InspireMD, Inc.
Form 10-Q
August 05, 2015

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: June 30, 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 incorporation or organization)	(I.R.S. Employer Identification No.)

321 Columbus Avenue

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 x
Non-accelerated filer ¨	Smaller reporting company ¨
(Do not check if a smaller reporting company)	

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

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of August 5, 2015: 77,856,317.

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(Unaudited)

June 30, 2015

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INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

June 30, 2015

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The amounts are stated in U.S. dollars

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	June 30, **2015**	December 31, **2014**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$9,768	$ 6,300
Accounts receivable:		
Trade	728	635
Other	193	359
Prepaid expenses	76	150
Inventory	1,229	1,924
Total current assets	11,994	9,368
NON-CURRENT ASSETS:		
Property, plant and equipment, net	546	622
Deferred issuance costs	119	153
Funds in respect of employees rights upon retirement	495	498
Long-term prepaid expenses	30	66
Royalties buyout	378	752
Total non-current assets	1,568	2,091
Total assets	$13,562	$ 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)

	June 30, **2015**	December 31, **2014**
LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$491	$ 909
Other	2,654	3,576
Advanced payment from customers	169	179
Current maturity of loan	4,015	3,809
Total current liabilities	7,329	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	698	687
Long-term loan	3,159	5,086
Total long-term liabilities	3,857	5,773
COMMITMENTS AND CONTINGENT LIABILITIES		
(Note 11)		
Total liabilities	11,186	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 76,048,385 and 41,368,889 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	118,870	104,620
Accumulated deficit	(116,501)	(107,411)
Total equity (capital deficiency)	2,376	(2,787)
Total liabilities and equity (net of capital deficiency)	$13,562	$ 11,459

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

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INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three months ended **June 30,**		Six months ended **June 30,**	
	2015	**2014**	**2015**	**2014**
REVENUES	$685	$193	$1,162	$1,675
COST OF REVENUES	897	584	1,411	1,209
GROSS PROFIT (LOSS)	(212)	(391)	(249)	466
OPERATING EXPENSES:				
Research and development	747	2,448	2,099	5,025
Selling and marketing	995	1,948	2,012	3,224
General and administrative	1,587	2,448	3,557	4,987
Restructuring and impairment expenses	32	-	546	-
Total operating expenses	3,361	6,844	8,214	13,236
LOSS FROM OPERATIONS	(3,573)	(7,235)	(8,463)	(12,770)
FINANCIAL EXPENSES, net:				
Interest expense	275	359	576	711
Other financial expenses (income)	47	(34)	52	27
Total financial expenses	322	325	628	738
LOSS BEFORE INCOME TAXES	(3,895)	(7,560)	(9,091)	(13,508)
TAX EXPENSES (INCOME)	(17)	2	(1)	22
NET LOSS	$(3,878)	$(7,562)	$(9,090)	$(13,530)
NET LOSS PER SHARE - basic and diluted	$(0.05)	$(0.22)	$(0.14)	$(0.40)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	76,035,721	34,115,814	63,067,454	34,083,936

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)

	Six months ended **June 30,**	
	2015	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(9,090)	$(13,530)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	135	122
Impairment of royalties buyout	316	
Change in liability for employees right upon retirement	11	135
Financial expenses	146	150
Share-based compensation expenses	1,999	2,099
Loss on amounts funded in respect of employee rights upon retirement, net	4	6
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	110	(44)
Decrease (increase) in trade receivables	(93)	1,362
Decrease (increase) in other receivables	166	(33)
Decrease in inventory	695	79
Decrease in trade payables	(418)	(94)
Increase (decrease) in other payables and advance payment from customers	(1,026)	1,394
Net cash used in operating activities	(7,045)	(8,354)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1)	(93)
Decrease in restricted cash		93
Amounts funded in respect of employee rights upon retirement, net	(1)	(65)
Net cash used in investing activities	(2)	(65)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(84)	(115)
Proceeds from issuance of shares and warrants, net of $1,315 issuance costs	12,432	
Repayment of long-term loan	(1,803)	
Net cash provided by (used in) financing activities	10,545	(115)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(30)	(13)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,468	(8,547)
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	$9,768	$8,988

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

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

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 June 30, 2015, 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 MGuard™ and CGuard™ products 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 for the next twelve months. Therefore, there is substantial doubt about the Company's ability to continue as a going concern.

Management's plans include the continued commercialization of the MGuard™ 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.

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.

During the first quarter of 2015, the board of directors approved to curtail 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.

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 $12.4 million after deducting placement agent fees and other offering expenses. See Note 4c.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 six months ended June 30, 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.

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.

On July 22, 2015, the FASB issued Accounting Standards Update 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 (LIFO) and the retail inventory method (RIM) 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.

NOTE 4 - EQUITY:

a. During the six months ended June 30, 2015, the Company granted stock options to employees and directors to purchase a total of 1,739,417 shares of the Company's common stock. The options have exercise prices ranging from $0.28 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 1,739,417 options described above, 671,951 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%-69.35%; 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 $0.62 million.

b. During the six months ended June 30, 2015, the Company granted a total of 1,323,349 restricted shares of the Company's common stock to employees, of which 432,988 restricted 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, 329,028 restricted shares are subject to a six-month vesting period and 468,833 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately $0.96 million.

c. 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 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 $12.4 million after deducting placement agent fees and other offering expenses.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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, and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants and restricted stock excluded from the calculations of diluted loss per share were 50,119,213 and 9,943,540 for the six and three month periods ended June 30, 2015 and 2014, 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. As of June 30, 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:

	June 30, 2015	December 31, **2014**
	($ in thousands)	
Finished goods	$443	$ 1,273
Work in process	541	326
Raw materials and supplies	245	325
	$1,229	$ 1,924

NOTE 8– IMPAIRMENT OF ROYALTIES BUYOUT

During the period ended June 30, 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	June 30, 2015	December 31, **2014**
	($ in thousands)	
Employees and employee institutions	$731	$ 1,022
Accrued vacation and recreation pay	399	410
Accrued clinical trial expenses	611	1,016
Accrued expenses	799	993
Provision for sales commissions	100	120
Taxes payable	14	15
	$2,654	$ 3,576

NOTE 10 - RELATED PARTIES:

a. During the six month period ended June 30, 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 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.

b. During the six month period ended June 30, 2015, directors of the Company were granted options to purchase an aggregate of 979,904 shares of common stock at exercise prices ranging from $0.28-$0.78, of which, 671,951 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 and second quarter of 2015. See Note 4a.

c.

On June 29, 2015, the Company amended the employment agreement with the Company's CEO in order to, among other things, (i) modify the term of employment to end on June 30, 2016 unless earlier terminated by either party; and (ii) provide that, until the Company raises an aggregate of $5 million from investors, the CEO will receive (A) with respect to his employment in 2015, 50% of his base salary in cash payments, with the remaining 50% having been paid to the CEO on January 26, 2015, through the issuance of 312,500 shares of restricted common stock of the Company valued at $0.72 per share, representing the fair market value of the Company's common stock as of the market close on January 26, 2015, which will be subsequently adjusted based upon the volume-weighted average price of the Company's common stock during the calendar year ended December 31, 2015 (or during the period from January 2, 2015 through his termination date if his employment is terminated upon his death or disability, by the CEO for good reason, or by the Company without cause prior to December 31, 2015) to represent the equivalent of 50% of the CEO's base salary in 2015, and (B) with respect to his employment in 2016, 50% of his base salary from January 1, 2016 through June 30, 2016 to be paid in shares of restricted common stock of the Company valued at the fair market value of the Company's common stock as of the market close on January 2, 2016. The amendment also amends those certain provisions in the Employment Agreement related to payments on termination of employment.

With respect to the adjustment of the 312,500 shares of restricted common stock mentioned above, the Company determined, based on the provisions of ASC 718, that following the employee amendment, the related restricted stock compensation was classified from equity to a liability in the consolidated balance sheets and measured at fair value in the amount of $83,000 and will subsequently be measured at fair value at each reporting period.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 11 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Litigation

1) 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. On May 27, 2015 the Company and the assignee of options accepted a settlement agreement pursuant to which the claim was removed and the plaintiff waived his entire claim against the Company, in consideration of the Company's consent to allow him to exercise 58,545 options of the Company's shares of common stock.

2) 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. As of the date of approval the financial statements, the Company reached a verbal agreement with the plaintiff in the amount of $80,000 plus $16,000 for legal fees. The Company's management, after considering the views of its legal counsel, believes that it is highly probable that the district court will accept the settlement as described above, which resulted in the provision decreasing to $100,000. The related decrease in provision amounting to $240,000 was recorded to "General and administrative" within the Consolidated Statements of Operations.

3) 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.

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 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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		Six months ended	
	June 30,		**June 30,**	
	2015	**2014**	**2015**	**2014**
	($ in thousands)			
Germany	$165	$27	$296	$92
Brazil	126		151	
Italy	88		116	83
Belarus	33	110	111	142
Middle East	31		67	624
Spain	26		71	201
Other	216	56	350	533
	685	$193	1,162	$1,675

The following is a summary of revenues by principal customers:

	Three months ended		Six months ended	
	June 30,		**June 30,**	
	2015	**2014**	**2015**	**2014**
Customer A	22%	14 %	21%	4 %
Customer B	5 %	57 %	10%	8 %
Customer C	0 %	0 %	0 %	36 %
Customer D	4 %	0 %	6 %	12 %

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;

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· adverse economic conditions;

· insufficient or inadequate reimbursement by governmental and other third party payers for our products;

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- 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 (“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, we launched a limited market release of our second product, CGuard™ carotid embolic prevention system ("CGuard™ 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™ EPS 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 curtail 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.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which was previously our focus. 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 were eliminated. In addition, we have since reduced all expenses not directly related to the CGuard™ EPS launch and drug eluting platform development.

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.

Contingencies

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 June 30, 2015 compared to the three months ended June 30, 2014

Revenues. For the three months ended June 30, 2015, revenue increased by $0.5 million, or 256.0%, to $0.7 million from $0.2 million during the same period in 2014. This increase was predominately driven by an increase in sales volume of MGuard™ Prime EPS, our coronary product, of $0.4 million, or 206.2%, compared to the sales volume of MGuard™ Prime EPS in the three months ended June 30, 2014, during which time we temporarily suspended sales of MGuard™ Prime EPS and initiated a voluntary field corrective action ("VFA") on April 30, 2014, as well as $0.2 million of sales of our new carotid product, CGuard™ EPS, which we launched in October 2014. This increase in sales volume was partially offset by $0.1 million, or 37.3%, of price decreases to distributors as well as the effects of the weakening of the Euro against the U.S dollar.

With respect to regions, the increase in revenue was primarily attributable to an increase of $0.3 million in revenue from our distributors in Europe and $0.2 million in revenue from our distributors in Latin America.

Gross Profit (Loss). For the three months ended June 30, 2015, our gross loss (revenue less cost of revenues) decreased by 45.8%, or $0.2 million, to $0.2 million, from $0.4 million during the same period in 2014. This improvement in gross loss was attributable to an increase in revenues of $0.5 million (see above for explanation) and a decrease of $0.4 million in costs associated with our VFA (as mentioned above), which occurred during the three months ended June 30, 2014. No such costs were incurred during the same period in 2015. These decreases in gross loss, however, were partially offset by an increase in labor and material costs of $0.4 million attributable to higher revenues, an increase of write-offs of inventory of $0.2 million related to the write-offs of MGuard™ Prime EPS units due to the expected lower sales in the future resulting from the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients and an increase of $0.1 million of underutilization of our manufacturing resources. Gross margin (gross profits as a percentage of revenue) increased from (202.6)% in the three months ended June 30, 2014 to (30.9)% in the same period in 2015.

Research and Development Expenses. For the three months ended June 30, 2015, research and development expenses decreased by 69.5%, or $1.7 million, to $0.7 million from $2.4 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of $0.8 million in clinical trial expenses associated with our MASTER II trial, for which enrollment was suspended in October 2014, $0.3 million in clinical trial expenses associated with our CARENET trial, for which enrollment was completed in 2014, $0.2 million of expenses related to our stent retention program, which we concluded in 2014, $0.1 million in compensation expenses and $0.3 million in miscellaneous expenses. These decreases in expenditures were primarily results of our cost reduction/focused spending plan. Research and development expenses as a percentage of revenue decreased to 109.1% for the three months ended June 30, 2015, from 1,268.4% in the same period in 2014.

Selling and Marketing Expenses. For the three months ended June 30, 2015, selling and marketing expenses decreased by 48.9%, or $1.0 million, to $1.0 million, from $2.0 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of $0.5 million in salaries, as we realigned to a new commercial strategy built on using third party distributors for our products resulting in a reduced sales force, a decrease of $0.2 million in travel expenses associated with the decreased size of our sales force and a decrease of $0.3 million in expenditures related to our participation in the European Percutaneous Coronary Revascularization (Euro PCR) Congress in Paris, France, incurred in the same period in 2014. Selling and marketing expenses as a percentage of revenue decreased to 145.3% in the three months ended June 30, 2015 from 1,009.3% in the same period in 2014.

General and Administrative Expenses. For the three months ended June 30, 2015, general and administrative expenses decreased by 35.2%, or $0.8 million, to $1.6 million, from $2.4 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of $0.6 million in compensation expenses due to lower salaries as part of our cost reduction/focused spending plan and the lower value of ESOP grants made to our management and directors, as well as a reduction in litigation expenses of $0.2 million due to our probable settlement of a claim for less than we had previously estimated. General and administrative expenses as a percentage of revenue decreased to 231.7% in the three months ended June 30, 2015 from 1,268.4% in the same period in 2014.

Restructuring and impairment expenses. For the three months ended June 30, 2015, we incurred $32,000 of restructuring and impairment expenses made up of $32,000 of cash payouts given to terminated employees in connection with our restructuring (as mentioned above).

Financial Expenses. For the three months ended June 30, 2015, financial expenses remained flat at $0.3 million compared to the same period in 2014. Financial expenses as a percentage of revenue decreased to 47.0% in the three months ended June 30, 2015, from 168.4% in the same period in 2014.

Tax Expenses (Income). For the three months ended June 30, 2015, tax expenses (income) decreased by $19,000 from $2,000 of tax expenses for the three months ended June 30, 2014, to $17,000 of tax income during the same period in 2015.

Net Loss. Our net loss decreased by $3.7 million, or 48.7%, to $3.9 million for the three months ended June 30, 2015 from $7.6 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of $3.5 million in operating expenses primarily associated with research and development and sales and marketing expenses, due to our cost reduction/focused spending plan and a decrease of $0.2 million in gross loss (see above for explanation).

Six months ended June 30, 2015 compared to the six months ended June 30, 2014

Revenues. For the six months ended June 30, 2015, revenue decreased by $0.5 million, or 30.6%, to $1.2 million from $1.7 million during the same period in 2014. This decrease was predominately driven by a decrease in sales volume of MGuard™ Prime EPS of $0.5 million, or 31.7%, 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 to our distributors drove the remaining decrease of $0.2 million, or 12.5%, 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. These decreases, however, were partially offset by $0.2 million of sales of our new product CGuard™ EPS, which was launched in October 2014.

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, partially offset by an increase of $0.1 million in revenue from our distributors in Latin America.

Gross Profit (Loss). For the six months ended June 30, 2015, we had a gross loss (revenue less cost of revenues) of $0.2 million, as compared to a gross profit of $0.5 million during the same period in 2014, representing a decrease of 153.4%, or $0.7 million. This decrease in gross profit was attributable to a decrease in revenues of $0.5 million (see above for explanation), an increase of write-offs of inventory of $0.4 million, of which, $0.3 million related to the write-offs of MGuard™ Prime EPS units due to expected lower sales in the future resulting from industry preferences for drug eluting stents (as mentioned above), and our transition to a third party distributor commercial strategy, as well as $0.1 million in write-offs of CGuard™ EPS resulting from us transitioning to an RX delivery system from an over the wire platform, as well as an increase in labor and material costs of $0.1 million attributable to higher material and labor costs for CGuard™ EPS and an increase of $0.1 million related to underutilization of our manufacturing resources. These decreases, however, were partially offset by a decrease of $0.4 million in costs associated with the VFA (as mentioned above). Gross margin (gross profits as a percentage of revenue) decreased from 27.8% in the six months ended June 30, 2014 to (21.4)% in the same period in 2015. The decrease in gross margin of 49.2% was driven mainly by write-offs of inventory (see above for explanation), the change in product mix, including CGuard™ EPS, which has higher material and labor costs than MGuard™ Prime EPS, and a lower average sales price of MGuard™ Prime EPS due to the new commercial strategy built on using third party distributors.

Research and Development Expenses. For the six months ended June 30, 2015, research and development expenses decreased by 58.2%, or $2.9 million, to $2.1 million from $5.0 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of $2.2 million in clinical trial expenses associated with our MASTER II trial, $0.2 million is salaries, $0.3 million of expenses related to our stent retention program, which we concluded in 2014, $0.1 million in travel expenses and $0.2 million in miscellaneous expenses. These decreases in expenditures were results of our cost reduction/focused spending plan. These decreases were partially offset by an increase of $0.3 million in share based compensation expenses primarily related to the hiring of our chief operating officer. Research and development expenses as a percentage of revenue decreased to 180.6% for the six months ended June 30, 2015, from 300.0% in the same period in 2014.

Selling and Marketing Expenses. For the six months ended June 30, 2015, selling and marketing expenses decreased by 37.6%, or $1.2 million, to $2.0 million, from $3.2 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of $0.6 million in salaries and $0.1 million in share based compensation expenses as we realigned to a new commercial strategy built on using third party distributors for our products resulting in a reduced sales force, a decrease of $0.2 million in travel expenses associated with the decreased size of our sales force and a decrease of $0.3 million in expenditures related to the Euro PCR Congress in Paris, France, incurred in the same period in 2014. Selling and marketing expenses as a percentage of revenue decreased to 173.1% in the six months ended June 30, 2015 from 192.5% in the same period in 2014.

General and Administrative Expenses. For the six months ended June 30, 2015, general and administrative expenses decreased by 28.7%, or $1.4 million, to $3.6 million, from $5.0 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of $1.1 million in compensation due to lower salaries as part of our cost reduction/focused spending plan and the lower value of ESOP grants made to our management and directors, a reduction in litigation expenses of $0.2 million due to our probable settlement of a claim for less than we had previously estimated and a decrease of $0.1 million in miscellaneous expenditures. General and administrative expenses as a percentage of revenue increased to 306.1% in the six months ended June 30, 2015 from 297.7% in the same period in 2014.

Restructuring and impairment expenses. For the six months ended June 30, 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™ Prime EPS royalty buyout option due to anticipated lower sales in the future due to the shift in industry preferences away from bare metal stents in favor of drug eluting stents (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 six months ended June 30, 2015, financial expenses decreased by 14.9%, or $0.1 million, to $0.6 million from $0.7 million during the same period in 2014. The decrease in financial expenses resulted from a decrease of $0.1 of interest expenses. Financial expenses as a percentage of revenue increased to 54.0% in the six months ended June 30, 2015, from 44.1% in the same period in 2014.

Tax Expenses (Income). For the six months ended June 30, 2015, tax expenses (income) decreased by $23,000 from $22,000 of tax expenses for the six months ended June 30, 2014, to $1,000 of tax income during the same period in 2015.

Net Loss. Our net loss decreased by $4.4 million, or 32.8%, to $9.1 million for the six months ended June 30, 2015 from $13.5 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of $5.0 million in operating expenses primarily associated with research and development expenses, due to our cost reduction/focused spending plan (see above for explanation), and a decrease of $0.1 million in financial expenses, partially offset by a decrease of $0.7 million in gross profit (see above for explanation).

Liquidity and Capital Resources

We had an accumulated deficit as of June 30, 2015, 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 MGuard™ and CGuard™ products 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 for the next twelve months. Therefore, there is substantial doubt about our ability to continue as a going concern.

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.

Six months ended June 30, 2015 compared to the six months ended June 30, 2014

General. At June 30, 2015, we had cash and cash equivalents of $9.8 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 $7.0 million for the six months ended June 30, 2015 and $8.4 million for the same period in 2014. The principal reason for the usage of cash in our operating activities for the six months ended June 30, 2015 was a net loss of $9.1 million, as well as an increase in working capital of $0.5 million, offset by $2.0 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 royalty buyout option (discussed above), $0.2 million of non-cash financial expenses and $0.1 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the six months ended June 30, 2014 was a net loss of $13.5 million, offset by a decrease in working capital of $2.8 million, $2.1 million in non-cash share based compensation that was largely paid to our directors and chief executive officer, $0.1 million of non-cash financial expenses and $0.1 million of depreciation and amortization expenses.

Cash used in our investing activities was $2,000 during the six months ended June 30, 2015, compared to $65,000 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 $93,000 in the same period in 2014, as well as the funding of employee retirement funds of $1,000 in the six months ended June 30, 2015, as compared to $65,000 in the same period in 2014. These decreases in cashed used in investing activities were partially offset by a decrease in restricted cash of $93,000 in the six months ended June 30, 2014, which did not occur during the same period in 2015.

Cash provided by financing activities for the six months ended June 30, 2015 was $10.5 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 six months ended June 30, 2015 relates to funds received from the issuance of shares and warrants of approximately $12.4 million, offset by the repayment of a loan of $1.8 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 six months ended June 30, 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 June 30, 2015, our current assets exceeded our current liabilities by a multiple of 1.6. Current assets increased by $2.6 million during the period, mainly due to cash provided by financing offset by cash used in operations, and current liabilities decreased by $1.1 million during the period. As a result, our working capital surplus increased by $3.8 million to $4.7 million at June 30, 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.

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.

On July 22, 2015, the FASB issued Accounting Standards Update 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 (LIFO) and the retail inventory method (RIM) 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.

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 six months ended June 30, 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 June 30, 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 June 30, 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 June 30, 2015.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 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 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 June 30, 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:

Risks Related to Our Business

Our financial statements for the six months ended June 30, 2015 contain an explanatory paragraph in the footnotes that expresses substantial doubt as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to continue as a going concern. Such doubts regarding our ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

Risks Related to Our Organization and Our Common Stock

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 $12.4 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: August 5, 2015 By:/s/ Alan Milinazzo

Name: Alan Milinazzo

Title: President and Chief Executive Officer

Date: August 5, 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+	Third Amendment to Employment Agreement, dated June 29, 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 July 6, 2015)
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 June 30, 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.