InspireMD, Inc.
Form 10-Q
May 10, 2016

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, 2016

OR

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

For the transition period from to

Commission file number: 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) 305-2410

(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 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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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 10, 2016: 10,721,082.

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(Unaudited)

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(Unaudited)

March 31, 2016

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The amounts are stated in U.S. dollars

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands other than share and per share data)

	March 31, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,999	$ 3,257
Accounts receivable:		
Trade, net	546	405
Other	204	142
Prepaid expenses	62	75
Inventory	511	753
Total current assets	3,322	4,632
NON-CURRENT ASSETS: PROPERTY, PLANT AND EQUPMENT, net	436	472
Funds in respect of employees rights upon retirement	411	502
Royalties buyout	75	87
Total non-current assets	922	1,061
Total assets	$ 4,244	$ 5,693

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 other than share and per share data)

	March 31, 2016	December 31, 2015
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$453	$ 512
Other	2,139	2,006
Advanced payment from customers	169	167
Current maturity of loan	4,294	4,149
Total current liabilities	7,055	6,834
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	584	706
Long-term loan	-	1,099
Total long-term liabilities	584	1,805
COMMITMENTS AND CONTINGENT LIABILITIES (Note 10)		
Total liabilities	7,639	8,639
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 50,000,000 shares authorized; 10,671,187 and 7,676,074 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	1	1
Additional paid-in capital	122,209	120,049
Accumulated deficit	(125,605)	(122,996)
Total capital deficiency	(3,395)	(2,946)
Total liabilities net of capital deficiency	$4,244	$ 5,693

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,	
	2016	2015
REVENUES	$563	$477
COST OF REVENUES	497	514
GROSS PROFIT (LOSS)	66	(37)
OPERATING EXPENSES:		
Research and development	478	1,352
Selling and marketing	386	1,017
General and administrative	1,589	1,970
Restructuring and impairment		514
Total operating expenses	2,453	4,853
LOSS FROM OPERATIONS	(2,387)	(4,890)
FINANCIAL EXPENSES, net:		
Interest expense	179	301
Other financial expenses	42	5
Total financial expenses	221	306
LOSS BEFORE INCOME TAXES	(2,608)	(5,196)
TAX EXPENSES	1	16
NET LOSS	$(2,609)	$(5,212)
NET LOSS PER SHARE - basic and diluted	$(0.32)	$(1.04)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	8,042,082	4,991,519

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,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,609)	$ (5,212)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	48	75
Impairment of royalties buyout		316
Change in liability for employees right upon retirement	(122)	12
Financial expenses	33	102
Share-based compensation expenses	741	1,029
Loss on amounts funded in respect of employee rights upon retirement, net	1	4
Changes in operating asset and liability items:		
Decrease in prepaid expenses	13	49
Increase in trade receivables	(141)	(84)
Decrease (increase) in other receivables	(62)	81
Decrease in inventory	242	174
Decrease in trade payables	(59)	(244)
Increase (decrease) in other payables and advance payment from customers	50	(924)
Net cash used in operating activities	(1,865)	(4,622)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment		(1)
Amounts gained (funded) in respect of employee rights upon retirement, net	90	(10)
Net cash provided by (used in) investing activities	90	(11)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(16)	(78)
Net proceeds from issuance of shares and warrants	1,520	12,529
Repayment of long-term loan	(988)	(891)
Net cash provided by financing activities	516	11,560
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	1	(41)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,258)	6,886
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	3,257	6,300
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 1,999	$ 13,186

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

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INSPIREMD, INC.

NOTES TO THE CONDENSED 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. 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. In January 2015, the Company received CE mark approval for the rapid exchange delivery system and launched CGuard in countries in Europe.

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). The Company markets its products through distributors in international markets, mainly in Europe and Latin America.

b. Liquidity

The Company has an accumulated deficit as of March 31, 2016, as well as net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations beyond June 2016. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. 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.

Management's plans include the continued commercialization of the Company's 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 products and raising capital, it may need to reduce activities, curtail or cease operations.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited condensed 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 condensed 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, 2015, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 28, 2016. The balance sheet for December 31, 2015 was derived from the Company's audited financial statements for the year ended December 31, 2015. The results of operations for the three months ended March 31, 2016 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 Accounting Standards Update No. 2015-03, "Simplifying 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.

INSPIREMD, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance became effective during the first quarter of 2016 and was applied on a retrospective basis.

As of March 31, 2016 and December 31, 2015, $68,000 and $85,000, respectively were deducted from the carrying value of the “Current maturity of loan” in the condensed consolidated balance sheets.

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued ASC 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after December 15, 2016.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers,” such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements.

On July 22, 2015, the FASB issued Accounting Standards Update No. 2015-11, “Simplifying the Measurement of Inventory,” which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out and the retail inventory method are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December

15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") which simplifies certain aspects of the accounting for share-based payments, including accounting for income taxes, classification of awards as either equity or liabilities, classification on the statement of cash flows as well as allowing an entity-wide accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. This ASU is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted in any annual or interim period for which financial statements have not yet been issued, and all amendments in the ASU that apply must be adopted in the same period. The Company is currently evaluating the new guidance to determine the impact it may have on its consolidated financial statements. In addition, the impact on the Company's consolidated financial statements upon adoption is dependent on the Company's share price at option expiration dates and restricted stock vesting dates.

NOTE 4 - EQUITY:

a. On January 26, 2016 the Company entered into an option cancellation and release agreement with certain directors, the CEO and CFO. See Note 9.

INSPIREMD, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

b. On March 21, 2016, the Company sold 2,933,051 shares of its common stock and warrants to purchase 1,466,526 shares of common stock in concurrent underwritten public offering and private placement. The common stock was sold at a price of $0.59 per share and each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants, which are classified as equity, are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to the Company of approximately $1.7 million ($1.4 million after deducting underwriting discount, placement agent fees and other offering expenses).

In connection with the underwritten public offering and the Private Placement in March 2016, on March 21, 2016, the Company issued to the underwriter and placement agent a five-year warrant to purchase up to 146,653 shares of common stock at an exercise price of $0.7375 per share. The warrants, which are classified as equity, are exercisable at any time during the period commencing six months following the date of issuance and ending five years from the date of issuance.

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 5,913,420 and 5,041,110 for the three month periods ended March 31, 2016 and 2015, respectively.

NOTE 6 - FAIR VALUE MEASURMENT:

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. 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.

As of March 31, 2016 and December 31, 2015, allowance for doubtful accounts was $359,000 and $346,000, respectively.

NOTE 7 - INVENTORY:

	March 31, 2016	December 31, 2015
	($ in thousands)	
Finished goods	$ 116	$ 301
Work in process	276	307
Raw materials and supplies	119	145
	$ 511	$ 753

INSPIREMD, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 8 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2016	December 31, 2015
	($ in thousands)	
Employees and employee institutions	$599	$ 412
Accrued vacation and recreation pay	253	377
Accrued clinical trial expenses	523	582
Accrued expenses	678	552
Provision for sales commissions	84	80
Taxes payable	2	3
	$2,139	$ 2,006

NOTE 9 - RELATED PARTIES:

a. On January 16, 2016, the Board of Directors appointed a new director as a Vice Chairman of the Board, effective as of January 22, 2016, with a term expiring at the Company's 2017 annual meeting of stockholders. In connection with his appointment, the new director was granted an option to purchase 780,000 shares of the Company's common stock on April 30, 2016 at an exercise price equal to the closing fair market value of the Common Stock on the date of grant on April 30, 2016, subject to the terms and conditions of the 2013 Plan and the 2011 Plan. Options to purchase 195,000 shares of Common Stock vest and become exercisable immediately upon the time of grant, and, until all 780,000 options shall have vested, options to purchase 195,000 shares of common stock will vest and become exercisable each time upon (i) the Company raising at least $15 million through an equity offering; (ii) the Company's market cap becoming equal to or greater than $25 million; (iii) the Company receiving research coverage by three new analysts at a leading investment bank; or (iv) the tripling of the Company's market cap from the date of appointment. Any of the foregoing conditions, if achieved following the director's appointment but prior to April 30, 2016, will be deemed satisfied on the date of grant. However, in the event (i) of the director's death or permanent disability, (ii) a change in control (as defined in the Plan) or (iii) if the director is asked to resign for any reason

other than cause (as defined in the Company's form of Nonqualified Stock Option Agreement under its Plan), the options shall vest immediately in full. The options have a term of 10 years from the date of grant and may be exercised for either cash or on a cashless basis. The fair value of the options will be determined on April 30, 2016. Some of the above events involve performance conditions and some involve market conditions. For grants that involve performance conditions, the expense will be recognized on a cumulative basis only if the targets will be achieved. For grants that involve market conditions, the expense will be recognized over the expected period for the conditions to occur.

b. On January 21, 2016, the Company and the Company's CEO, entered into a fourth amendment to the CEO's Employment Agreement by and between the Company and the CEO, in order to, among other things, (i) modify the term of the CEO's employment to end on the earlier of June 30, 2016 or the date upon which a new president and/or chief executive officer (or executive performing a similar role) commences employment with the Company (or, if such individual is promoted internally, the date such individual is promoted to the position of president and/or chief executive officer); and (ii) provide that, during the remaining term of his employment, the CEO will receive (A) 50% of his base salary in cash payments, for all days that the CEO works during the remaining term of his employment, at the monthly rate of $18,750, payable in accordance with the Company's regular payroll practices, and (B) a lump-sum payment equivalent to 50% of the CEO's base salary through June 30, 2016, at the monthly rate of $18,750, payable within 20 business days from the earlier of (x) the Company raising an aggregate of $5 million from investors, or (y) June 30, 2016.

INSPIREMD, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

On January 26, 2016 the Company entered into an option cancellation and release agreement with certain directors, the CEO and CFO (“the Optionholders”), pursuant to which the parties agreed to cancel options to purchase an aggregate of 422,443 shares of common stock of the Company previously granted to each of the Optionholders. For accounting purpose the cancellation was treated as a settlement for no consideration and accordingly all remaining unrecognized compensation cost amounting to approximatly $800,000 was recognized.

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Litigation

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 settled with the plaintiff in the amount of $80,000 plus $20,000 for legal fees, which was approved by the Labor Court and paid by the Company in March 2016.

The Company received written communication from a distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action. After considering the views of its legal counsel as well as other factors, the Company’s management believes that a loss from any related future proceedings would range from a minimal amount up to 1,075,000 Euros and is reasonably possible.

In November 2015, the Company received written communication from a service provider to remit payment amounting to $1,965,000. Given the preliminary stage, the Company’s management and legal counsel cannot estimate the outcome of any legal proceedings or settlements, however believes that neither a court loss nor settlement are probable.

On April 26, 2016 an alleged finder of the Company filed a suit seeking damages from the Company amounting to $2.2 million in cash and unspecified compensation in equity in connection with certain finders' fees that he claims are owed to him. The Company's management, after considering the views of its legal counsel as well as other factors, is of the opinion that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

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.

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:

INSPIREMD, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

By geographic areas:

	Three months ended March 31,	
	2016	2015
	($ in thousands)	
Germany	$ 160	$ 131
Italy	155	28
Spain	63	45
Belarus	20	78
Other	165	195
	$ 563	$ 477

By product:

	Three months ended March 31,	
	2016	2015
	($ in thousands)	
CGuard	$ 320	$ 60
MGuard*	243	417
	$ 563	$ 477

*The three months ended March 31, 2015 include revenue from sales of both MGuard Prime and MGuard.

The following is a summary of revenues by principal customers:

	Three months ended March 31,			
	2016		2015	
Customer A	22	%	0	%
Customer B	17	%	2	%
Customer C	11	%	9	%
Customer D	6	%	21	%
Customer E	4	%	16	%

All tangible long-lived assets are located in Israel.

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 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, 2015, 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 vascular and coronary 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 CGuard™ carotid embolic prevention system ("CGuard EPS") combines our MicroNet mesh and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize CGuard EPS in Argentina and Colombia. Following the receipt of such regulatory approval, we launched CGuard EPS in Argentina in the first quarter of 2016 and Colombia in the fourth quarter of 2015.

Our MGuard™ coronary product, MGuard Prime™ Embolic Protection System ("MGuard Prime EPS"), is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). We market and sell MGuard Prime EPS, a bare-metal cobalt-chromium based stent, for the treatment of coronary disease in the European Union. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility and incorporating our MicroNet in-house onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to open diseased vessels in the brain.

Presently, none of our products may be sold or marketed in the United States.

Recent Events

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million, before deducting the underwriting discount and estimated offering expenses.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the private placement. The warrants are exercisable

immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This private placement resulted in gross proceeds to us of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses.

These sales of securities on March 21, 2016 resulted in aggregate net proceeds to us of approximately $1.4 million, after deducting underwriting discount, 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, 2015. There have not been any material changes to such critical accounting policies since December 31, 2015.

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

Contingencies

We and our subsidiaries are involved in legal proceedings that arise from time to time in the ordinary course of business. We record accruals for these types of contingencies to the extent that we conclude the occurrence of such contingencies is probable and that the related liabilities are estimable. When accruing these costs, we recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. Legal costs are expensed as incurred.

Results of Operations

Three months ended March 31, 2016 compared to the three months ended March 31, 2015

Revenues. For the three months ended March 31, 2016, revenue increased by $0.1 million, or 18.2%, to $0.6 million, from $0.5 million during the same period in 2015. This increase was predominantly driven by a 437.4% increase in sales of CGuard EPS from $60,000 in the three months ended March 31, 2015 to $0.3 million in the same period in 2016. This increase in CGuard EPS sales were partially offset by a 41.7% decrease in sales of MGuard Prime EPS from $0.4 million in the three months ended March 31, 2015 to $0.3 million in the same period in 2016, predominantly driven by a decrease in sales due to the trend of doctors increasingly using drug-eluting stents rather than bare metal stents in STEMI patients.

With respect to regions, the increase in revenue was primarily attributable to an increase of $0.1 million in revenue from our distributors in Europe.

Gross Profit (Loss). For the three months ended March 31, 2016, we had a gross profit (revenue less cost of revenues) of $66,000, as compared to a gross loss (revenue less cost of revenues) of $37,000, during the same period in 2015, representing an increase of $0.1 million. This increase in gross profit was attributable to an increase in revenues of $0.1 million (see above for explanation) and a decrease of write-offs of inventory of $0.2 million, which were primarily related to a decrease of write-offs of MGuard Prime EPS units during the three months ended March 31, 2016, as compared to the same period in 2015, partially offset by an increase of $0.1 million in material and labor costs due to the increased sales and an increase of $0.1 million related to the underutilization of our manufacturing resources. Gross margin (gross profits as a percentage of revenue) increased to 11.7% in the three months ended March 31, 2016 from (7.8)% in the same period in 2015.

Research and Development Expenses. For the three months ended March 31, 2016, research and development expenses decreased by 64.6%, or $0.9 million, to $0.5 million, from $1.4 million during the same period in 2015. This decrease in research and development expenses resulted primarily from a decrease of $0.3 million in clinical trial and development costs associated with CGuard EPS, a decrease of $0.3 million in compensation expenses, a decrease of $0.1 million in clinical trial expenses associated with our MASTER II trial, a decrease of $0.1 million of expenses related to the development of a drug eluting coronary stent and a decrease of $0.1 million in miscellaneous clinical and development expenditures related to MGuard Prime EPS. The decreases in compensation and miscellaneous clinical and development expenditures related to MGuard Prime EPS are the results of the implementation of our cost reduction/focused spending plan beginning in the first quarter of 2015.

Selling and Marketing Expenses. For the three months ended March 31, 2016, selling and marketing expenses decreased by 62.0%, or $0.6 million, to $0.4 million, from $1.0 million during the same period in 2015. This decrease in selling and marketing expenses resulted primarily from a decrease of $0.4 million in compensation expenses due to our transition away from direct sales in favor of using third party distributors, a decrease of $0.1 million in travel expenses associated with the decreased size of our sales force and a decrease of $0.1 million in miscellaneous expenses. The decrease in spending was a result of our cost reduction/focused spending plan.

General and Administrative Expenses. For the three months ended March 31, 2016, general and administrative expenses decreased by 19.3%, or $0.4 million, to $1.6 million, from $2.0 million during the same period in 2015. The decrease in general and administrative expenses resulted primarily from a decrease of $0.2 million in miscellaneous expenses such as investor relations, audit, rent, consultants and travel, as part of our cost reduction/focused spending plan, a decrease of $0.1 million of share based compensation expenses pertaining to the change in our forfeiture rate assumptions of restricted stock of our chief executive officer and a decrease of $0.1 million in litigation expenses following a one-time charge in Argentina of $0.1 million in the three months ended March 31, 2015.

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, $0.1 million of cash payouts and $0.1 million of restricted shares given to terminated employees in connection with our restructuring. No such expense occurred during the same period in 2016.

Financial Expenses. For the three months ended March 31, 2016, financial expenses decreased by 27.8% or $0.1 million, to $0.2 million, from $0.3 million during the same period in 2015. The decrease in financial expenses resulted from a decrease of $0.1 million of interest expenses due to the reduction in principal of our outstanding indebtedness.

Tax Expenses (Income). For the three months ended March 31, 2016 there was no material change in tax expenses (income) compared to the same period in 2015.

Net Loss. Our net loss decreased by $2.6 million, or 49.9%, to $2.6 million for the three months ended March 31, 2016 from $5.2 million during the same period in 2015. The decrease in net loss resulted primarily from a decrease of $2.4 million in operating expenses primarily associated with lower research and development, sales and marketing and restructuring expenses, due to our cost reduction/focused spending plan, a decrease of $0.1 million in financial expenses and an increase of $0.1 million in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of March 31, 2016, as well as net losses and negative operating cash flows in recent years. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we do not have sufficient resources to fund operations beyond June 2016. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued commercialization of our 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 products and raising capital, we may need to reduce activities, curtail or cease operations.

Three months ended March 31, 2016 compared to the three months ended March 31, 2015

General. At March 31, 2016, we had cash and cash equivalents of $2.0 million, as compared to $3.3 million as of December 31, 2015. 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 $1.9 million for the three months ended March 31, 2016 and $4.6 million for the same period in 2015. The principal reason for the usage of cash in our operating activities for the three months ended March 31, 2016 was a net loss of $2.6 million, offset primarily by $0.7 million in non-cash share based compensation that was largely paid to our directors and chief executive officer. 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.

Cash provided by our investing activities was $90,000 during the three months ended March 31, 2016, resulting from the receipt of cash previously funded to employee retirement funds, compared to $11,000 of cash used by our investing activities during the same period in 2015.

Cash provided by financing activities for the three months ended March 31, 2016 was $0.5 million, compared to $11.6 million during the same period in 2015. The principal source of the cash provided by financing activities during the three months ended March 31, 2016 was the issuance of shares and warrants in a concurrent public offering and private placement for approximately $1.5 million of proceeds, offset by loan repayments of $1.0 million 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 in a public offering, 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.

As of March 31, 2016, our current liabilities exceeded our current assets by a multiple of 2.1. Current assets decreased by $1.3 million during the period and current liabilities increased by $0.2 million during the period. As a result, our working capital deficit increased by $1.5 million to $3.7 million at March 31, 2016.

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

See Note 3 – “Recently Issued Accounting Pronouncements” in the accompanied financial statements.

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. For a discussion of these and other risks that relate to our business, 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 year ended December 31, 2015, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

Contractual Obligations and Commitments

During the three months ended March 31, 2016, there were no material changes to our contractual obligations and commitments.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of March 31, 2016, 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, 2016.

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, 2016 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 or any such proceedings known to be contemplated by governmental authorities.

We are not aware of any 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 a party adverse to or has a material interest adverse to, us or any of our subsidiaries.

Item 1A. Risk Factors

During the fiscal quarter ended March 31, 2016, there were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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 10, 2016 By: /s/ Alan Milinazzo

Name: Alan Milinazzo

Title: President and Chief Executive Officer

Date: May 10, 2016 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, as amended through September 30, 2015 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)
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 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)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 5, 2013)
4.2	Rights Agreement dated as of October 22, 2013 between InspireMD, Inc. and Action Stock transfer Corporation, as Rights Agent, including exhibits thereto (incorporated by reference to an exhibit to the Registration Statement on Form 8-A filed with Securities and Exchange Commission on October 25, 2013)
10.1+	Offer Letter, between InspireMD, Inc. and Isaac Blech, dated January 16, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 22, 2016)
10.2+	Fourth Amendment to Employment Agreement, dated January 21, 2016, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 22, 2016)
10.3+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Sol J. Barer (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 28, 2016)
10.4+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and James Barry (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 28, 2016)
10.5+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Michael Berman (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on January 28, 2016)
10.6	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Paul Stuka (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on January 28, 2016)

10.7	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Campbell Rogers (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on January 28, 2016)
10.8+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and James Loughlin (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on January 28, 2016)
10.9+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed on January 28, 2016)
10.10+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed on January 28, 2016)
10.11+	Third Amendment to Employment Agreement, dated March 28, 2016, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.66 to the Annual Report on Form 10-K filed on March 28, 2016)
10.12	Form of $0.59 Underwritten Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.13	Form of $0.7375 Underwriter Warrant (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.14	Form of $0.59 Private Placement Warrant (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.15	Form of $0.7375 Placement Agent Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
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, 2016, 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.

^ Certain portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission under a confidential treatment request pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

+ Management contract or compensatory plan or arrangement.

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