

IMMUNOMEDICS INC
Form 10-Q
February 04, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2014

or

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

For the transition period from _____ to _____

Commission File Number: 0-12104

Immunomedics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
300 The American Road, Morris Plains, New Jersey 07950
(Address of principal executive offices) (Zip Code)
(973) 605-8200

61-1009366
(I.R.S. Employer

Identification No.)

(Registrant's Telephone Number, Including Area Code)

Former Name, Former Address and Former Fiscal Year,

If Changed Since Last Report: Not Applicable

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

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

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

Large Accelerated Filer ☐ Accelerated Filer ☒

Non-Accelerated Filer ☐ Smaller Reporting Company ☐

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

The number of shares of the registrant's common stock outstanding as of February 3, 2015 was 93,387,149.

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IMMUNOMEDICS, INC.

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

	December 31, 2014	June 30, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,848,690	\$ 6,961,494
Marketable securities	18,413,852	34,871,120
Accounts receivable, net of allowance for doubtful accounts of \$67,857 at December 31, 2014 and \$88,609 at June 30, 2014	551,429	674,617
Inventory	676,777	778,989
Other receivables	101,420	303,102
Prepaid expenses	1,554,464	1,614,897
Other current assets	381,235	180,678
Total current assets	24,527,867	45,384,897
Property and equipment, net of accumulated depreciation of \$27,594,558 and \$27,312,924 at December 31, 2014 and June 30, 2014, respectively	2,053,440	1,895,475
Value of life insurance policies	176,110	176,110
Other long-term assets	30,000	30,000
Total Assets	\$ 26,787,417	\$ 47,486,482
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 8,951,445	\$ 6,886,682
Deferred revenues	228,470	240,158
Total current liabilities	9,179,915	7,126,840
Other liabilities	1,550,002	1,500,244
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at December 31, 2014 and June 30, 2014		
Common stock, \$0.01 par value; authorized 155,000,000 shares at December 31, 2014 (135,000,000 at June 30, 2014); issued 93,246,188 shares and outstanding 93,211,463 shares at December 31, 2014; and issued 93,113,480 shares and outstanding 93,078,755 shares at June 30, 2014	932,462	931,134
Capital contributed in excess of par	301,454,274	300,080,804
	(458,370)	(458,370)

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Treasury stock, at cost, 34,725 shares at December 31, 2014 and at June 30, 2014

Accumulated deficit	(285,311,293)	(261,465,638)
Accumulated other comprehensive (loss) income	(6,447)	261,837
Total Immunomedics, Inc. stockholders' equity	16,610,626	39,349,767
Noncontrolling interest in subsidiary	(553,126)	(490,369)
Total stockholders' equity	16,057,500	38,859,398
Total Liabilities and Stockholders' Equity	\$ 26,787,417	\$ 47,486,482

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,	
	2014	2013	2014	2013
Revenues:				
Product sales	\$ 761,664	\$ 949,901	\$ 1,489,297	\$ 1,508,924
License fee and other revenues				4,623,333
Research and development	241,127	252,549	585,492	568,014
Total revenues	1,002,791	1,202,450	2,074,789	6,700,271
Costs and Expenses:				
Costs of goods sold	68,983	103,071	145,269	180,270
Costs of license fee and other revenues				1,189,170
Research and development	10,364,850	7,243,108	19,756,867	15,079,907
Sales and marketing	174,795	424,510	403,432	642,542
General and administrative	1,856,036	2,042,081	5,675,228	3,774,752
Total costs and expenses	12,464,664	9,812,770	25,980,796	20,866,641
Operating loss	(11,461,873)	(8,610,320)	(23,906,007)	(14,166,370)
Interest and other income	11,216	18,305	36,288	24,516
Foreign currency transaction gain	11,899	12,540	162	17,992
Loss before income tax expense.	(11,438,758)	(8,579,475)	(23,869,557)	(14,123,862)
Income tax (expense) benefit	(26,892)	4,501	(38,855)	
Net loss	(11,465,650)	(8,574,974)	(23,908,412)	(14,123,862)
Net loss attributable to noncontrolling interest	(30,415)	(25,220)	(62,757)	(50,419)
Net loss attributable to Immunomedics, Inc. stockholders	\$ (11,435,235)	\$ (8,549,754)	\$ (23,845,655)	\$ (14,073,443)
Loss per common share attributable to Immunomedics, Inc. stockholders, (basic and diluted)	\$ (0.12)	\$ (0.10)	\$ (0.26)	\$ (0.17)

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Weighted average shares used to calculate loss per common share, (basic and diluted)	93,157,279	83,174,835	93,127,741	83,060,980
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustments	(79,703)	47,514	(257,833)	119,881
Unrealized gains on available-for-sale securities	(5,999)	19,982	(10,451)	15,022
Other comprehensive (loss) income	(85,702)	67,496	(268,284)	134,903
Comprehensive loss	(11,551,352)	(8,507,478)	(24,176,696)	(13,988,959)
Less comprehensive loss attributed to noncontrolling interest	(30,415)	(25,220)	(62,757)	(50,419)
Comprehensive loss attributable to Immunomedics, Inc. stockholders	\$ (11,520,937)	\$ (8,482,258)	\$ (24,113,939)	\$ (13,938,540)

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,	
	2014	2013
Cash flows used in operating activities:		
Net loss	\$ (23,908,412)	\$ (14,123,862)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	281,634	314,376
Amortization of deferred revenue	(11,688)	(2,492,149)
(Decrease) increase in allowance for doubtful accounts	(20,752)	11,923
Non-cash expense related to stock compensation	1,515,129	1,540,987
Gain from sale of marketable securities	(9,898)	
Non-cash increase in value of life insurance policy		(8,500)
Amortization of deferred rent	49,758	49,758
Amortization of bond premiums	233,440	102,454
Changes in operating assets and liabilities	2,296,480	(518,860)
Net cash used in operating activities	(19,574,309)	(15,123,873)
Cash flows provided by (used in) investing activities:		
Proceeds from sales/maturities of marketable securities	19,478,097	
Purchase of marketable securities	(3,244,370)	(20,127,248)
Purchases of property and equipment	(439,599)	(214,259)
Net cash provided by (used in) investing activities	15,794,128	(20,341,507)
Cash flows (used in) provided by financing activities:		
Tax withholding payments for stock compensation	(221,291)	(217,004)
Exercise of stock options	80,959	1,076,220
Net cash (used in) provided by financing activities	(140,332)	859,216
Effect of changes in exchange rates on cash and cash equivalents	(192,291)	90,112
Net decrease in cash and cash equivalents	(4,112,804)	(34,516,052)
Cash and cash equivalents, beginning of period	6,961,494	41,326,000
Cash and cash equivalents, end of period	\$ 2,848,690	\$ 6,809,948

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, 2014, which contains our audited consolidated financial statements and the notes thereto.

1. Business Overview and Basis of Presentation

Immunomedics is a clinical-stage biopharmaceutical company that develops monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has continued to transition its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company still manufactures and commercializes its LeukoScan® 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 Darmstadt, Germany, that assist the Company in managing sales efforts and coordinating clinical trials in Europe. In addition, included in the accompanying condensed financial statements is the majority-owned U.S. subsidiary, IBC Pharmaceuticals, Inc. (IBC), which works on the development of novel cancer radiotherapeutics using patented pre-targeting technologies with proprietary, bispecific antibodies.

The accompanying unaudited condensed consolidated financial statements of Immunomedics, which incorporate our subsidiaries, have been prepared in accordance with U.S. generally accepted accounting principles (GAAP), for interim financial information and the instructions to the Quarterly Report on Form 10-Q and Regulation S-X. Accordingly, the statements do not include all of the information and footnotes required by GAAP for complete annual financial statements. With respect to the financial information for the interim periods included in this Quarterly Report on Form 10-Q, which is unaudited, management believes that all adjustments (consisting of normal recurring accruals), considered necessary for a fair presentation of the results for such interim periods have been included. Operating results for the three and six-month periods ended December 31, 2014 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2015, or any other period.

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

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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, which could provide up-front and milestone payments, as well as funding of development costs and other licensing possibilities. The Company's ability to raise capital through public and private debt or equity financings may be negatively impacted by the economy. There can be no assurances that financings will be available when

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needed with acceptable terms to it, if at all. If the Company were unable to raise capital on acceptable terms, its ability to continue its business would be materially and adversely affected. Furthermore, the terms of any such debt or equity financing may include covenants which may limit the Company's future ability to manage the business. At the present time, the Company is unable to determine whether any of these future activities will be successful and, if so, the terms and timing of any definitive agreements.

The Company's budgeted cash requirements in fiscal year 2015 are expected to be approximately \$41.0 million, which includes expenses related to the clivatuzumab tetraxetan Phase 3 clinical trial for the treatment of patients with pancreatic cancer, as well as for expenses for the ongoing Phase 2 expansion ADC clinical trials (IMMU-132 and IMMU-130). The Company has the ability to reduce its cash flow spending requirements if necessary, after considering certain planned discretionary spending, including the funding of the Company's clinical trial programs. For the six-month period ended December 31, 2014, the Company utilized cash aggregating \$20.5 million. As of December 31, 2014, the Company has \$21.3 million of cash, cash equivalents and marketable securities. The Company will require additional funding in order to fund its operating expenses, the ongoing Phase 3 trial, the Phase 2 clinical trials and further the advancement of clinical trial programs in fiscal 2015 and beyond.

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

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

2. Summary of Significant Accounting Policies

These unaudited condensed consolidated interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended June 30, 2014. The Company adheres to the same accounting policies in preparation of its interim financial statements.

Principles of Consolidation and Presentation

The condensed consolidated financial statements include the accounts of Immunomedics and its subsidiaries. Noncontrolling interests in consolidated subsidiaries in the condensed consolidated balance sheets represent minority

stockholders proportionate share of the equity (deficit) in such subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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

Estimated Fair Value of Financial Instruments

The Company has categorized its financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. The Company does not have any financial liabilities that are required to be measured at fair value on a recurring basis. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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

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

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

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

	(\$ in thousands)			
December 31, 2014	Level 1	Level 2	Level 3	Total
Money Market Funds	\$ 347	\$	\$	\$ 347
Marketable Securities:				
U.S. Treasury Bonds	2,002			2,002
U.S. Government Sponsored Agencies	4,199			4,199
Corporate Debt Securities	12,213			12,213

Total