

InspireMD, Inc.
Form 10-Q
May 11, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 2015

OR

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

For the transition period from to

Commission file number: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware **26-2123838**
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) 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 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 during the preceding 12 months (or for such shorter period that 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 “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

(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

The number of shares of the registrant’s common stock, \$0.0001 par value, outstanding as of May 11, 2015: 77,995,335.

TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. <u>Financial Statements</u>	
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	3
Item 3. <u>Qualitative and Quantitative Disclosures About Market Risk</u>	7
Item 4. <u>Controls and Procedures</u>	7
<u>PART II</u>	
Item 1. <u>Legal Proceedings</u>	8
Item 1A. <u>Risk Factors</u>	8
Item 5. <u>Other Information</u>	8
Item 6. <u>Exhibits</u>	8

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

March 31, 2015

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

March 31, 2015

TABLE OF CONTENTS

	Page
INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:	
<u>Condensed Consolidated Balance Sheets</u>	F-2 - F-3
<u>Condensed Consolidated Statements of Operations</u>	F-4
<u>Condensed Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to the Condensed Consolidated Financial Statements</u>	F-6 - F-11

The amounts are stated in U.S. dollars

INSPIREMD, INC.**CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,186	\$ 6,300
Accounts receivable:		
Trade	719	635
Other	278	359
Prepaid expenses	109	150
Inventory	1,750	1,924
Total current assets	16,042	9,368
NON-CURRENT ASSETS:		
Property, plant and equipment, net	584	622
Deferred issuance costs	136	153
Funds in respect of employees rights upon retirement	504	498
Long-term prepaid expenses	58	66
Royalties buyout	400	752
Total non-current assets	1,682	2,091
Total assets	\$ 17,724	\$ 11,459

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, 2015	December 31, 2014
LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 665	\$ 909
Other	2,766	3,576
Advanced payment from customers	162	179
Current maturity of loan	3,909	3,809
Total current liabilities	7,502	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	699	687
Long-term loan	4,138	5,086
Total long-term liabilities	4,837	5,773
COMMITMENTS AND CONTINGENT LIABILITIES (Note 11)		
Total liabilities	12,339	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 75,940,566 and 41,368,889 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	118,001	104,620
Accumulated deficit	(112,623)	(107,411)
Total equity (capital deficiency)	5,385	(2,787)
Total liabilities and equity (net of capital deficiency)	\$ 17,724	\$ 11,459

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

INSPIREMD, INC.**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

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

	Three months ended March 31,	
	2015	2014
REVENUES	\$477	\$1,482
COST OF REVENUES	514	625
GROSS PROFIT (LOSS)	(37) 857
OPERATING EXPENSES:		
Research and development	1,352	2,577
Selling and marketing	1,017	1,276
General and administrative	1,970	2,539
Restructuring and impairment expenses	514	-
Total operating expenses	4,853	6,392
LOSS FROM OPERATIONS	(4,890) (5,535
FINANCIAL EXPENSES, net:		
Interest expense	301	352
Other financial expenses	5	61
Total financial expenses	306	413
LOSS BEFORE INCOME TAXES	(5,196) (5,948
TAX EXPENSES	16	20
NET LOSS	\$(5,212) \$(5,968
NET LOSS PER SHARE - basic and diluted	\$(0.10) \$(0.18
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	49,915,187	34,051,703

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

F-4

INSPIREMD, INC.**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Unaudited)

(U.S. dollars in thousands)

	Three months ended March 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(5,212)	\$(5,968)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	75	56
Impairment of royalties buyout	316	
Change in liability for employees right upon retirement	12	26
Financial expenses	102	93
Share-based compensation expenses	1,029	1,019
Loss on amounts funded in respect of employee rights upon retirement, net	4	
Changes in operating asset and liability items:		
Decrease in prepaid expenses	49	60
Decrease (increase) in trade receivables	(84)	361
Decrease (increase) in other receivables	81	(78)
Decrease in inventory	174	250
Decrease in trade payables	(244)	(218)
Increase (decrease) in other payables and advance payment from customers	(924)	690
Net cash used in operating activities	(4,622)	(3,709)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1)	(13)
Amounts funded in respect of employee rights upon retirement, net	(10)	(21)
Net cash used in investing activities	(11)	(34)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(78)	(77)
Proceeds from issuance of shares and warrants, net of \$1,315 issuance costs	12,529	
Repayment of long-term loan	(891)	
Net cash provided by (used in) financing activities	11,560	(77)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(41)	(9)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	6,886	(3,829)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	6,300	17,535
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$ 13,186	\$ 13,706

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

F-5

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the “Company”), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. The Company’s coronary products combining MicroNet and a bare-metal stent (MGuard Prime™ EPS) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). In October 2014, the Company launched a limited market release of its carotid embolic prevention system (CGuard™ EPS), which combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease, using an over-the-wire delivery system. In January 2015, the Company received CE mark approval for the rapid exchange delivery system and fully launched CGuard in countries in Europe. The Company markets its products through distributors in international markets, mainly in Europe, Southeast Asia, India, Latin America and Israel.

b. Liquidity

The Company has an accumulated deficit as of March 31, 2015, as well as net losses and negative operating cash flows in recent years and the current year. The Company expects to continue incurring losses and negative cash flows from operations. Management of the Company presently anticipates that it has sufficient resources to fund its operations for at least the next twelve months. During the next twelve months management expects that the Company will need to raise additional capital to finance its losses and negative cash flows from operations beyond the next twelve months and may continue to be dependent on additional capital raising as long as its products do not reach commercial profitability.

Management’s plans include the continued commercialization of the MGuard™ and CGuard™ products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. 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™ or CGuard™ products and raising capital, it may need to reduce activities, curtail or cease operations.

During the fourth quarter of 2014, the Company began implementing a focused spending plan. The plan included reducing the focus of clinical and development expenses related to the Company's bare metal stent product and increasing the focus on the Company's drug eluting stent product. Prior to the fourth quarter of 2014, a large portion of the Company's organization was supporting the MASTER II trial, in which the Company determined not to resume enrollment, and instead allocated resources to drug eluting stents and the CGuard platform.

During the first quarter of 2015, the board of directors approved to cease developing and promoting our bare metal stent platform and implementing another cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to only those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, etc.). Prior to the cost reduction plan, a large portion of the Company's organization supported clinical trials and promotional activities related to the Company's bare metal stent platform. In light of the above noted change in focus, many positions related to the development and promotion of the Company's bare metal stent platform have since been eliminated. The Company will invest in a next generation MGuard EPS drug eluting platform only upon entering into a strategic partnership.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

c. Fundraising

On March 9, 2015, the Company sold 34,369,675 shares of its common stock and warrants to purchase 34,369,675 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of exercise of 5 years from the date of issuance and an exercise price of \$0.55. This offering resulted in net proceeds to the Company of approximately \$12.5 million after deducting placement agent fees and other offering expenses. See Note 4c.

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 year ended December 31, 2014, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 12, 2015. The balance sheet for December 31, 2014 was derived from the Company's audited financial statements for the twelve months ended December 31, 2014. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 – RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In April, 2015, the Financial Accounting Standards Board ("FASB") issued guidance related to the presentation of Debt Issuance Costs. The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

NOTE 4 - EQUITY:

During the three months ended March 31, 2015, the Company granted stock options to employees and directors to purchase a total of 1,492,525 shares of the Company's common stock. The options have exercise prices ranging from a.\$0.32 to \$0.83 per share, which were the fair market value of the Company's common stock on the date of each respective grant. Of the 1,492,525 options described above, 425,059 options are fully vested as of their grant date. The remaining 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%; expected term of 5-6.5 years; expected volatility of 62.68%-67.84%; and risk-free interest rate of 1.41%-1.71%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$0.58 million.

During the three months ended March 31, 2015, the Company granted a total of 1,512,409 restricted shares of the Company's common stock to employees. Of the 1,512,409 restricted shares described above, 502,604 restricted b. shares are subject to a one-year vesting period, 92,500 restricted shares are fully vested as of their grant date and are subject to a 6 month lock up period and 917,305 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The fair value of the above restricted shares was approximately \$1.1 million.

On March 9, 2015, the Company sold 34,369,675 shares of its common stock and warrants to purchase 34,369,675 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants, which are classified^c as equity, have a term of exercise of 5 years from the date of issuance and an exercise price of \$0.55. This offering resulted in net proceeds to the Company of approximately \$12.5 million after deducting placement agent fees and other offering expenses.

NOTE 5- 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 50,411,102 and 9,984,674 for the three month periods ended March 31, 2015 and 2014, respectively.

NOTE 6 - FAIR VALUE MEASUREMENT:

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, 2015, 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. The fair value of the loan received on October 23, 2013 (the "Loan") approximated its carrying amount since it bears interest at rates that approximate current market rates.

NOTE 7 - INVENTORY:

	March 31, 2015	December 31, 2014
	(\$ in thousands)	
Finished goods	\$965	\$ 1,273
Work in process	493	326
Raw materials and supplies	292	325
	\$1,750	\$ 1,924

F-8

INSPIREMD, INC.**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

(UNAUDITED)

NOTE 8- IMPAIRMENT OF ROYALTIES BUYOUT

During the period ended March 31, 2015 the Company recorded expenses related to the impairment of our royalties buyout asset amounting to \$316,000 due to anticipated lower sales of MGuard Prime in the future resulting from industry preferences for drug eluting stents. The expense is recorded under “Restructuring and impairment expenses” in the consolidated statements of operations.

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2015	December 31, 2014
	(\$ in thousands)	
Employees and employee institutions	\$ 608	\$ 1,022
Accrued vacation and recreation pay	395	410
Accrued clinical trial expenses	691	1,016
Accrued expenses	958	993
Provision for sales commissions	94	120
Taxes payable	20	15
	\$2,766	\$ 3,576

F-9

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 10 - RELATED PARTIES:

During the three month period ended March 31, 2015, the Company's chief executive officer was granted options to purchase 307,736 shares of common stock at an exercise price of \$0.72 per share, as well as 517,583 shares of a. restricted stock. Of the 517,583 shares of restricted stock, 312,500 were in lieu of salary as part of his amendment for his base salary to be paid 50% in cash payments with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock. See Note 4.

During the three month period ended March 31, 2015, directors of the Company were granted options to purchase b. an aggregate of 733,012 shares of common stock at exercise prices ranging from \$0.32-\$0.78, of which, 425,059 were in lieu of cash compensation that was owed to them for their services as directors for the third and fourth quarters of 2014 and the first quarter of 2015. See Note 4a.

NOTE 11 - 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 CEO and President for a declaratory and enforcement order that it is entitled to options to purchase 83,637 shares of the Company's common stock at an exercise price of \$0.76 per share. In December 2014 the court accepted a motion to dismiss the former CEO and president from the lawsuit. 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. In March 2015, the interest rate made by the Court of Appeal in Argentina was increased retroactively, which resulted in the provision increasing to \$340,000. The related expense for the increase of \$90,000 was recorded to "General and administrative" within the Consolidated Statements of

Operations. The Company's management estimates that the ultimate resolution of this matter could reasonably result in a loss of up to \$110,000 in excess of the amount accrued.

b. Liens and pledges

The Company's obligations under the Loan (as defined in Note 6) 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.

F-10

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 12 - 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,	
	2015	2014
	(\$ in thousands)	
Germany	\$ 131	66
Belarus	78	32
Spain	45	201
Middle East	36	624
Other	187	559
	\$ 477	\$ 1,482

The following is a summary of revenues by principal customers:

	Three months ended			
	March 31,			
	2015		2014	
Customer A	21	%		
Customer B	16	%	2	%
Customer C	9	%	14	%
Customer D			40	%

All tangible long-lived assets are located in Israel.

F-11

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," "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 management's 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;

- market acceptance of our existing and new products;

- negative clinical trial results or lengthy product delays in key markets;

- an inability to secure and maintain regulatory approvals for the sale of our products;

- our dependence on single suppliers for certain product components and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

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;
- our limited manufacturing capabilities and reliance on subcontractors for assistance;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third party payers for our products;

our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;

- legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions;

the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain;

the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;

- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and

- loss or retirement of key executives and research scientists.

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 Annual Report on Form 10-K for the twelve month period ended December 31, 2014, 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 focusing on the development and commercialization of our proprietary MicroNet stent platform technology for the treatment of complex coronary and vascular disease. A stent is an expandable “scaffold-like” device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. Our initial MGuard coronary products (MGuard and MGuard Prime Embolic Protection Stent (EPS)) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

In October 2014, we launched a limited market release of our second product, CGuard carotid embolic prevention system (“EPS”) in certain European countries. CGuard EPS combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease. In January 2015, we received CE mark approval for the rapid exchange delivery system and fully launched CGuard in countries in Europe.

We are also developing a pipeline of other products and additional applications by leveraging our MicroNet technology, including a coronary stent product incorporating drug-eluting (drug-coated) stents with MicroNet, and new products to improve peripheral and neurovascular procedures.

Presently, none of our products may be sold or marketed in the U.S.

Recent Events

During the first quarter of 2015, we decided to cease developing and promoting our bare metal stent platform and implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) continuing to limit the focus of clinical and development expenses to only the drug eluting stent product, which was begun during the fourth quarter of 2014; (iii) limiting sales and marketing expenses to only those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, etc.). Prior to implementing these measures, a large portion of our organization supported clinical trials and promotional activities related to our bare metal stent platform. In light of the above noted change in focus, many positions related to the development and promotion of our bare metal stent platform have since been eliminated. In addition, we have since reduced all expenses not directly related to the CGuard launch and drug eluting platform development.

On March 9, 2015, we sold 34,369,675 shares of our common stock and warrants to purchase 34,369,675 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of years and an exercise price of \$0.55 per share. This offering resulted in net proceeds to us of approximately \$12.5 million after deducting placement agent fees and other offering expenses.

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) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2014. There have not been any material changes to such critical accounting policies since December 31, 2014.

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, 2015 compared to the three months ended March 31, 2014

Revenues. For the three months ended March 31, 2015, revenue decreased by \$1.0 million, or 67.8%, to \$0.5 million from \$1.5 million during the same period in 2014. This decrease was predominately driven by a decrease in sales volume of \$0.9 million, or 60.7%, due to the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients and the impact of the transition to a new commercial strategy from a direct sales model to one focused on third party distributors. Price decreases drove the remaining decrease of \$0.1 million, or 7.1% due to lower average sales prices received from distributor sales rather than direct sales to hospitals, as well as the effects of the weakening of the Euro against the U.S dollar.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of \$0.6 million in revenue from our distributors in the Middle East, \$0.3 million in revenue from our distributors in Europe and \$0.1 million in revenue from our distributors in the rest of the world.

Gross Profit (Loss). For the three months ended March 31, 2015, we had a gross loss (revenue less cost of revenues) of \$37,000, as compared to a gross profit of \$0.9 million during the same period in 2014, representing a decrease of 104.3% or \$0.9 million. This decrease in gross profit was attributable to a decrease in revenues of \$1.0 million (see above for explanation) and an increase of write-offs of inventory of \$0.2 million, of which, \$0.1 million related to the write-offs of MGuard units due to expected lower sales in the future resulting from industry preferences for DES

stents (as mentioned above), and our transition to a third party distributor commercial strategy (as mentioned above), as well as \$0.1 million in write-offs of CGuard resulting from us transitioning to an RX delivery system from an over the wire platform, partially offset by a decrease in labor and material costs of \$0.3 million attributable to lower revenues. Gross margin (gross profits as a percentage of revenue) decreased from 57.8% in the three months ended March 31, 2014 to (7.8)% in the same period in 2015. The decrease in gross margin of 65.8% was driven mainly due to the write-offs of inventory (see above for explanation), the change in product mix, including CGuard, which has higher material and labor costs than MGuard and a lower average sales price of MGuard due to the new commercial strategy built on using third party distributors.

Research and Development Expenses. For the three months ended March 31, 2015 research and development expenses decreased by 47.5%, or \$1.2 million, to \$1.4 million from \$2.6 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of \$1.4 million in clinical trial expenses associated with our MASTER II trial as part of our cost reduction/focused spending plan and a decrease of \$0.2 million in miscellaneous expenses partially offset by an increase of \$0.2 million in clinical trial and development expenses associated with our CGuard EPS product, an increase of \$0.1 million of clinical trial and development expenses associated with our drug eluting stent product and an increase of \$0.1 million in employee compensation, primarily related to the hiring of our chief operating officer. Research and development expenses as a percentage of revenue increased to 283.4% for the three months ended March 31, 2015, from 173.9% in the same period in 2014.

Selling and Marketing Expenses. For the three months ended March 31, 2015, selling and marketing expenses decreased by 20.3%, or \$0.3 million, to \$1.0 million, from \$1.3 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of \$0.1 million in salaries and a decrease of \$0.1 million in share-based compensation as we realigned to a new commercial strategy built on using third party distributors for our products resulting in a reduced sales force and a decrease of \$0.1 million in travel expenses associated with the decreased size of our sales force. Selling and marketing expenses as a percentage of revenue increased to 213.2% in the three months ended March 31, 2015 from 86.1% in the same period in 2014.

General and Administrative Expenses. For the three months ended March 31, 2015, general and administrative expenses decreased by 22.4%, or \$0.5 million, to \$2.0 million, from \$2.5 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of \$0.3 million in salaries and \$0.2 million in share-based compensation as part of our cost reduction plan. General and administrative expenses as a percentage of revenue increased to 413.0% in the three months March 31, 2015 from 171.3% in the same period in 2014.

Restructuring and impairment expenses. For the three months ended March 31, 2015 we incurred \$0.5 million of restructuring and impairment expenses made up of \$0.3 million of expenses related to the impairment of an MGuard royalties buyout option due to anticipated lower sales in the future (as discussed above), \$0.1 million of cash payouts and \$0.1 million of restricted shares given to terminated employees in connection with our restructuring (as mentioned above).

Financial Expenses. For the three months ended March 31, 2015, financial expenses decreased by 25.9%, or \$0.1 million, to \$0.3 million from \$0.4 million during the same period in 2014. The decrease in financial expenses partially resulted from a decrease of \$51,000 of interest expenses, as well as a decrease in exchange rate differences expense of \$44,000. Financial expenses as a percentage of revenue increased to 64.2% in the three months ended March 31, 2015, from 27.9% in the same period in 2014.

Tax Expenses. For the three months ended March 31, 2015, tax expenses decreased by \$4,000 to \$16,000 from \$20,000 during the same period in 2014.

Net Loss. Our net loss decreased by \$0.8 million, or 12.7%, to \$5.2 million for the three months ended March 31, 2015 from \$6.0 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of \$1.5 million in operating expenses primarily associated with research and development and general and administrative expenses, due to our cost reduction/focused spending plan (see above for explanation) and a decrease of \$0.1 million in financial expenses (see above for explanation), partially offset by a decrease of \$0.9 million in gross profit (see above for explanation).

Liquidity and Capital Resources

We have an accumulated deficit as of March 31, 2015, as well as net losses and negative operating cash flows in recent years and the current year. We expect to continue incurring losses and negative cash flows from operations. We presently anticipate that we have sufficient resources to fund our operations for at least the next twelve months. During the next twelve months management expects that we will need to raise additional capital to finance its losses and negative cash flows from operations beyond the next twelve months and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

Our plans include the continued commercialization of the MGuard™ and CGuard™ products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our MGuard™ or CGuard™ products and raising capital, we may need to reduce activities, curtail or cease operations.

Three months ended March 31, 2015 compared to the three months ended March 31, 2014

General. At March 31, 2015, we had cash and cash equivalents of \$13.2 million, as compared to \$6.3 million as of December 31, 2014. 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 research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was \$4.6 million for the three months ended March 31, 2015 and \$3.7 million for the same period in 2014. The principal reason for the usage of cash in our operating activities for the three months ended March 31, 2015 was a net loss of \$5.2 million, as well as an increase in working capital of \$0.9 million, offset by \$1.0 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, \$0.3 million of non-cash expenses related to the impairment of our royalties buyout option (discussed above), \$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, 2014 included a net loss of \$6.0 million offset by a decrease in working capital of \$1.1 million, \$1.0 million in non-cash share-based compensation, \$0.1 million in non-cash financial expenses and \$0.1 million in depreciation and amortization expenses.

Cash used in our investing activities was \$11,000 during the three months ended March 31, 2015, compared to \$34,000 during the same period in 2014. The principal reason for the decrease in cash used in investing activities during 2015 was purchase of property, plant and equipment of \$1,000, as compared to \$13,000 in the same period in 2014, as well as the funding of employee retirement funds of \$10,000 in the three months ended March 31, 2015, as compared to \$21,000 in the same period in 2014.

Cash provided by financing activities for the three months ended March 31, 2015 was \$11.6 million, compared to \$0.1 million of cash used during the same period in 2014. The principal source of the cash provided by financing activities during the three months ended March 31, 2015 relates to funds received from the issuance of shares and warrants of approximately \$12.5 million, offset by the repayment of a loan of \$0.9 million and \$0.1 million of payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by some of our employees. The reason for the 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, 2015, our current assets exceeded our current liabilities by a multiple of 2.1. Current assets increased by \$6.7 million during the period, mainly due to cash provided by financing offset by cash used in operations, and current liabilities decreased by \$1.0 million during the period. As a result, our working capital surplus increased by \$7.7 million to \$8.5 million at March 31, 2015.

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

In April, 2015, the Financial Accounting Standards Board (“FASB”) issued guidance related to the presentation of Debt Issuance Costs. The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

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.

Contractual Obligations and Commitments

During the three months ended March 31, 2015, there were no material changes to our contractual obligations and commitments.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our market risk profile as of March 31, 2015 has not significantly changed since December 31, 2014. Our market risk profile as of December 31, 2014 is disclosed in our Annual Report on Form 10-K.

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of March 31, 2015, 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, 2015.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2015 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 aware of any material legal proceedings to which we or any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial stockholder of more than 5% of our common stock, or any associate of any of the foregoing, is an adverse party or has a material interest adverse to our interest.

Item 1A. Risk Factors

During the fiscal quarter ended March 31, 2015, there were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, except for the following:

Our common stock could be delisted from the NYSE MKT if we fail to regain compliance with the NYSE MKT's continued listing standards on the schedule required by the NYSE MKT.

On January 20, 2015, we received a notice indicating that we do not meet certain of the NYSE MKT's continued listing standards as set forth in Part 10 of the NYSE MKT Company Guide ("Company Guide"). Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than \$6 million as of September 30, 2014 and had net losses in our five most recent fiscal years. In addition, the NYSE MKT indicated that we were not in compliance with Section 1003(a)(iv) of the Company Guide because we had sustained losses that are substantial in relation to our overall operations or our then-existing financial resources, or our financial condition had become impaired such that it appeared questionable, in the opinion of the NYSE MKT, as to whether we would be able to continue operations and/or meet our obligations as they matured. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide.

In order to maintain our listing on the Exchange, we submitted a plan of compliance to the NYSE MKT on February 19, 2015 addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide by July 20,

2016 and Section 1003(a)(iv) of the Company Guide by June 1, 2015. On March 9, 2015, we closed a public offering of our common stock and warrants that resulted in net proceeds of approximately \$12.5 million after deducting placement agent fees and other estimated offering expenses. In light of this, the Exchange determined that we have resolved the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide. In addition, the Exchange has accepted our plan to gain compliance with the Section 1003(a)(iii) of the Company Guide by July 20, 2016.

If we do not maintain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE MKT will initiate delisting proceedings. The market price and liquidity of our common stock could be adversely affected by the commencement of such proceedings. If those proceedings resulted in delisting of our common stock and resulting cessation of trading of the stock on the NYSE MKT, we believe that the market price and liquidity of our common stock would be adversely affected.

Item 5. Other Information

Not applicable

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 11, 2015 By: /s/ Alan Milinazzo

Name: Alan Milinazzo

Title: President and Chief Executive Officer

Date: May 11, 2015 By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer, Secretary and Treasurer

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+	Second Amendment to Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.2+	Amendment to Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.3+	First Amendment to Amended and Restated Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.4+	Amendment Number Two to Employment Agreement, dated February 22, 2015, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2015)
10.5	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
10.6	Form of Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
10.7	Placement Agency Agreement, dated as of March 4, 2015, by and among InspireMD, Inc., H.C. Wainwright & Co., LLC and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Edgar Filing: InspireMD, Inc. - Form 10-Q

- 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, 2015, 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

* Filed herewith.

+ Management contract or compensatory plan or arrangement.