InspireMD, Inc.
Form 10-Q
May 07, 2014

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: March 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: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

321 Columbus Avenue

Boston, MA 02116
(Address of principal executive offices)
(Zip Code)

(857) 453-6553
(Registrant's telephone number, including area code)

Indicate by check mark whether 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 x 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 that the registrant was required to submit and post such files). Yes x 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 "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x
(Do not check if a 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 x

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of May 6, 2014: 34,983,437**.**

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INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

March 31, 2014

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The amounts are stated in U.S. dollars

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INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,706	$ 17,535
Restricted cash	93	93
Accounts receivable:		
Trade	1,494	1,855
Other	465	387
Prepaid expenses	110	141
Inventory	1,343	1,593
Total current assets	17,211	21,604
PROPERTY, PLANT AND EQUIPMENT, net	624	652
NON-CURRENT ASSETS:		
Deferred issuance costs	293	310
Funds in respect of employees rights upon retirement	455	434
Long term prepaid expenses	85	114
Royalties buyout	837	852
Total other non-current assets	1,670	1,710
Total assets	$ 19,505	$ 23,966

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2014	December 31, 2013
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 1,405	$ 1,623
Other	3,814	3,141
Advanced payment from customers	190	179
Current maturity of loan	2,099	1,181
Total current liabilities	7,508	6,124
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	636	610
Long term loan	7,748	8,593
Total long-term liabilities	8,384	9,203
COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)		
Total liabilities	15,892	15,327
EQUITY :		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 34,054,060 and 33,983,346 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	3	3
Additional paid-in capital	91,894	90,952
Accumulated deficit	(88,284)	(82,316)
Total equity	3,613	8,639
Total liabilities and equity	$ 19,505	$ 23,966

The accompanying notes are an integral part of the condensed consolidated financial statements.

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INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(U.S. dollars in thousands, except share and per share data)

	Three months ended March 31,	
	2014	2013
REVENUES	$1,482	$1,514
COST OF REVENUES	625	674
GROSS PROFIT	857	840
OPERATING EXPENSES:		
Research and development	2,577	907
Selling and marketing	1,276	804
General and administrative (including $861 and $1,201 of share-based compensation for the three months ended March 31, 2014 and 2013, respectively)	2,539	2,340
Total operating expenses	6,392	4,051
LOSS FROM OPERATIONS	(5,535)	(3,211)
FINANCIAL EXPENSES, net:		
Interest expense	352	1,276
Other financial expenses	61	416
Total financial expenses	413	1,692
LOSS BEFORE INCOME TAXES	(5,948)	(4,903)
TAX EXPENSES (INCOME)	20	(18)
NET LOSS	(5,968)	$(4,885)
NET LOSS PER SHARE - basic and diluted	$(0.18)	$(0.27)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	34,051,703	18,196,083

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(U.S. dollars in thousands)

	Three months ended March 31,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,968)	$ (4,885)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	56	51
Change in liability for employees right upon retirement	26	44
Financial expenses	93	1,466
Share-based compensation expenses	1,019	1,299
Changes in operating asset and liability items:		
Decrease in prepaid expenses	60	3
Decrease (increase) in trade receivables	361	(873)
Increase in other receivables	(78)	(66)
Decrease in inventory on consignment		20
Decrease (increase) in inventory on hand	250	(5)
Decrease in trade payables	(218)	(125)
Increase in other payables and advance payment from customers	690	254
Net cash used in operating activities	(3,709)	(2,817)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(13)	(31)
Decrease in restricted cash		2
Amounts funded in respect of employee rights upon retirement, net	(21)	(45)
Net cash used in investing activities	(34)	(74)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(77)	(20)
Net cash used by financing activities	(77)	(20)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(9)	(8)
DECREASE IN CASH AND CASH EQUIVALENTS	(3,829)	(2,919)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	17,535	5,433
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 13,706	$ 2,514

The accompanying notes are an integral part of the condensed consolidated financial statements.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

InspireMD, Inc., a Delaware corporation (the “Company”), together with its subsidiaries, is a medical device company focused on the development and commercialization of its proprietary stent platform technology, MGuard™. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. The Company’s initial products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). The Company markets its products through distributors in international markets, mainly in Europe, Latin America and the Middle East, and through direct sales to hospitals in Europe.

The Company has an accumulated deficit of $88.3 million as of March 31, 2014, as well as net losses and negative operating cash flows in recent years as well as in the current quarter. The Company expects to continue incurring losses and negative cash flows from operations until its MGuard™ products reach commercial profitability. Based on managements' most recent forecasts, it does not anticipate that the Company will have sufficient resources to fund operations into the third quarter of 2015. Therefore, there is substantial doubt about the Company’s ability to continue as a going concern.

Management’s plans include the continued commercialization of the MGuard™ products and raising capital through the sale of additional equity securities or debt, including through the Company’s “At-the-Market” equity program. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its MGuard™ products and raising capital, it may need to reduce activities or curtail or, in the extreme case, cease operations.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

On April 30, 2014, the Company initiated a voluntary field corrective action of our MGuard Prime EPS. See Note 12.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the six month period ended December 31, 2013, as found in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission on February 26, 2014. The balance sheet for December 31, 2013 was derived from the Company's audited financial statements for the six month period ended December 31, 2013. The results of operations for the three months ended March 31, 2014 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3- EQUITY:

a. During the three months ended March 31, 2014, the Company granted stock options to employees and directors to purchase a total of 1,286,932 shares of the Company's common stock. The options have exercise prices ranging from $2.97-$3.23 per share, which were the fair market value of the Company's common stock on the date of each respective grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 66.8%-67.9%; and risk-free interest rate of 1.64%-2.01%.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $2.4 million.

b. During the three months ended March 31, 2014, the Company granted a total of 445,240 restricted shares of the Company's common stock to employees. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately $1.4 million.

NOTE 4- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, convertible loans and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, convertible loans and restricted stock excluded from the calculations of diluted loss per share were 9,984,674 and 8,512,041 for the three month periods ended March 31, 2014 and 2013, respectively.

NOTE 5 - FAIR VALUE MEASURMENT:

Financial Assets and Liabilities Not Measured Using Fair Value Method

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. As of March 31, 2014, the carrying amount of cash and cash equivalents, accounts receivable, other current assets and accounts payables and accrued expenses approximated their fair values due to the short-term maturities of these instruments. The fair value of the loan received on October 23, 2013 (the "Loan") approximated its carrying amount.

NOTE 6 - INVENTORY:

	March 31, 2014	December 31, 2013
	($ in thousands)	
Finished goods	$ 882	$ 1,097
Work in process	336	341
Raw materials and supplies	125	155
	$ 1,343	$ 1,593

As of March 31, 2014 and December 31, 2013, the Company had provisions for slow moving inventory of approximately $455,000 and $418,000, respectively.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2014	December 31, 2013
	($ in thousands)	
Employees and employee institutions	$985	$ 1,133
Accrued vacation and recreation pay	432	325
Accrued clinical trial expenses	1,487	622
Accrued expenses	727	886
Provision for sales commissions	133	139
Other	50	36
	$3,814	$ 3,141

NOTE 8 - FINANCIAL EXPENSES, NET:

	Three months ended March 31,	
	2014	2013
	($ in thousands)	
Bank commissions	$ 10	$ 6
Interest income		(7)
Exchange rate differences	40	6
Interest expense (including debt issuance costs)	352	1,276
Change in fair value of warrants, embedded derivatives and other	(6)	411
Other	17	
	$ 413	$ 1,692

NOTE 9 - RELATED PARTIES:

During the three month period ended March 31, 2014, the Company's chief executive officer was granted options to purchase 399,675 shares of common stock at exercise prices ranging from $2.97-$3.10 per share, as well as 182,725 shares of restricted stock. See Note 3.

During the three month period ended March 31, 2014, directors of the Company were granted options to purchase an aggregate of 335,000 shares of common stock at an exercise price of $3.10 per share. See Note 3a.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Litigation

In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company's former chief executive officer and president for a declaratory and enforcement order that this purported assignee is entitled to options to purchase 83,637 shares of the Company's commons stock at an exercise price of $0.76 per share. After considering the views of its legal counsel as well as other factors, the Company's management believes that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of $193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of $250,000 in the financial statements for the quarter ended December 31, 2012. The Company's management estimates that the ultimate resolution of this matter could result in a possible loss of up to $80,000 in excess of the amount accrued.

b. Liens and pledges

1) The Company's obligations under the Loan (as defined in Note 5) were secured by Israeli security agreements and deposit account control agreements on all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd.

2) As of March 31, 2014, the Company had fixed liens aggregating $93,000 to Bank Mizrahi in connection with the Company's credit cards.

NOTE 11 - ENTITY WIDE DISCLOSURE:

The Company operates in one operating segment.

Disaggregated financial data is provided below as follows:

(1) Revenues by geographic area and

(2) Revenues from principal customers.

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues by geographic areas:

	Three months ended March 31,	
	2014	2013
	($ in thousands)	
Middle East	$ 624	$ 108
Spain	201	157
Russia	3	435
Other	654	814
	$ 1,482	$ 1,514

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The following is a summary of revenues by principal customers:

	Three months ended March 31,			
	2014		2013	
Customer A	40	%	0	%
Customer B	14	%	10	%
Customer C	0	%	29	%

All tangible long-lived assets are located in Israel.

NOTE 12 - SUBSEQUENT EVENTS:

On April 30, 2014, the Company initiated a voluntary field corrective action (“VFA”) of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements. To date, there have been no reports of any patients being harmed in these recent reports reviewed by the Company. The Company believ es that it has identified the root cause of these dislodgements and, upon approval from the European regulatory agency, intends to modify all existing units of the MGuard Prime EPS in order to improve stent retention and performance. The Company began notifying its clinical and commercial partners worldwide of its VFA and intends to modify all units in the field once regulatory approval is received. The VFA will have a short term impact on both the commercial and clinical activities relating to the MGuard Prime EPS. The Company anticipates regulatory review to be completed by the end of the current, second quarter and would then commence shipping MGuard Prime EPS back into the marketplace.

The expense associated with the VFA, which the Company expects to incur primarily during the second quarter of 2014, is currently estimated to be between $200,000 and $300,000.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Form 10-Q to the "Company," "InspireMD," "we," "our" and "us" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "p "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- disputes over ownership of intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that the MGuard™ technology is an attractive alternative to other procedures and products;

- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;

- entry of new competitors and products and potential technological obsolescence of our products;

- loss of a key customer or supplier;

- technical problems with our research and products and potential product liability claims;

- adverse economic conditions;

- adverse federal, state and local government regulation, in the United States, Europe, Asia or Israel;

- price increases for supplies and components;

- inability to carry out research, development and commercialization plans; and

- loss or retirement of key executives and research scientists.

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For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Transition Report on Form 10-KT for the six month period ended December 31, 2013, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Overview

We are a medical device company focused on the development and commercialization of our proprietary stent platform technology, MGuard. MGuard provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

We effectuated a one-for-four reverse stock split of our common stock on December 21, 2012. Our authorized shares of common stock were not adjusted as a result of this reverse stock split. All share and related option and warrant information presented in the following discussion and analysis of our financial condition and results of operations and the accompanying consolidated interim financial statements have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

Recent Events

On April 30, 2014, we publicly announced our decision to initiate a voluntary field corrective action or product recall with respect to our MGuard Prime embolic protection systems to address reports of stent dislodgement. In connection with such action, we have ceased shipments of all MGuard Prime units and suspended enrollment in our MASTER II trial pending a review by the U.S. Food and Drug Administration and other regulatory agencies. We believe that we have identified the cause of the dislodgement issue and, upon approval from the European regulatory agency, intend to modify all existing units of the MGuard Prime to improve stent retention and performance. Our voluntary recall and field corrective action is subject to numerous risks and uncertainties as discussed more fully in the section entitled "Risk Factors."

Critical Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) the Management's Discussion and Analysis of Financial Condition and Results of Operations section and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in our Transition Report on Form 10-KT for the six month period ended December 31, 2013. There have not been any material changes to such critical accounting policies since December 31, 2013.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ("$" or "dollar"). Accordingly, our currency is the dollar.

Results of Operations

Three months ended March 31, 2014 compared to the three months ended March 31, 2013

Revenues. For the three months ended March 31, 2014, revenue decreased by $32,000, or 2.2%, to $1.5 million from $1.5 million during the same period in 2013. This decrease was driven by a decrease in sales volume of $16,000, or 1.1%, with price decreases to our repeat distributors driving the remaining decrease of $16,000, or 1.1%.

With respect to regions, revenue from our distributors in the Middle East increased $0.5 million, which was offset by a decrease of $0.5 million in revenue from our distributors in Europe as we moved to direct sales channels in key European countries. Moving from distributor based sales to direct sales adversely impacted revenues for the three months ended March 31, 2014, as we did not either (i) sell material quantities of product to distributors in territories where we chose to transition to direct sales or (ii) begin material direct sales in those affected territories as the affected distributors already had inventory consigned to individual hospitals that must be consumed before direct sales can successfully commence. This transition can last two to three quarters or longer based on inventory levels. We believe that the move to direct sales activities, however, will prove to be successful in the long term, as it allows us to work directly with customers to better deliver clinical education and improve adoption of our technology. Direct sales should also translate into a higher gross margin, as it will allow us to benefit from end user versus transfer pricing in those select markets.

Gross Profit. For the three months ended March 31, 2014, gross profit (revenue less cost of revenues) increased 2.0%, or $17,000, to $0.9 million from $0.8 million during the same period in 2013. This increase in gross profit was attributable to a decrease in cost of revenues of $49,000. This increase in gross profit was partially offset by a decrease in revenue of $32,000, as described above. Gross margin (gross profits as a percentage of revenue) increased from 55.5% in the three months ended March 31, 2013 to 57.8% in same period in 2014 mostly as a result of the decrease in cost of revenues, as noted above. The cost of revenues for the three months ended March 31, 2014 included a write-off of slow moving inventory of $52,000. If the effects of the write-off of slow moving inventory in the three months ended March 31, 2014, are removed, gross margin for the three months ended March 31, 2014 would have been 61.3%.

Research and Development Expenses. For the three months ended March 31, 2014, research and development expenses increased 184.1%, or $1.7 million, to $2.6 million, from $0.9 million during the same period in 2013. This increase in research and development expenses resulted primarily from increases of $0.2 million in related salaries, $0.1 million in related travel expenses, $0.2 million in miscellaneous expenses and $1.4 million in clinical trial expenses associated with our MASTER II trial moving from the pre-clinical stage to the set-up and enrollment phases. This increase in research and development expenses, however, was partially offset by a decrease of $0.2 million in expenses associated with the conclusion of our MASTER I trial in 2013. Research and development expense as a percentage of revenue increased to 173.9% for the three months ended March 31, 2014, from 59.9% in the same period in 2013.

Selling and Marketing Expenses. For the three months ended March 31, 2014, selling and marketing expenses increased 58.7%, or $0.5 million, to $1.3 million, from $0.8 million during the same period in 2013. This increase in selling and marketing expenses resulted primarily from an increase of $0.3 million in salaries and an increase of $0.1 million in share based compensation, as we hired additional sales personnel in an effort to expand our sales activities

worldwide, an increase of $0.1 million in travel expenses for our increased sales force and an increase of $0.2 million in miscellaneous expenses. Much of these sales initiatives were driven by our efforts to capitalize on the publication of our MASTER I trial results, our first randomized data related to our MGuard technology, and efforts to support our new direct sales channels in key European countries. This increase in selling and marketing expenses, however, was partially offset by a decrease of $0.2 million in product promotion expenses. Selling and marketing expenses as a percentage of revenue increased to 86.1% in the three months ended March 31, 2014 from 53.1% in the same period in 2013.

General and Administrative Expenses. For the three months ended March 31, 2014, general and administrative expenses increased 8.5%, or $0.2 million, to $2.5 million from $2.3 million during the same period in 2013. The increase in general and administrative expenses resulted primarily from an increase of $0.1 million in salaries, an increase in director's compensation of $0.1 million, an increase in travel expense of $0.1 million and an increase in miscellaneous expenses of $0.2 million. This increase was partially offset by a decrease in share based compensation of $0.3 million. General and administrative expenses as a percentage of revenue increased to 171.3% in the three months ended March 31, 2014 from 154.6% in the same period in 2013.

Financial Expenses. For the three months ended March 31, 2014, financial expenses decreased 75.6%, or $1.3 million, to $0.4 million from $1.7 million during the same period in 2013. The decrease in financial expenses resulted from a decrease of $0.9 million of amortization and interest expenses. In the three months ended March 31, 2014, we recognized $0.4 million in amortization and interest expense, in contrast to the three months ended March 31, 2013, during which we recognized $1.3 million of amortization and interest expense pertaining to our previously outstanding senior convertible debentures and their related issuance costs (of which $1.0 million represented the non-cash amortization of the discount of the convertible debentures and their related issuance costs). In addition, we incurred $1.3 million of non-cash expense in the three months ended March 31, 2013 pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders and the non-cash revaluations of our warrants. No such expense occurred during the three months ended March 31, 2014. This decrease in expenses was partially offset by the absence of any non-cash revaluations of our warrants during the three months ended March 31, 2014. During the three months ended March 31, 2013, we recognized $0.9 million of financial income pertaining to the non-cash revaluation of certain of our warrants due to our stock price decreasing from $3.90 to $2.52 during such period. No such income was recognized during the three months ended March 31, 2014. Financial expense as a percentage of revenue decreased to 27.9% in the three months ended March 31, 2014, from 111.8% in the same period in 2013.

Tax Expenses. For the three months ended March 31, 2014, tax expenses increased $38,000 to $20,000 from $18,000 of tax income during the same period in 2013.

Net Loss. Our net loss increased by $1.1 million, or 22.2%, to $6.0 million for the three months ended March 31, 2014 from $4.9 million during the same period in 2013. The increase in net loss resulted primarily from an increase of $2.4 million in operating expenses primarily associated with research and development and sales and marketing expansion (see above for explanation), partially offset by a decrease of $1.3 million in financial expenses, of which $1.5 million were non-cash (see above for explanation). If the non-cash effects of the warrant revaluation, amortization expense and effects of the anti-dilution rights in the three months ended March 31, 2013 are removed our net loss would be $3.4 million for the three months ended March 31, 2013, as compared to a net loss of $6.0 million for the same period in 2014.

Liquidity and Capital Resources

We had an accumulated deficit of $88.3 million as of March 31, 2014, as well as net losses and negative operating cash flows in recent years and the current quarter. We expect to continue incurring losses and negative cash flows from operations until our MGuard products reach profitability. Based on our most recent forecasts, we do not anticipate having sufficient resources to fund operations into the third quarter of 2015. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued successful commercialization of the MGuard product and raising capital through the sale of additional equity securities or debt, including through our “At-the-Market” equity program. There are no assurances, however, that we will be successful in obtaining sufficient financing to fund our operations. If we are unsuccessful in commercializing our MGuard products to the level of profitability and raising capital, we may need to reduce activities or curtail or, in the extreme case, cease operations.

Three months ended March 31, 2014 compared to the three months ended March 31, 2013

General. At March 31, 2014, we had cash and cash equivalents of $13.7 million, as compared to $17.5 million as of December 31, 2013. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was $3.7 million for the three months ended March 31, 2014 and $2.8 million for the same period in 2012. The principal reason for the usage of cash in our operating activities for the three months ended March 31, 2014 was a net loss of $6.0 million, offset by $1.0 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, a decrease in working capital of $1.1 million, $0.1 million of non-cash financial expense, and $0.1 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the three months ended March 31, 2013 included a net loss of approximately $4.9 million and an increase in working capital of approximately $0.8 million, offset by approximately $1.3 million in non-cash share-based compensation, approximately $1.5 million in non-cash financial expenses and approximately $0.1 million in depreciation and amortization expenses.

Cash used in our investing activities was $34,000 during the three months ended March 31, 2014, compared to $74,000 during the same period in 2013. The principal reason for the decrease in cash used in investing activities during 2014 was the purchase of property, plant and equipment of $13,000, as compared to $31,000 in the same period in 2013, as well as the funding of employee retirement funds of $21,000 in the three months ended March 31, 2014, as compared to $45,000 in the same period in 2013.

Cash used by financing activities for the three months ended March 31, 2014 was $77,000, compared to $20,000 during the same period in 2013. The reason for the increase in cash used by financing activities during the three months ended March 31, 2014 related largely to payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by our chief executive officer.

As of March 31, 2014, our current assets exceeded our current liabilities by a multiple of 2.3. Current assets decreased $4.3 million during the period, mainly due to cash used in operations, and current liabilities increased by $1.4 million during the period. As a result, our working capital surplus decreased by $5.7 million to $9.7 million at March 31, 2014.

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

None.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of March 31, 2014, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of March 31, 2014.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended March 31, 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

Item 1A. Risk Factors

During the three months ended March 31, 2014, there were no material changes to the risk factors disclosed in our Transition Report on Form 10-KT for the six month period ended December 31, 2013, except for the following:

Risks Related to Our Business

We face several challenges in implementing a product recall or voluntary field corrective action for our MGuard Prime embolic protection systems ("MGuard Prime EPS") to address the issue of stent dislodgement, which could have a significant adverse impact on us.

In late April 2014, we initiated a voluntary field corrective action or recall of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. Our voluntary recall and field corrective action is subject to numerous risks and uncertainties, including the following:

- because we have limited experience designing and carrying out a field initiative or other corrective action plan of the magnitude under contemplation, we are likely to encounter challenges that could cause a delay in the implementation of the field initiative or negatively impact its effectiveness;

- our suspension of shipments will adversely impact revenue until we are able to upgrade the existing inventory of MGuard Prime EPS units and resume shipments in the market, both of which remain subject to the review and approval of the European regulatory agency;

- as a result of the voluntary recall, we have suspended enrollment in our MASTER II clinical trial pending a review by the U.S. Food and Drug Administration of the proposed manufacturing improvements to the MGuard Prime EPS, which could cause an increase in costs and delays or result in the failure of the clinical trial which would prevent us from entering the U.S. market;

- we are more susceptible to products liability claims and class action lawsuits as a result of the reported product malfunction and voluntary field action, which could significantly increase our costs and may have a material adverse effect on our business, financial condition and results of operations;

- the field initiative will likely divert managerial, financial and other resources and have an adverse effect on our financial condition and operating results, which could hinder our ability to carry out initiatives relating to new products or product enhancements; and

- our decision to recall and discontinue shipments may harm our reputation or the market’s perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events, such as the MGuard Prime EPS stent dislodgements, have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

The following table sets forth information with respect to purchases by us of our equity securities during the three months ended March 31, 2014:

Issuer's Purchases of Equity Securities

Period	**Total number of shares (or units) purchased[1]**	**Average price paid per share (or unit)[1]**	Total number of shares (or units) purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
1/1/2014 to 1/31/2014	29,286	$ 2.63	—	—
2/1/2014 to 2/28/2014	—	—	—	—
3/1/2014 to 3/31/2014	—	—	—	—
Total	29,286	$ 2.63	—	—

(1) Includes 29,286 shares of our common stock surrendered by Alan Milinazzo in order to satisfy tax withholding obligations in connection with the vesting of restricted stock on January 3, 2014. For purposes of determining the number of shares to be surrendered by Mr. Milinazzo to meet tax withholding obligations, the price per share deemed to be paid was the closing price of our common stock on the NASDAQ Capital Market on the applicable vesting date.

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Item 5. Other Information.

Amended and Restated Employment Agreement with Craig Shore

On May 5, 2014, we entered into an amended and restated employment agreement with Craig Shore, our chief financial officer and chief administrative officer, pursuant to which that certain employment agreement dated November 24, 2010 by and between Mr. Shore and InspireMD Ltd., our wholly owned subsidiary, was amended and restated in its entirety. The employment agreement has an initial term that ends on April 20, 2017 and will automatically renew for additional one-year periods on April 21, 2017 and on each April 21st thereafter unless either party gives the other party written notice of its election not to extend such employment at least six months prior to the next April 21st renewal date. If a change in control occurs when less than two full years remain in the initial term or during any renewal term, the employment agreement will automatically be extended for two years from the change in control date and will terminate on the second anniversary of the change in control date.

Under the terms of the employment agreement, Mr. Shore is entitled to an annual base salary of at least $220,000, retroactive to January 1, 2014. Such amount may be reduced only as part of an overall cost reduction program that affects all of our senior executives and does not disproportionately affect Mr. Shore, so long as such reduction does not reduce the base salary to a rate that is less than 90% of the amount set forth above (or 90% of the amount to which it has been increased). The base salary will be reviewed annually by our chief executive officer for increase as part of our annual compensation review. Mr. Shore is also eligible to receive an annual bonus in an amount equal to 45% of his then-annual salary upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with Mr. Shore and based on the percentages set forth in his employment agreement. In addition, Mr. Shore is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion. Mr. Shore will also be considered for grants of equity awards each year as part of the board's annual compensation review, which will be made at the sole discretion of the board of directors. Each grant will, with respect to any awards that are options, have an exercise price equal to the fair market value of our common stock, and will be subject to a three-year vesting period subject to Mr. Shore's continued service with us, with one-third of each additional grant vesting equally on the first, second, and third anniversary of the date of grant for such awards.

The employment agreement also contains certain standard noncompetition, no solicitation, confidentiality, and assignment of inventions requirements for Mr. Shore.

If during the term of the employment agreement, Mr. Shore's employment is terminated upon his death or disability or by us without cause (as such term is defined in Mr. Shore's employment agreement), Mr. Shore will be entitled to receive, in addition to any other unpaid amounts owed to him under the manager's insurance policy: (i) any unpaid base salary and accrued unpaid vacation or earned incentive compensation plus the pro rata amount of any bonus for the fiscal year of such termination (based on the number of business days he was actually employed by us during the

fiscal year of such termination and based on the percentage of the goals that he actually achieved under the bonus plan) that he would have received had his employment not been terminated; (ii) a one-time lump sum severance payment equal to 100% of his base salary, provided that he executes a release relating to employment matters and the circumstances surrounding his termination in favor of us, our subsidiaries and our officers, directors and related parties and agents, in a form reasonably acceptable to us at the time of such termination; (iii) vesting of 50% of all unvested stock options granted to Mr. Shore; (iv) an extension of the exercise period of all vested stock options granted to Mr. Shore until the earlier of (a) two years from the date of termination or (b) the latest date that each stock option would otherwise expire by its original terms; (v) to the fullest extent permitted by our then-current benefit plans, continuation of health, dental, vision and life insurance coverage for the lesser of 12 months after termination or until Mr. Shore obtains coverage from a new employer; and (vi) reimbursement of up to $30,000 for executive outplacement services, subject to certain restrictions. The payments described above will be reduced by any payments received by Mr. Shore pursuant to any of our employee welfare benefit plans providing for payments in the event of death or disability. If, during or after the term of his employment agreement, Mr. Shore’s employment is terminated by us for cause or by Mr. Shore voluntarily, Mr. Shore will only be entitled to unpaid amounts owed to him (e.g., for base salary, accrued vacation and incentive vacation earned through the date of such termination) and whatever rights, if any, are available to him pursuant to our stock-based compensation plan or any award documents related to any stock-based compensation.

Mr. Shore has no specific right to terminate the employment agreement or right to any severance payments or other benefits solely as a result of a change in control. However, if within 24 months following a change in control, (a) Mr. Shore terminates his employment for good reason, or (b) we terminate Mr. Shore's employment without cause, he is entitled to receive the full lump sum severance payment equal to 100% of his base salary and all stock options, stock appreciation rights or similar stock-based rights granted to him will vest in full and be immediately exercisable and any risk of forfeiture included in restricted or other stock grants previously made to him will immediately lapse.

Mr. Shore is also entitled to participate in or receive benefits under our social insurance and benefits plans, including but not limited to our manager's insurance policy and education fund, which are customary benefits provided to executive employees in Israel. A management insurance policy is a combination of severance savings (in accordance with Israeli law), defined contribution tax-qualified pension savings and disability pension payments. An education fund is a savings fund of pre-tax contributions to be used after a specified period of time for advanced educational training and other permitted purposes, as set forth in the by-laws of the education fund. We will make periodic contributions to these insurance and social benefits plans based on certain percentages of Mr. Shore's base salary, including (i) 7.5% to the education fund and (ii) 15.83% to the manager's insurance policy, of which 8.33% will be allocated to severance pay, 5% to pension fund payments and 2.5% to disability pension payments. Upon the termination of Mr. Shore's employment for any reason other than for cause, Mr. Shore will be entitled to receive the total amount contributed to and accumulated in his manager insurance policy fund.

Item 6. Exhibits

See Index to Exhibits.

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.

INSPIREMD, INC.

Date: May 7, 2014 By: /s/ Alan Milinazzo
Name: Alan Milinazzo
Title: President and Chief Executive Officer

Date: May 7, 2014 By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer, Secretary and Treasurer

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EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2012)
3.4	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.1	Consulting Agreement, dated February 25, 2014, by and between InspireMD, Inc. and James Barry (incorporated by reference to Exhibit 10.55 to Transition Report on Form 10-KT filed with the Securities and Exchange Commission on February 26, 2014)
10.2*	Amended and Restated Employment Agreement, dated May 5, 2014, by and between InspireMD, Inc. and Craig Shore.
10.3*	First Amendment to the InspireMD, Inc. Amended and Restated 2011 UMBRELLA Option Plan.
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

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* Filed herewith.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.