IMMUNOMEDICS INC
Form 10-Q
November 04, 2011
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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 September 30, 2011

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number: 0-12104

Immunomedics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**61-1009366**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

300 The American Road, Morris Plains, New Jersey 07950

(Address of principal executive offices) (Zip Code)

(973) 605-8200

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large Accelerated Filer ¨	Accelerated Filer þ
Non-Accelerated Filer ¨ (Do not check if a smaller reporting company)	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 þ

The number of shares of the registrant s common stock outstanding as of November 3, 2011 was 75,485,736.

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IMMUNOMEDICS, INC.

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IMMUNOMEDICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2011 (unaudited)	June 30, 2011 (audited)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,650,728	$ 27,097,610
Accounts receivable, net of allowance for doubtful accounts of $30,000 at September 30, 2011 and $32,000 at June 30, 2011	570,778	736,980
Inventory	691,409	289,604
Other receivables	2,029,222	974,331
Prepaid expenses	852,980	514,388
Other current assets	161,679	644,705
Total current assets	24,956,796	30,257,618
Property and equipment, net of accumulated depreciation of $24,578,000 and $24,211,000 at September 30, 2011 and June 30, 2011, respectively	3,281,630	3,456,150
Value of life insurance policies	590,505	581,005
Other long-term assets	30,000	30,000
Total Assets	$ 28,858,931	$ 34,324,773
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,890,137	$ 5,548,318
Total current liabilities	4,890,137	5,548,318
Other liabilities	1,209,774	1,134,492
Commitments and Contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value; authorized 10,000,000 shares; no shares issued and outstanding at September 30, 2011 and June 30, 2011		
Common stock, $0.01 par value; authorized 110,000,000 shares; issued and outstanding, 75,477,735 shares at September 30, 2011 and 75,463,066 shares at June 30, 2011	754,777	754,630
Capital contributed in excess of par	245,445,693	245,023,414
Treasury stock, at cost, 34,725 shares at September 30, 2011 and at June 30, 2011	(458,370)	(458,370)
Accumulated deficit	(222,999,161)	(217,898,394)
Accumulated other comprehensive income	216,181	394,669
Total Immunomedics, Inc. stockholders equity	22,959,120	27,815,949
Noncontrolling interest in subsidiary	(200,100)	(173,986)
Total stockholders equity	22,759,020	27,641,963
Total Liabilities and Stockholders Equity	$ 28,858,931	$ 34,324,773

See accompanying notes to unaudited condensed consolidated financial statements

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IMMUNOMEDICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND

COMPREHENSIVE LOSS

	Three months ended September 30,	
	2011	2010
	(unaudited)	
Revenues:		
Product sales	$ 859,867	$ 1,130,271
Research and development	284,787	363,550
Total revenues	1,144,654	1,493,821
Costs and Expenses:		
Costs of goods sold	95,865	109,016
Research and development	4,812,252	5,845,014
Sales and marketing	211,886	182,163
General and administrative	1,167,523	2,057,493
Total costs and expenses	6,287,526	8,193,686
Operating loss	(5,142,872)	(6,699,865)
Interest and other income	7,881	252,563
Foreign currency transaction gain	22,074	28,675
Loss before income tax expense	(5,112,917)	(6,418,627)
Income tax (expense)	(13,964)	(46,902)
Net (loss)	(5,126,881)	(6,465,529)
Less net (loss) attributable to noncontrolling interest	(26,114)	
Net (loss) attributable to Immunomedics, Inc. stockholders	$ (5,100,767)	$ (6,465,529)
(Loss) per common share attributable to Immunomedics, Inc. stockholders, (basic and diluted)	$ (0.07)	$ (0.09)
Weighted average shares used to calculate loss per common share, (basic and diluted)	75,435,131	75,269,134
Comprehensive (loss):		
Net (loss)	$ (5,126,881)	$ (6,465,529)
Other comprehensive (loss) income, net of tax:		
Foreign currency translation adjustments	(178,488)	150,059
Unrealized gain on securities available for sale net		123,674
Other comprehensive (loss) income	(178,488)	273,733
Comprehensive (loss)	$ (5,305,369)	$ (6,191,796)

See accompanying notes to unaudited condensed consolidated financial statements

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IMMUNOMEDICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three Months Ended September 30,	
	2011	2010
	(unaudited)	
Cash flows from operating activities:		
Net (loss)	$ (5,126,881)	$ (6,465,529)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	367,552	405,704
Gain on insurance claim for equipment failure		(100,000)
Decrease in allowance for doubtful accounts	(2,258)	
Amortization of discounts of auction rate securities		(59,663)
Gain on sale of auction rate securities		(40,650)
Non-cash expense relating to issuance of stock options	417,140	426,477
Non-cash increase in value of life insurance policy	(9,500)	(14,009)
Amortization of deferred rent	75,282	26,644
Changes in other operating assets and liabilities	(1,801,983)	(1,433,973)
Other	(178,488)	150,059
Net cash used in operating activities	(6,259,136)	(7,104,940)
Cash flows from investing activities:		
Proceeds from sales of auction rate securities		957,000
Purchases of property and equipment	(193,032)	(312,055)
Proceeds from insurance claim for equipment failure		100,000
Net cash (used in) provided by investing activities	(193,032)	744,945
Cash flows from financing activities:		
Exercise of stock options, net	5,286	5,525
Net cash provided by financing activities	5,286	5,525
Net decrease in cash and cash equivalents	(6,446,882)	(6,354,470)
Cash and cash equivalents, beginning of period	27,097,610	29,533,230
Cash and cash equivalents, end of period	$ 20,650,728	$ 23,178,760

See accompanying notes to unaudited condensed consolidated financial statements.

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IMMUNOMEDICS, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED

FINANCIAL STATEMENTS

Reference is made to the Annual Report on Form 10-K of Immunomedics, Inc., a Delaware corporation (Immunomedics, the Company, we, our or us), for the fiscal year ended June 30, 2011, which contains our audited consolidated financial statements and the notes thereto.

1. Business Overview and Basis of Presentation

Immunomedics, Inc. is a biopharmaceutical company focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. The Company has continued to transition its focus away from the development and commercialization of diagnostic imaging products in order to accelerate the development of its therapeutic product candidates, although the Company manufactures and commercializes its LeukoScan® product in territories where regulatory approvals have previously been granted. LeukoScan is indicated for diagnostic imaging for determining the location and extent of infection/inflammation in bone in patients with suspected osteomyelitis, including patients with diabetic foot ulcers. The Company has two foreign subsidiaries, Immunomedics B.V. in the Netherlands and Immunomedics GmbH in Darmstadt, Germany, to assist the Company in managing sales efforts and coordinating clinical trials in Europe. In addition, included in the accompanying condensed financial statements is the majority-owned subsidiary, IBC Pharmaceuticals, Inc. (IBC), which has been working since 1999 on the development of novel cancer radiotherapeutics using patented pre-targeting technologies with proprietary, bispecific antibodies.

The accompanying unaudited condensed consolidated financial statements of Immunomedics, which incorporate our majority-owned subsidiaries, have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and the instructions to the Quarterly Report on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, the statements do not include all of the information and footnotes required by GAAP for complete annual financial statements. With respect to the financial information for the interim periods included in this Quarterly Report on Form 10-Q, which is unaudited, management believes that all adjustments (consisting of normal recurring accruals), considered necessary for a fair presentation of the results for such interim periods have been included. The balance sheet at June 30, 2011 has been derived from the Company s audited fiscal 2011 consolidated financial statements. Operating results for the three-month period ended September 30, 2011 are not necessarily indicative of the results that may be expected for the full fiscal year ending June 30, 2012, or any other period.

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

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

As of September 30, 2011, the Company has $20.7 million of cash and cash equivalents. Based on the Company s historical cash utilization rate, the Company believes it has sufficient funds to continue its operations and research and development programs for at least the next twelve months, after taking into consideration a significant reduction or delay of planned discretionary spending, if necessary, principally for the clinical trial programs.

Cash utilization of $6.4 million in the first quarter of fiscal 2012 is approximately $0.9 million lower than the previous year s level of activity after taking into consideration the $1.0 million of proceeds received from the sales of ARS in the previous year, which was no longer available during the current fiscal year. The rate of cash utilization for the three-month period ended September 30, has historically been higher than the expected annual cash burn rate due to the historical pattern of paying insurance renewals and certain employee incentive compensation during the first quarter of the fiscal year. The use of funds during the 2012 fiscal year is expected to be at a lower level than if one were to annualize the first quarter of 2012 usage and lower than in fiscal year 2011 if the reduced discretionary spending plan is implemented. If the Company is able to raise additional funds, of which there is no assurance, the Company s use of cash will increase over fiscal 2011 due primarily to higher amounts spent on clinical trial including the initiation of a Phase III registration trial of clivatuzumab in pancreatic cancer. The Company will need to secure additional funding over the second half of fiscal 2012, to advance its clinical trial programs including clivatuzumab into the Phase III trial.

The Company is pursuing partnering opportunities and other activities for its other product candidates, which could provide up-front and milestone payments, as well as funding of development costs and other licensing possibilities. In the event that the Company is unable to secure funding from partnering arrangements, it would seek to raise additional capital or pursue other strategic options. Since its inception in 1982, the Company s principal sources of funds have been the private and public sale of debt and equity securities and revenues from licensing agreements. There can be no assurance that Immunomedics will be able to raise the additional capital it will need on commercially acceptable terms, if at all. If the Company is unable to raise capital on acceptable terms, enter into new licensing agreements and successfully implement significant cost control programs, its ability to continue its business will be materially and adversely affected.

Over the long term, the Company does not believe, as currently funded, it will have adequate cash on hand to complete its pipeline of research and development programs in accordance with its corporate strategy.

2. Summary of Significant Accounting Policies

These unaudited condensed consolidated interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended June 30, 2011. The Company adheres to the same accounting policies in preparation of its interim financial statements.

Principles of Consolidation and Presentation

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

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Revenue Recognition

In October 2009, the Financial Accounting Standards Board, or (FASB), issued Accounting Standard Update, or (ASU), No. 2009-13, Multiple-Deliverable Revenue Arrangements, which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to the fair value with an allocation based on selling price. The Company applies ASU 2009-13 to its revenue arrangements containing multiple deliverables that are entered into. The Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or the Company s estimate of selling price when fair value is not available for a given unit of accounting. ASU 2009-13 was effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The adoption of this amendment did not have a material impact on its condensed consolidated financial statements. The Company concluded that the License and Collaboration Agreement with Nycomed GmbH, or the Nycomed Agreement, and the Development, Collaboration and License Agreement dated May 9, 2006 with UCB, S.A., or the UCB Agreement, are each accounted for as a single unit of accounting. Under the single unit of accounting method, for purposes of revenue recognition, the revenue is deferred and amortized over the obligation period.

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

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

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