

InspireMD, Inc.
Form 10-Q
August 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: June 30, 2017

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.

Exchange Act.]

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

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of August 8, 2017:
7,450,952

TABLE OF CONTENTS

	Page
<u>PART I</u>	
Item 1. <u>Financial Statements</u>	F-2
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	3
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	9
Item 4. <u>Controls and Procedures</u>	9
<u>PART II</u>	
Item 1. <u>Legal Proceedings</u>	10
Item 1A. <u>Risk Factors</u>	10
Item 5. <u>Other Information</u>	10
Item 6. <u>Exhibits</u>	10

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

June 30, 2017

TABLE OF CONTENTS

	Page
<u>Consolidated Balance Sheets</u>	F-2 - F- 3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to the Consolidated Financial Statements</u>	F-6 - F-12

The amounts are stated in U.S. dollars in thousands

F-1

PART I**Item 1. Financial statements****INSPIREMD, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)**

(U.S. dollars in thousands)

	June 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$6,879	\$ 7,516
Accounts receivable:		
Trade, net	451	356
Other	161	157
Prepaid expenses	73	65
Inventory	429	500
TOTAL CURRENT ASSETS	7,993	8,594
NON-CURRENT ASSETS:		
Property, plant and equipment, net	459	379
Funds in respect of employee rights upon retirement	430	399
Royalties buyout	25	38
TOTAL NON-CURRENT ASSETS	914	816
TOTAL ASSETS	\$8,907	\$ 9,410

INSPIREMD, INC.**CONSOLIDATED BALANCE SHEETS****(Unaudited)**

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

	June 30, 2017	December 31, 2016
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Current maturity of long-term loan	-	\$2,680
Accounts payable and accruals:		
Trade	473	618
Other	2,066	1,447
Advanced payment from customers	54	33
TOTAL CURRENT LIABILITIES	2,593	4,778
LONG-TERM LIABILITIES-		
Liability for employees rights upon retirement	572	587
TOTAL LONG-TERM LIABILITIES	572	587
COMMITMENTS AND CONTINGENT LIABILITIES (Note 10)		
TOTAL LIABILITIES	3,165	5,365
EQUITY:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at June 30, 2017 and December 31, 2016; 7,467,646 and 1,475,318 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at June 30, 2017 and December 31, 2016; 181,295 and 311,521 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at June 30, 2017; 745,775 shares issued and outstanding at June 30, 2017	-	-
Additional paid-in capital	142,508	135,959
Accumulated deficit	(136,767)	(131,914)
Total equity	5,742	4,045
<u>Total liabilities and equity</u>	<u>\$8,907</u>	<u>\$9,410</u>

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

F-3

INSPIREMD, INC.**CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2017	2016	2017	2016
REVENUES	\$640	\$540	\$1,209	\$1,103
COST OF REVENUES	493	478	988	975
GROSS PROFIT	147	62	221	128
OPERATING EXPENSES:				
Research and development	403	278	753	657
Selling and marketing	632	403	1,164	768
General and administrative	1,406	1,147	3,002	2,499
Total operating expenses	2,441	1,828	4,919	3,924
LOSS FROM OPERATIONS	(2,294)	(1,766)	(4,698)	(3,796)
FINANCIAL EXPENSES, net:				
Interest expenses	-	188	119	367
Other financial expenses	-	(8)	35	34
Total financial expenses	-	180	154	401
LOSS BEFORE TAX EXPENSES	(2,294)	(1,946)	(4,852)	(4,197)
TAX EXPENSES	-	-	1	1
NET LOSS	\$(2,294)	\$(1,946)	\$(4,853)	\$(4,198)
NET LOSS PER SHARE - basic and diluted	\$(0.21)	\$(4.56)	\$(0.73)	\$(11.21)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - Basic and diluted	10,983,402	426,976	7,484,399	374,330

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

INSPIREMD, INC.**CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

(U.S. dollars in thousands)

	Six months ended June 30,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(4,853)	\$(4,198)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	84	95
Loss from sale of property, plant and equipment	13	-
Change in liability for employees right upon retirement	(15)	(167)
Financial expenses	(514)	120
Share-based compensation expenses	484	633
Loss on amounts funded in respect of employee rights upon retirement, net	-	1
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	(8)	34
Increase in trade receivables	(95)	(27)
Decrease (increase) in other receivables	(4)	12
Decrease in inventory	71	366
Increase (decrease) in trade payables	(145)	686
Increase (decrease) in other payables and advance payment from customers	634	(214)
Net cash used in operating activities	(4,348)	(2,659)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(164)	(11)
Amounts (funded) gained in respect of employee rights upon retirement, net	(31)	121
Net cash provided by (used in) investing activities	(195)	110
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	-	(17)
Net proceeds from issuance of shares and warrants	6,072	1,520
Repayment of long-term loan	(2,179)	(1,323)
Net cash provided by financing activities	3,893	180
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	13	(3)
DECREASE IN CASH AND CASH EQUIVALENTS	(637)	(2,372)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	7,516	3,257
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$6,879	\$885
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Issuance costs		\$375
Warrant Liability		\$123

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

F-5

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the “Company”), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary 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, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, the Company announced the full market launch of CGuard EPS 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 June 30, 2017, as well as a history of 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™ EPS) 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 has sufficient resources to fund operations only for a period of up to 6 months from the date of issuing these interim consolidated financial statements. 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 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, 2016, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 16, 2017. The results of operations for the six and three months ended June 30, 2017 are not necessarily indicative of results that could be expected for the entire fiscal year.

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

(Unaudited)

NOTE 3 – RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

In March 2016, the FASB issued ASU 2016-09 – Improvements to Employee Share Based Payment Accounting 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. The Company adopted the update during the quarter ended 1) December 31, 2016, and has retroactively applied the guidance effective as of January 1, 2016. The Company elected to account for forfeitures as they occur rather than estimate expected forfeitures which resulted in a cumulative-effect adjustment to retained earnings as of the beginning of the comparative period, January 1, 2016, of \$457,000. Certain amounts or ratios presented herein for 2016 interim periods have been adjusted to reflect the adoption of this new guidance. Adoption of this update does not affect the Company's total equity. The following table summarizes the Company's As Reported and As Adjusted changes to the consolidated statement of operations for the six and three months periods ended June 30, 2016:

	3 Months Ended		6 Months Ended	
	June 30, 2016		June 30, 2016	
	As	As	As	As
	Reported	Adjusted	Reported	Adjusted
	(\$ in thousands)		(\$ in thousands)	
NET LOSS	\$(1,980)	\$(1,946)	\$(4,589)	\$(4,198)
NET LOSS PER SHARE - basic and diluted	\$(4.64)	\$(4.56)	\$(12.26)	\$(11.21)

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The new standard is effective for annual periods and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The Company is currently evaluating the impact of adopting this guidance. 2)

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

3) The FASB has issued the following standards that the Company has determined will not have a material impact on its consolidated financial statements upon their adoption:

In May 2014, the FASB issued Accounting Standards Codification (“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, 2017.

On July 22, 2015, the FASB issued ASU 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 was adopted by the Company during the first quarter of 2017. Prospective application is required.

In February 2016, the FASB issued ASU 2016-02, Leases, which requires to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The accounting standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted.

NOTE 4 - LONG-TERM LOAN:

On March 21, 2017, the Company paid the remaining balance under the Company’s Loan and Security Agreement, dated as of October 23, 2013, in consideration of \$1,159,000. All liens and other security interests granted by the Company and its subsidiaries in connection with the Loan and Security Agreement were terminated upon such payment.

NOTE 5 - EQUITY:

On March 14, 2017, the Company closed a public offering of 1,069,822 shares of Series C Convertible Preferred Stock, Series B warrants to purchase up to 4,279,288 shares of common stock and Series C warrants to purchase up to 4,279,288 shares of common stock (the "March 2017 Offering"). Each share of Series C Convertible Preferred Stock and the accompanying warrants were sold at a price of \$6.40. Each share of Series C Convertible Preferred Stock is convertible into 4 shares of common stock reflecting a conversion price equal to \$1.60 per share.

F-8

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

The Company received gross proceeds of approximately \$6.8 million from the offering, before deducting placement agent fees payable by the Company equal to 8.0% of the gross proceeds of the offering and a solicitation fee equal to 3.0% of the proceeds from the exercise of the Series C Warrants and offering expenses payable by the Company.

The holders of Series C Convertible Preferred Stock may elect to convert at anytime. The Series C Convertible Preferred Stock has certain anti-dilution provisions.

The Series B warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of \$2.00 per share of common stock.

The Series C warrants are exercisable immediately and have a term of exercise of six months from the date of issuance and have an exercise price of \$1.60 per share of common stock.

For accounting purposes, the Company analyzed the classification of the Series C Convertible Preferred Stock, including whether the embedded conversion options should be bifurcated. As the Series C Convertible Preferred Stock is not redeemable, and the host contract was determined to be akin to equity, the entire instrument was classified as equity.

The Company has also concluded that the warrants accompanying Series C Convertible Preferred Stock are classified as equity, since the warrants bear a fixed conversion ratio and all other criteria for equity classification have been met.

The Company's obligation to pay the placement agent a solicitation fee equal to 3.0% of the proceeds from the exercise of the Series C Warrants when and if the warrants are exercised is a financial liability, classified under "Other Payables" and reduced the amount from Additional Paid-in Capital.

During the 6 month period ended June 30, 2017, 324,047 shares of Series C Convertible Preferred Stock were converted into 1,296,188 shares of common stock.

Pursuant to the terms of the public offering of Series B Convertible Preferred Stock and accompanying warrants closed in July 2016, that provided the holders of the Series B Convertible Preferred Stock with certain anti-dilution protections, upon closing of the March 2017 offering, the conversion price of the Series B Convertible Preferred Stock was adjusted to \$1.60 per share of common stock, and each share of Series B Convertible Preferred Stock became convertible into 20.625 shares of common stock. The holders of Series B Convertible Preferred Stock are entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value for five years, payable in cash or common stock, at our discretion. As a result of such adjustment, the Company was required to issue to the holders of the Series B Convertible Preferred Stock an aggregate of 9,063,314 additional shares of common stock upon conversion of the Series B Convertible Preferred Stock and the payment of the dividends thereunder in common stock, based on 311,521 shares of Series B Convertible Preferred Stock outstanding as of March 8, 2017.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

During the 6 month period ended June 30, 2017, 130,226 shares of Series B Convertible Preferred Stock was converted into 4,700,345 shares of common stock.

b. As of June 30, 2017 the Company has authorized 155,000,000 shares of capital stock, par value \$0.0001 per share, of which 150,000,000 are shares of common stock and 3,328,000 are shares of “blank check” preferred stock.

NOTE 6- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period attributable to common stock (after adding the beneficial conversion feature included in the series C preferred shares) by the weighted average number of shares of common stock outstanding during the period, including 2,523,606 and 3,739,209 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the six and three month periods ended June 30, 2017, respectively (since they are convertible based on passage of time). The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, restricted stocks and placement agent unit as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Convertible Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 14,625,902 for the six and three month periods ended June 30, 2017.

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 323,753 for the six and three month periods ended June 30, 2016.

NOTE 7 - FAIR VALUE MEASUREMENT

Fair value of financial instruments

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.

As of June 30, 2017 and December 31, 2016, allowance for doubtful accounts was \$70,000 and \$336,000, respectively, with the decrease resulting primarily from bad debt write offs.

NOTE 8 - INVENTORY:

	June 30, 2017	December 31, 2016
	(\$ in thousands)	
Finished goods	\$ 113	\$ 83
Work in process	93	233
Raw materials and supplies	223	184
	\$ 429	\$ 500

F-10

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

(Unaudited)

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	June 30, 2017	December 31, 2016
	(\$ in thousands)	
Employees and employee institutions	\$878	\$ 357
Accrued vacation and recreation pay	156	137
Accrued clinical trial expenses	498	467
Accrued expenses	437	430
Provision for sales commissions	97	56
	\$2,066	\$ 1,447

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:**Litigation:**

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 there is a reasonably possible likelihood of a loss from any related future proceedings that would range from a minimal amount up to 1,075,000 Euros.

On April 26, 2016, the Company received 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. 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.

In July 2016, a service provider filed a suit seeking damages from the Company's subsidiary amounting to \$1,967,822. 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.

F-11

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

(Unaudited)

NOTE 11 - ENTITY WIDE DISCLOSURES:

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	(\$ in thousands)		(\$ in thousands)	
Germany	\$ 133	\$ 163	\$ 235	\$ 323
Italy	132	165	233	320
Belarus	85	3	90	23
Middle East	20	55	35	78
Other	270	154	616	359
	\$ 640	\$ 540	\$ 1,209	\$ 1,103

By product:

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	(\$ in thousands)		(\$ in thousands)	
CGuard	\$ 430	\$ 355	\$ 789	\$ 675
MGuard	210	185	420	428
	\$ 640	\$ 540	\$ 1,209	\$ 1,103

By principal customers:

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Customer A	18%	0 %	9 %	0 %
Customer B	11%	24 %	11%	21 %
Customer C	10%	6 %	8 %	7 %
Customer D	3 %	10 %	3 %	7 %
Customer E	0 %	26 %	5 %	24 %

All tangible long lived assets are located in Israel.

F-12

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

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

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

Forward-Looking Statements

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

our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;

our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;

our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;

our ability to adequately protect our intellectual property;

our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

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

market acceptance of our 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;

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;

inability to carry out research, development and commercialization plans;

loss of a key customer or supplier;

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

product malfunctions;

price increases for supplies and components;

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;

adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;

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, 2016, 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 MicroNet 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. Subsequently, we launched CGuard EPS in Argentina, Colombia and Russia.

Our 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). MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent and, together with our first generation MGuard stent combining MicroNet with a bare-metal stainless steel stent, unless otherwise indicated, we refer to both kinds of bare-metal stents as our MGuard coronary products. We market and sell MGuard Prime EPS 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, MGuard DES™. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter (“NGuard”), 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 completed initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models. However, as we plan to focus our resources on the further expansion of our sales and marketing activities for CGuard EPS and MGuard Prime EPS and, provided that we have sufficient resources, the development of CGuard EPS with a smaller delivery catheter (5 French gauge) and its submission for CE mark approval, we do not intend to resume further development of NGuard until at least the third quarter of 2018.

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.

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, 2016. There have not been any material changes to such critical accounting policies since December 31, 2016.

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 June 30, 2017 compared to the three months ended June 30, 2016

Revenues. For the three months ended June 30, 2017, revenue increased by \$100,000, or 18.5%, to \$640,000 from \$540,000 during the three months ended June 30, 2016. This increase was predominantly driven by a 21.1% increase in sales of CGuard EPS from \$355,000 in the three months ended June 30, 2016, to \$430,000 in the three months ended June 30, 2017 as we transitioned from our prior exclusive distribution partner for most of Europe to local distributors in an effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well as our expansion into new geographies such as Russia. In addition to the increase in sales of CGuard EPS, revenue from sales of MGuard EPS increased by 13.5% from \$185,000 in the three months ended June 30, 2016, to \$210,000 in the three months ended June 30, 2017,

due to a relatively large tender won in Belarus, one of our MGuard EPS countries.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$76,000 in revenue from sales of CGuard EPS from our distributors in Europe, an increase of \$33,000 in revenue from sales of MGuard Prime EPS in Latin America and an increase of \$17,000 in revenue from sales of MGuard Prime EPS from our distributors in Europe, partially offset by a decrease of \$25,000 in revenue from sales of MGuard Prime EPS from our distributors in the Middle East.

Gross Profit. For the three months ended June 30, 2017, gross profit (revenue less cost of revenues) increased by 137.1%, or \$85,000, to \$147,000, compared to \$62,000 during the same period in 2016. The increase in gross profit resulted primarily from an increase of \$100,000 in revenues (as mentioned above), a decrease in write-offs of inventory of MGuard Prime EPS of \$43,000 and a decrease of miscellaneous expenses of \$10,000. These increases in gross profit were partially offset by an increase in material and labor costs of \$68,000, which resulted from our increase in sales. Gross margin (gross profits as a percentage of revenue) increased to 23.0% in the three months ended June 30, 2017 from 11.5% in the three months ended June 30, 2016.

Research and Development Expenses. For the three months ended June 30, 2017, research and development expenses increased by 45.0%, or \$125,000, to \$403,000, from \$278,000 during the three months ended June 30, 2016. This increase in research and development expenses resulted primarily from an increase of \$76,000 in salary expenses in the three months ended June 30, 2017, compared to the same period in 2016, due to the replacement of our former vice president of research and development who resigned in March 2016, not occurring until after June 30, 2016, lowering our expenses in the three months ended June 30, 2016, as well as a non-cash salary related accrual adjustment in 2017, and an increase of \$64,000 in development and clinical expenses associated with CGuard EPS primarily for our pre-IDE submission meeting with the U.S. Food and Drug Administration (“FDA”). This increase was partially offset by a decrease of \$15,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended June 30, 2017, selling and marketing expenses increased by 56.8%, or \$229,000, to \$632,000, from \$403,000 during the three months ended June 30, 2016. This increase in selling and marketing expenses resulted primarily from an increase of \$89,000 in salary expenses, an increase of \$56,000 in travel expenses, an increase of \$30,000 in expenditures related to our participation in trade shows and promotional activities and an increase of \$54,000 in miscellaneous expenses. The increase in selling and marketing expenses was primarily to support the CGuard EPS sales and marketing related activities as we transitioned away from our prior exclusive distribution partner for most of Europe to using local distributors.

General and Administrative Expenses. For the three months ended June 30, 2017, general and administrative expenses increased by 22.6%, or \$259,000, to \$1,406,000, from \$1,147,000 during the three months ended June 30, 2016. The increase in general and administrative expenses resulted primarily from an increase of \$264,000 in compensation expenses, primarily due to a non-cash compensation accrual adjustment as well as the equity grants to our chief executive officer in July and August 2016 which vest over one year, rather than the usual three years, resulting in a higher than usual quarterly compensation expense. This increase in general and administrative expenses was partially offset by a decrease of \$5,000 in miscellaneous expenses.

Financial Expenses. For the three months ended June 30, 2017, financial expenses decreased by 100% or \$180,000, to \$0, from \$180,000 during the three months ended June 30, 2016. The decrease in financial expenses resulted from a decrease in interest expenses due to the repayment of the remaining balance of our outstanding indebtedness of \$1.2 million prior to the beginning of the three months ended June 30, 2017.

Tax Expenses (Income). For the three months ended June 30, 2017, there was no material change in tax expenses (income) compared to the same period in 2016.

Net Loss. Our net loss increased by \$348,000, or 17.9%, to \$2,294,000 for the three months ended June 30, 2017, from \$1,946,000 during the three months ended June 30, 2016. The increase in net loss resulted primarily from an increase of \$613,000 in operating expenses, partially offset by a decrease of \$180,000 in financial expenses and an increase of \$85,000 in gross profit.

Six months ended June 30, 2017 compared to the six months ended June 30, 2016

Revenues. For the six months ended June 30, 2017, revenue increased by \$106,000, or 9.6%, to \$1,209,000, from \$1,103,000 during the six months ended June 30, 2016. This increase was predominantly driven by a 16.8% increase in sales of CGuard EPS from \$675,000 in the six months ended June 30, 2016, to \$789,000 in the six months ended June 30, 2017, as we entered new regional markets as well as transitioned from our prior exclusive distribution partner for most of Europe to local distributors in our effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists. This increase in sales of CGuard EPS was partially offset by a 1.9% decrease in sales of MGuard Prime EPS from \$428,000 in the six months ended June 30, 2016, to \$420,000 in the six months ended June 30, 2017, largely driven by doctors increasingly using drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$146,000 in revenue from sales of MGuard Prime EPS from our distributors in Latin America and an increase of \$100,000 in revenue from sales of CGuard EPS from our distributors in Europe, partially offset by a decrease of \$117,000 in revenue from sales of MGuard Prime EPS from our distributors in Europe and a decrease of \$37,000 in revenue from sales of MGuard Prime EPS from our distributors in the Middle East.

Gross Profit. For the six months ended June 30, 2017, gross profit (revenue less cost of revenues) increased by 72.7%, or \$93,000, to \$221,000, compared to \$128,000 during the same period in 2016. The increase in gross profit resulted primarily from an increase of \$106,000 in revenues (as mentioned above) and a decrease in write-offs of inventory of MGuard Prime EPS of \$70,000. These increases in gross profit were partially offset by an increase in material and labor costs of \$79,000, which resulted from our increase in sales and an increase of miscellaneous expenses of \$4,000. Gross margin (gross profits as a percentage of revenue) increased to 18.3% in the six months ended June 30, 2017 from 11.6% in the six months ended June 30, 2016.

Research and Development Expenses. For the six months ended June 30, 2017, research and development expenses increased by 14.6%, or \$96,000, to \$753,000, from \$657,000 during the six months ended June 30, 2016. This increase in research and development expenses resulted primarily from an increase of \$139,000 in salary expenses primarily due to the resignation and timing of the replacement of our former vice president of research and development who resigned on March 10, 2016, lowering our expenses in the six months ended June 30, 2016. In addition to the increase in salary expenses, the increase in research and development expenses for the six months ended June 30, 2017, compared to the same period in 2016 resulted from an increase of \$108,000 in development and clinical expenses associated with CGuard EPS, primarily due to our pre-IDE meeting with the FDA, and an increase of \$19,000 in miscellaneous expenses. This increase however, was partially offset by a decrease of \$170,000 in share-based compensation expenses due to the recognition of all remaining unrecognized costs following the option cancellation agreement with our chief executive officer in 2016 while he was our chief operating officer, resulting in higher share-based compensation expenses in 2016.

Selling and Marketing Expenses. For the six months ended June 30, 2017, selling and marketing expenses increased by 51.6%, or \$396,000, to \$1,164,000, from \$768,000 during the six months ended June 30, 2016. This increase in selling and marketing expenses resulted primarily from an increase of \$100,000 in consulting fees, an increase of \$82,000 in travel expenses, an increase of \$78,000 in share-based compensation expenses due to a former employee's forfeiture of the former employee's share-based compensation in 2016, reducing our 2016 share-based compensation expenses, for which, no such reduction occurred during 2017, an increase of \$74,000 in expenditures related to our participation in trade shows and promotional activities and an increase of \$69,000 in salary expenses. These increases were partially offset by a decrease of \$7,000 in miscellaneous expenses. The increase in selling and marketing expenses was primarily to support the new sales and marketing CGuard EPS related activities due to the transition from our prior exclusive distribution partner for most of Europe to local distributors.

General and Administrative Expenses. For the six months ended June 30, 2017, general and administrative expenses increased by 20.1%, or \$503,000, to \$3,002,000, from \$2,499,000 during the six months ended June 30, 2016. The increase in general and administrative expenses resulted primarily from an increase of \$169,000 in non-cash salary expense accrual, an increase of \$113,000 in rent and related expense, primarily due to a city tax refund we received in 2016, which reduced our 2016 rent and related expenses, while no such refund was received in 2017, as well as a termination fee for our Boston office in the six months ended June 30, 2017, which increased our rent and related expenses, an increase of \$69,000 in legal expenses and an increase of \$152,000 in miscellaneous expenses.

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

Financial Expenses. For the six months ended June 30, 2017, financial expenses decreased by 61.6%, or \$247,000, to \$154,000, from \$401,000 during the six months ended June 30, 2016. The decrease in financial expenses primarily resulted from a decrease in interest expenses due to the repayment of the remaining balance of our outstanding indebtedness of \$1.2 million prior to the beginning of the three months ended June 30, 2017.

Tax Expenses (Income). For the six months ended June 30, 2017, there was no material change in tax expenses (income) compared to the same period in 2016.

Net Loss. Our net loss increased by \$655,000, or 15.6%, to \$4,853,000 for the six months ended June 30, 2017, from \$4,198,000 during the six months ended June 30, 2016. The increase in net loss resulted primarily from an increase of \$995,000 in operating expenses, partially offset by a decrease of \$247,000 in financial expenses and an increase of \$93,000 in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of June 30, 2017, of \$137 million, as well as a net loss of \$4,853,000 and negative operating cash flows. 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 only have sufficient resources to fund operations for a period of up to six months from the date of filing of this Quarterly Report on Form 10-Q. 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.

On March 14, 2017, we announced the closing of a “best efforts” public offering of Series C Convertible Preferred Stock, Series B warrants to purchase shares of common stock and Series C warrants to purchase shares of common stock. We received gross proceeds of approximately \$6.8 million from the offering, before deducting placement agent fees and offering expenses.

On March 21, 2017, we paid down the remaining \$1.2 million balance under our Loan and Security Agreement (the “Loan Agreement”), dated as of October 23, 2013, with Hercules Technology Growth Capital, Inc. (“Hercules”). All liens and other security interests granted to Hercules by us and our subsidiaries in connection with the Loan Agreement were terminated upon such payment.

Six months ended June 30, 2017 compared to the six months ended June 30, 2016

General. At June 30, 2017, we had cash and cash equivalents of \$6,879,000, as compared to \$7,516,000 as of December 31, 2016. 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 costs, capital expenditures and general working capital.

For the six months ended June 30, 2017, net cash used in our operating activities increased \$1,689,000 to \$4,348,000, from \$2,659,000 in the same period in 2016. The primary reason for the increase in cash used in our operating activities was an increase of payments for third party related expenses and for professional services of \$1,742,000

including the end of term charge of \$520,000 to Hercules, from \$1,748,000 to \$3,490,000, as well as an increase of \$39,000 in salary payments from \$1,985,000 in the six months ended June 30, 2016 to \$2,024,000 in the same period in 2017. These increase in cash used in operating activities were partially offset by an increase of \$92,000 in payments received from customers from \$1,074,000 in the six months ended June 30, 2016 to \$1,166,000 in the same period in 2017.

Cash used by our investing activities was \$195,000 during the six months ended June 30, 2017, resulting primarily from the purchase of production equipment, compared to \$110,000 of cash provided during the same period in 2016 resulting primarily from the receipt of cash previously funded to employee retirement funds.

Cash provided by financing activities for the six months ended June 30, 2017 was \$3,893,000, compared to \$180,000 during the same period in 2016. The principal source of the cash provided by financing activities during the six months ended June 30, 2017, was the funds received from our March 2017 public offering of preferred stock and warrants that resulted in approximately \$6,072,000 of aggregate net proceeds, offset by loan repayments of \$2,179,000. The principal source of the cash provided by financing activities during the six months ended June 30, 2016 was the issuance of shares and warrants in a concurrent public offering and private placement for approximately \$1,520,000 of proceeds, offset by loan repayments of \$1,323,000.

As of June 30, 2017, our current assets exceeded our current liabilities by a multiple of 3.1. Current assets decreased by \$601,000 during the period and current liabilities decreased by \$2,185,000 during the period. As a result, our working capital increased by \$1,584,000 to \$5,400,000 million at June 30, 2017.

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, 2016, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

Contractual Obligations and Commitments

During the six months ended June 30, 2017, 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 June 30, 2017, 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, 2017.

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, 2017, 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.

On April 26, 2016, Microbanc, LLC and Todd Spenla of Microbanc, LLC filed suit in the New York State Supreme Court (New York County) against us asserting claims for breach of agreement, quantum meruit, unjust enrichment and fraud and seeking approximately \$2.2 million and 9% of the amount of stock and warrants sold in 2011 and 2012 in alleged damages relating to certain alleged finders' fees that they claim are owed. We removed the suit to federal court and filed a motion to dismiss all claims on June 30, 2016. By Order dated February 23, 2017, the U.S. District Court for the Southern District of New York granted our motion to dismiss the suit in its entirety. Microbanc, LLC and Todd Spenla had until March 16, 2017, to file a motion for application for leave to replead its claims for breach of contract. On March 16, 2017, Microbanc, LLC filed a motion for leave to file an amended complaint to replead all claims and to substitute Estate of Todd Spenla for the deceased plaintiff, Todd Spenla. We have opposed this motion, which remains pending before the district court. On April 14, 2017, James D. Burchetta filed a motion to intervene as a plaintiff. On April 19, 2017, the court granted our request for an adjournment of this motion to intervene, pending resolution of Microbanc, LLC's motion for leave to file the amended complaint and to substitute the Estate of Todd Spenla for the deceased plaintiff, Todd Spenla. We intend to contest the matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

On July 12, 2016, Medpace Inc., a former service provider, filed suit with the Court of Common Pleas, Hamilton County, Ohio, against us asserting that we breached a master services agreement with Medpace Inc. by failing to pay Medpace Inc. certain fees purportedly owed to it in connection with Medpace Inc.'s provision of certain clinical development program services to Inspire Ltd. We have removed the suit to the U.S. District Court for the Southern District of Ohio. Since removal, Medpace Inc. has amended its complaint to name InspireMD Ltd., our wholly owned subsidiary, as the only defendant. Medpace Inc. is seeking \$1,967,822 in damages plus interest, costs, attorneys' fees and expenses against InspireMD Ltd. InspireMD Ltd. filed a motion to dismiss all claims on February 10, 2017. On May 17, 2017, the district court denied InspireMD's motion to dismiss, but ordered Medpace Inc. to file a second amended complaint by June 5, 2017. Medpace Inc. filed a second amended complaint on June 5, 2017, and InspireMD again moved to dismiss all claims on June 19, 2017. That motion is fully briefed and awaits resolution in the district court. InspireMD Ltd. intends to contest this matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that InspireMD Ltd. will prevail on any claims made against InspireMD Ltd. in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

Item 1A. Risk Factors

During the fiscal quarter ended June 30, 2017, there were no material changes to the risk factors disclosed in Part I, Item 1A of the Annual Report on Form 10-K for the year ended December 31, 2016, under the heading “Risk Factors” other than the description of risk factors set forth in Part II, Item 1A of the Quarterly Report on Form 10-Q for the period ended March 31, 2017. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

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 8, 2017 By: */s/ James Barry, Ph.D.*

Name: James Barry, Ph.D

Title: President and Chief Executive Officer

Date: August 8, 2017 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)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.5 to the Quarterly Report on Form 10-Q filed on August 9, 2016)
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)
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)
4.3	Form of Series B Warrant Agent Agreement and Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Amendment No.3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2017)
4.4	Form of Series C Warrant Agent Agreement and Form of Series C Warrant (incorporated by reference to Exhibit 4.4 to Amendment No.3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2017)
10.1	First Amendment to Nonqualified Stock Option Agreement dated November 16, 2011, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 2, 2017)

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

10.2 First Amendment to Nonqualified Stock Option Agreement dated March 31, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on June 2, 2017)

10.3 First Amendment to Nonqualified Stock Option Agreement dated June 30, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on June 2, 2017)

10.4 First Amendment to Nonqualified Stock Option Agreement dated September 30, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on June 2, 2017)

10.5 First Amendment to Nonqualified Stock Option Agreement dated June 30, 2016, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on June 2, 2017)

10.6 First Amendment to Nonqualified Stock Option Agreement dated December 7, 2016, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on June 2, 2017)

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, 2017, 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.

