan  
Cynthia L. Sullivan  
President and Chief  
Executive Officer  
(Principal Executive Officer)

February 9, 2017 By: /s/ Michael R. Garone  
Michael R. Garone  
Vice President, Finance and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amendment to Second Amended and Restated By-Laws of Immunomedics, Inc. (Incorporated by reference to exhibit 3.1 to the Company's current report on Form 8-K, as filed with the Commission on November 28, 2016).
4.1	Warrant Agreement, dated as of October 11, 2016, between the Company and Broadridge Financial Solutions, Inc., as warrant agent (Incorporated by reference to exhibit 4.1 to the Company's current report on Form 8-K, as filed with the Commission on October 12, 2016).
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.*
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from this Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2016, 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.

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\*Filed herewith.