INSPIREMD, INC.

FORM 10-Q
(Quarterly Report)

Filed 05/09/17 for the Period Ending 03/31/17

Telephone	(888) 776-6804
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Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: March 31, 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.
(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.)

4 Menorat Hamaor St.
Tel Aviv, Israel 6744832
(Address of principal executive offices)
(Zip Code)

(888) 776-6204
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	(Do not check if a smaller reporting company)
Smaller reporting company [X]	Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the 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 [X]

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of May 9, 2017: 7,421,846

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INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

March 31, 2017

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

PART I

Item 1. Financial statements

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	March 31, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 8,572	$ 7,516
Accounts receivable:		
Trade, net	471	356
Other	189	157
Prepaid expenses	21	65
Inventory	329	500
TOTAL CURRENT ASSETS	9,582	8,594
NON-CURRENT ASSETS:		
Property, plant and equipment, net	496	379
Fund in respect of employee rights upon retirement	402	399
Royalties buyout	32	38
TOTAL NON-CURRENT ASSETS	930	816
TOTAL ASSETS	$ 10,512	$ 9,410

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands other than share and per share data)

	March 31, 2017	December 31, 2016
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Current maturity of long-term loan	$ -	$ 2,680
Accounts payable and accruals:		
Trade	351	618
Other	1,884	1,447
Advanced payment from customers	23	33
TOTAL CURRENT LIABILITIES	2,258	4,778
LONG-TERM LIABILITIES-		
Liability for employees rights upon retirement	540	587
TOTAL LONG-TERM LIABILITIES	540	587
COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)		
TOTAL LIABILITIES	2,798	5,365
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 and 50,000,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 6,830,070 and 1,475,318 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	1	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 191,993 and 311,521 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2017 and December 31, 2016, respectively; 808,612 and 0 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	-	-
Additional paid-in capital	142,186	135,959
Accumulated deficit	(134,473)	(131,914)
Total equity	7,714	4,045
Total liabilities and equity	$ 10,512	$ 9,410

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

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Three months ended March 31,	
	2017	**2016**
REVENUES	$ 569	$ 563
COST OF REVENUES	495	497
GROSS PROFIT	74	66
OPERATING EXPENSES:		
Research and development	350	379
Selling and marketing	532	365
General and administrative	1,596	1,352
Total operating expenses	2,478	2,096
LOSS FROM OPERATIONS	(2,404)	(2,030)
FINANCIAL EXPENSES, net:		
Interest expenses	119	179
Other financial expenses	35	42
Total financial expenses	154	221
LOSS BEFORE TAX EXPENSES	(2,558)	(2,251)
TAX EXPENSES	1	1
NET LOSS	$ (2,559)	$ (2,252)
NET LOSS PER SHARE - basic and diluted	$ (0.81)	$ (7.00)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	3,946,434	321,684

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

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Three months ended March 31,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,559)	$ (2,252)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	42	48
Change in liability for employees right upon retirement	(47)	(122)
Financial expenses	(488)	33
Share-based compensation expenses	263	384
Loss on amounts funded in respect of employee rights upon retirement, net		1
Changes in operating asset and liability items:		
Decrease in prepaid expenses	44	13
Increase in trade receivables	(115)	(141)
Increase in other receivables	(32)	(62)
Decrease in inventory	171	242
Decrease in trade payables	(267)	(59)
Increase in other payables and advance payment from customers	230	50
Net cash used in operating activities	(2,758)	(1,865)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(153)	
Amounts (funded) gained in respect of employee rights upon retirement, net	(3)	90
Net cash provided by (used in) investing activities	(156)	90
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance		(16)
Proceeds from issuance of shares and warrants, net of $issuance costs	6,162	1,520
Repayment of long-term loan	(2,179)	(988)
Net cash provided by financing activities	3,983	516
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(13)	1
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,056	(1,258)
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	$ 8,572	$ 1,999
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Placement Agent Fees in connection with short term warrants, see also note 5a	$ 107	
Issuance costs	$ 90	

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

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 March 31, 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 eight 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 three months ended March 31, 2017 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 – RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

1) 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. The Company expects that the adoption of this standard will not have a material impact on its consolidated financial statements.

2) 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 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. The adoption of this standard did not have a material impact on the consolidated financial statements.

3) In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230) Restricted Cash". The new guidance requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include restricted cash and restricted cash equivalents. If restricted cash is presented separately from cash and cash equivalents on the balance sheet, companies will be required to reconcile the amounts presented on the statement of cash flows to the amounts on the balance sheet. Companies will also need to disclose information about the nature of the restrictions. The guidance is effective for annual and interim reporting periods beginning after December 15, 2017, and early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

4) In August 2016, the FASB issued ASU No. 2016-15 "Statement of Cash Flows Topic 230: Classification of Certain Cash Receipts and Cash Payments." ASU No. 2016-15 issued guidance to clarify how certain cash receipts and cash payments should be presented in the statement of cash flows. ASU 2016-15 is effective for annual and interim reporting periods beginning on or after December 15, 2017 and early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

5) 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.

6) 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. The Company expects that the adoption of this standard will not have a material impact on its consolidated financial statements.

7) 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 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 three months ended March 31, 2016:

	3 Months Ended March 31, 2016	
	As Reported	As Adjusted
	($ in thousands)	
NET LOSS	$ (2,609)	$ (2,252)
NET LOSS PER SHARE - basic and diluted	$ (8.11)	$ (7.00)

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:

a. 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.

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 will be exercised is a financial liability, classified under "Other Payables" and reduced the amount from Additional Paid-in Capital.

During the 3 month period ended March 31, 2017, 261,210 shares of Series C Convertible Preferred Stock were converted into 1,044,840 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 is 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.

During the three month period ended March 31, 2017, 119,528 shares of Series B Convertible Preferred Stock was converted into 4,314,214 shares of common stock.

b. As of March 31, 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 Convertible Preferred Stock) by the weighted average number of shares of common stock outstanding during the period, including 1,370,883 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the three month periods ended March 31, 2017 (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 14,900,945 and 236,537 for the three month period ended March 31, 2017 and 2016, respectively.

NOTE 7 - FAIR VALUE MEASURMENT

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 March 31, 2017 and December 31, 2016, allowance for doubtful accounts was $71,000 and $336,000, respectively, with the decrease resulting primarily from bad debt write offs.

NOTE 8 - INVENTORY:

	March 31, 2017	December 31, 2016
	($ in thousands)	
Finished goods	$ 109	$ 83
Work in process	97	233
Raw materials and supplies	123	184
	$ 329	$ 500

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2017	December 31, 2016
	($ in thousands)	
Employees and employee institutions	$ 459	$ 357
Accrued vacation and recreation pay	141	137
Accrued clinical trial expenses	452	467
Accrued expenses	767	430
Provision for sales commissions	65	56
	$ 1,884	$ 1,447

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

a. 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.

NOTE 12 - 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 March 31,	
	2017	**2016**
	($ in thousands)	
Germany	$ 102	$ 160
Italy	101	155
Argentina	75	13
Russia	63	-
Spain	29	63
Other	199	172
	$ 569	$ 563

By product:

	Three months ended March 31,	
	2017	**2016**
	($ in thousands)	
CGuard	$ 359	$ 320
MGuard*	210	243
	$ 569	$ 563

By principal customers:

	Three months ended March 31,	
	2017	**2016**
Customer A	13%	2%
Customer B	12%	17%
Customer C	11%	22%
Customer D	11%	0%
Customer E	5%	11%

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," "plans," "believes," "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. If we receive sufficient proceeds from the exercise of our six-month warrants to purchase common stock at an exercise price of $1.60 per share of common stock (the "Series C warrants") sold in a public offering in March 2017, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval within three calendar quarters of receiving such proceeds. We believe that CGuard EPS with a smaller delivery catheter will enable us to meet the market demand for minimally invasive devices, have a competitive advantage in penetrating the Asia Pacific market and offer our product for transradial catheterization, which, we believe, is gaining favor among interventionalists. We cannot give any assurance that we will receive sufficient (or any) proceeds from the exercise of the Series C warrants or the timing of receipt of such proceeds, if ever. We cannot predict when or if the Series C warrants will be exercised. It is possible that the Series C warrants may expire and may never be exercised.

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.

Recent Events

On March 14, 2017, we closed a "best efforts" public offering of 1,069,822 shares of Series C Convertible Preferred Stock, Series B warrants to purchase 4,279,288 shares of common stock and Series C warrants to purchase 4,279,288 shares of common stock. Each share of Series C Convertible Preferred Stock is initially convertible into 4 shares of common stock at a conversion price equal to $1.60 per share. 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 be 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. We received gross proceeds of approximately $6.8 million from the offering, before deducting placement agent fees and offering expenses.

Critical Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 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 March 31, 2017 compared to the three months ended March 31, 2016

Revenues . For the three months ended March 31, 2017, revenue increased by $6,000, or 1.0%, to $569,000 from $563,000 during the three months ended March 31, 2016. This increase was predominantly driven by a 12.1% increase in sales of CGuard EPS from $320,000 in 2016 to $359,000 in 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 an effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well. This increase in sales of CGuard EPS was partially offset by a 13.5% decrease in sales of MGuard Prime EPS from $243,000 in the three months ended March 31, 2016, to $210,000 in the three months ended March 31, 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 $113,000 in revenue from sales of MGuard Prime EPS from our distributors in Latin America and an increase of $25,000 in revenue from sales of CGuard EPS from our distributors in Europe, partially offset by a decrease of $134,000 in revenue from sales of MGuard Prime EPS from our distributors in Europe.

Gross Profit (Loss) . For the three months ended March 31, 2017, gross profit (revenue less cost of revenues) remained relatively flat at $74,000 compared to $66,000 during the three months ended March 31, 2016. Gross margin (gross profits as a percentage of revenue) increased to 13.0% in the three months ended March 31, 2017 from 11.7% during 2016.

Research and Development Expenses . For the three months ended March 31, 2017, research and development expenses decreased by 7.7%, or $29,000, to $350,000, from $379,000 during the three months ended March 31, 2016. This decrease in research and development expenses resulted primarily from a decrease of $152,000 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 expenses. This decrease in research and development expenses was partially offset by an increase of $63,000 in salary expenses, an increase of $45,000 in development and clinical expenses associated with CGuard EPS and an increase of $15,000 in miscellaneous expenses.

Selling and Marketing Expenses . For the three months ended March 31, 2017, selling and marketing expenses increased by 45.8%, or $167,000, to $532,000, from $365,000 during the three months ended March 31, 2016. This increase in selling and marketing expenses resulted primarily from an increase of $72,000 in share based compensation expenses, due to the forfeiture of a 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 $44,000 in in expenditures related to our participation in trade shows and promotional activities and an increase of $51,000 in miscellaneous expenses. The increase in expenses related to our participation in trade shows and promotional activities, as well as miscellaneous expenses, were primarily to support the commercialization of CGuard EPS.

General and Administrative Expenses . For the three months ended March 31, 2017, general and administrative expenses increased by 18.0%, or $244,000 to $1,596,000, from $1,352,000 during the three months ended March 31, 2016. The increase in general and administrative expenses resulted primarily from an increase of $107,000 in legal expenses, an increase of $74,000 in rent and related expense, primarily due to a city tax refund we received in 2016, reducing our 2016 rent and related expenses, for which, no such refund was received in 2017, as well as a termination fee for our Boston offices in the three months ended March 31, 2017, which increased our expenses, an increase of $55,000 in NYSE MKT fees, due to fees associated with listing of Series C warrants in 2017, and an increase of $8,000 in miscellaneous expenses.

Financial Expenses . For the three months ended March 31, 2017, financial expenses decreased by 30.3% or $67,000, to $154,000, from $221,000 during the three months ended March 31, 2016. The decrease in financial expenses primarily resulted from a decrease in interest expenses due to the reduction in principal of our outstanding indebtedness.

Tax Expenses (Income). For the three months ended March 31, 2017, there was no material change in tax expenses (income) compared to the same period in 2016.

Net Loss . Our net loss increased by $307,000, or 13.6%, to $2,559,000 for the three months ended March 31, 2017, from $2,252,000 during the three months ended March 31, 2016. The increase in net loss resulted primarily from an increase of $382,000 in operating expenses, partially offset by a decrease of $67,000 in financial expenses and an increase of $8,000 in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of March 31, 2017 of $134 million, as well as a net loss of $2,559,000 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 eight months from the date of filing of this Quarterly Report on Form 10-Q.

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.

Three months ended March 31, 2017 compared to the three months ended March 31, 2016

General . At March 31, 2017, we had cash and cash equivalents of $8,572,000, 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 cost, capital expenditures and general working capital.

For the three months ended March 31, 2017, net cash used in our operating activities increased $893,000 to $2,758,000, from $1,865,000 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 $906,000 including the end of term charge of $520,000 to Hercules, from $1,283,000 to $2,189,000, as well as an increase of $30,000 in salary payments from $1,000,000 in the three months ended March 31, 2016 to $1,030,000 in the same period in 2017. These increase in cash used in operating activities were partially offset by an increase of $43,000 in payments received from customers from $418,000 in the three months ended March 31, 2016 to $461,000 in the same period in 2017.

Cash used by our investing activities was $156,000 during the three months ended March 31, 2017, resulting primarily from the purchase of production equipment, compared to $90,000 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 three months ended March 31, 2017 was $3,983,000, compared to $516,000 during the same period in 2016. The principal source of the cash provided by financing activities during the three months ended March 31, 2017, was the funds received from our March 2017 public offering of preferred stock and warrants that resulted in approximately $6,162,000 of aggregate net proceeds, offset by loan repayments of $2,179,000. The principal source of the cash provided by financing activities during the three months ended March 31, 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 $988,000.

As of March 31, 2017, our current assets exceeded our current liabilities by a multiple of 4.2. Current assets increased by $988,000 during the period and current liabilities decreased by $2,520,000 during the period. As a result, our working capital increased by $3,508,000 to $7,324,000 million at March 31, 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 three months ended March 31, 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 March 31, 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 March 31, 2017.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 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. The motion to dismiss 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

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with our business previously 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." 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.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Form 10-Q. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-Q.

Risks Related to Our Business

We have a history of net losses and may experience future losses.

We have yet to establish any history of profitable operations. We reported a net loss of $8.5 million for the fiscal year ended December 31, 2016 and had a net loss of approximately $15.6 million during the fiscal year ended December 31, 2015. As of March 31, 2017, we had an accumulated deficit of $134 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

The report of our independent registered public accounting firm contains an explanatory paragraph 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, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, the report of Kesselman & Kesselman, our independent registered public accounting firm, with respect to our financial statements for the year ended December 31, 2016, includes an explanatory paragraph as to our potential inability to continue as a going concern. The doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

We will 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 our stockholders' ownership interests.

The net proceeds from the offering of our shares of Series C Convertible Preferred Stock and accompanying six-month and five-year warrants that closed on March 14, 2017, will only be sufficient to enable us to continue operations for a short period of time. In order to fully realize all of our business objectives, we will need to raise additional capital, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- development of our current and future products, including CGuard EPS with a smaller delivery catheter;
- pursuing growth opportunities, including more rapid expansion and funding regional distribution systems;
- making capital improvements to improve our infrastructure;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. In connection with the public offering closed in March 2017, we entered into a placement agency agreement with Dawson James Securities, Inc., which contains a restriction on sales of our capital stock by us until June 7, 2017, which restriction may be waived by Dawson James Securities, Inc., at any time, in its sole discretion. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares. Further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

The voluntary field action of our MGuard Prime EPS we initiated in 2014 could continue to have a significant adverse impact on us.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

On April 30, 2014 we initiated a voluntary field corrective action of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. We received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, and we resumed shipping products to new customers in our direct markets in Europe in late September 2014. We completed the full re-launch of MGuard Prime EPS in 2015.

As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

- although we resumed manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, our suspension of shipments has and may continue to adversely impact revenue;

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

- our decision to implement the voluntary field action and discontinue shipments, and any additional action related to such decision, may harm our reputation or the market's perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

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

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

We expect to derive our revenue from sales of our MGuard Prime EPS and CGuard EPS stent products and other products we may develop, such as CGuard EPS with a smaller delivery catheter. If we fail to generate revenue from these sources, our results of operations and the value of our business would be materially and adversely affected.

We expect our revenue to be generated from sales of our MGuard Prime EPS and CGuard EPS stent products and other products we may develop. Future sales of CGuard EPS will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. In addition, sales of MGuard Prime EPS have been hampered by weakened demand for bare metal stents, which may never improve, and we may not be successful in developing a drug-eluting stent product. In addition, there may be insufficient demand for other products we are seeking to develop, such as CGuard EPS with a smaller delivery catheter. If we fail to generate expected revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Similarly, the ability to protect our trademark rights might be important to prevent third party counterfeiters from selling poor quality goods using our designated trademarks/trade names. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patent applications and patents may not provide us with commercially meaningful protection for our products or may not afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us now or in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States.

In addition, statutory differences in patentable subject matter depending on the jurisdiction may limit the protection we obtain on certain of the technologies we develop. The laws of some foreign jurisdictions do not offer the same protection to, or may make it more difficult to effect the enforcement of, proprietary rights as in the United States, risk that may be exacerbated if we move our manufacturing to certain countries in Asia. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights on any patents issued on pending patent applications, which may prompt adversaries in such litigation to challenge the validity, scope, ownership, or enforceability of our patents. Third parties can sometimes bring challenges against a patent holder to resolve these issues, as well. If a court decides that any such patents are not valid, not enforceable, not wholly owned by us, or are of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patent rights are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor do they provide us with freedom to operate unimpeded by the patent and other intellectual property rights of others that may cover our products. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

If our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our MGuard Prime EPS and CGuard EPS products at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard Prime EPS or CGuard EPS stents until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard Prime EPS or CGuard EPS stents to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

Additionally, any damage to or destruction of our Tel Aviv facility or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce either MGuard Prime EPS or CGuard EPS stents.

Finally, the production of our stents must occur in a highly controlled, clean environment to minimize particles and other yield and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and results of operations.

Pre-clinical and clinical trials will be lengthy and expensive, and any delay or failure of clinical trials could prevent us from commercializing our MicroNet products, which would materially and adversely affect our results of operations and the value of our business.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including, if we seek in the future to sell our products in the United States, the U.S. Food and Drug Administration. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. They require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. In some trials, a greater number of patients and a longer follow-up period may be required. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our existing products and those under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials. In addition, market demand may change for products being tested due to the length of time needed to complete requisite clinical trials.

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our stents provides a safe and effective alternative to other existing treatments for coronary artery disease and carotid artery disease.

We believe that physicians will not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our products provide a safe and effective alternative to other existing treatments for the conditions we are seeking to address.

If we fail to demonstrate safety and efficacy that is at least comparable to existing and future therapies available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Clinical trials conducted with our products may involve procedures performed by physicians who are technically proficient and are high-volume stent users of such products. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our products will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

Physicians currently consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. None of our current coronary products is a drug-eluting stent, and this may adversely affect our business.

Our ability to attract customers depends to a large extent on our ability to provide goods that meet the customers' and the market's demands and expectations. If we do not have a product that is expected by the market, we may lose customers. The market demand has shifted away from bare metal stents in favor of drug-eluting stents. Our MGuard Prime EPS is a bare-metal stent product and has experienced a substantial reduction in sales over the past two years. Such sales may never recover and we do not currently have the resources to develop a drug-eluting stent product. Our failure to provide industry standard devices could adversely affect our business, financial condition and results of operations.

Our products are based on a new technology, and we have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory approvals, if such approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Because our products are new and long-term success measures have not been completely validated, regulatory agencies may take a significant amount of time in evaluating product approval applications. Treatments may exhibit a favorable measure using one metric and an unfavorable measure using another metric. Any change in accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only four employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. There can be no assurance that such approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us. Furthermore, there can be no assurance that all necessary regulatory approvals will be obtained for the manufacture, marketing and sale in any market of any new product developed or that any potential licensee will develop using our licensed technology.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any regulatory approvals that we receive for our products will require surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. In addition, if a regulatory authority approves our products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements.

Moreover, if we obtain regulatory approval for any of our products, we will only be permitted to market our products for the indication approved by the regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products. In addition, later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The applicable regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. In addition, the healthcare regulatory environment may change in a way that restricts our operations.

We are subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products in such jurisdictions.

We market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from those obtained in the United States and Europe. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE mark or U.S. Food and Drug Administration approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE mark or U.S. Food and Drug Administration approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE mark approval does not ensure approval by regulatory authorities in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in certain markets.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our current products and products under development. We face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. When we commercialize our products, we expect to face intense competition from Boston Scientific Corporation, Guidant Corporation, Medtronic, Inc., Abbott Vascular Devices, Johnson & Johnson, Terumo Corporation, Covidien Ltd., Cordis Corporation (currently part of Cardinal Health, Inc.) and others. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

We may become subject to claims by much larger and better capitalized competitors seeking to invalidate our intellectual property or our rights thereto.

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our stents based on one or more of these patents. These companies also own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange that might be alleged to cover one or more of our products. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. In addition, it is possible that a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us of which we are not aware. As the number of competitors in the stent market grows and as the geographies in which we commercially market grow in number and scope, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, C.R. Bard, Inc., W.L. Gore & Associates, Inc. and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products. Such litigation or claims would divert attention and resources away from the development and/or commercialization of our products and product development, and could result in an adverse court judgment that would make it impossible or impractical to sell our products in one or more territories.

If we fail to maintain or establish satisfactory agreements or arrangements with suppliers or if we experience an interruption of the supply of materials from suppliers, we may not be able to obtain materials that are necessary to develop our products.

We depend on outside suppliers for certain raw materials. These raw materials or components may not always be available at our standards or on acceptable terms, if at all, and we may be unable to locate alternative suppliers or produce necessary materials or components on our own.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. For MGuard Prime EPS and CGuard EPS, we depend on MeKo Laserstrahl-Materialbearbeitung for the laser cutting of the stent, Natec Medical Ltd. for the supply of catheters, and Biogeneral Inc. for the fiber. We may have difficulty obtaining similar components from other suppliers that are acceptable to the U.S. Food and Drug Administration or foreign regulatory authorities if it becomes necessary.

If we have to switch to a replacement supplier, we will face additional regulatory delays and the interruption of the manufacture and delivery of our stents for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the U.S. Food and Drug Administration or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

We may be exposed to product liability claims and insurance may not be sufficient to cover these claims.

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in the market or clinical trials. We may also be exposed to product liability claims based on the sale of any products under development following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our business. Insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverage, or expand our insurance coverage to include future clinical trials or the sale of products incorporating our licensed technology if marketing approval is obtained for such products, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

We face risks associated with litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, personal injury and product liability matters.

There are two lawsuits filed against us or InspireMD Ltd., one filed by Microbanc, LLC and Todd Spenla of Microbanc, LLC in April 2016, 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, and another filed by Medpace Inc. in July 2016, seeking $1,967,822 in damages plus interest, costs, attorneys' fees and expenses against InspireMD Ltd. See "Business — Legal Proceedings" for more information. Due to the uncertainties of litigation, however, we can give no assurance that we or InspireMD Ltd. will prevail on any claims made against us or 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. Adverse outcomes in some or all of these claims may result in significant monetary damages that could adversely affect our ability to conduct our business.

The successful management of operations depends on our ability to attract and retain talented personnel.

We depend on the expertise of our senior management and research personnel, which would be difficult to replace. The loss of the services of any of our senior management could compromise our ability to achieve our objectives. Furthermore, recruiting and retaining qualified personnel will be crucial to future success. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the competition among medical device, biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced management, scientists, researchers, sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel, our operations may be jeopardized and our results of operations may be materially and adversely affected.

We are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations.

We operate globally and develop and market products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International sales and operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;

- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and
- general economic and political conditions in these foreign markets.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies. Since our principal operating subsidiary is an Israeli corporation, these restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

If we fail to obtain an adequate level of reimbursement for our products by third party payors, there may be no commercially viable markets for our products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payors affect the market for our products. The efficacy, safety, performance and cost-effectiveness of our products and of any competing products will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the U.S. and in international markets. There is increasing pressure by governments worldwide to contain health care costs by limiting both the coverage and the level of reimbursement for therapeutic products and by refusing, in some cases, to provide any coverage for products that have not been approved by the relevant regulatory agency. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products and limit our ability to sell our products on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and future revenues, if any, would be adversely affected.

In the United States and in the European Union, our business could be significantly and adversely affected by healthcare reform legislation and other administration and legislative proposals.

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were enacted into law in the United States in March 2010 and are known collectively as the "Affordable Care Act." Certain provisions of these acts are not yet fully implemented and it is unclear what the full impact will be from the legislation. The legislation levies a 2.3% excise tax, that began on January 1, 2013, on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. If we commence sales of our MGuard Prime EPS or CGuard EPS stent in the United States, this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of provisions aimed at improving quality, broadening access to health insurance, enhancing remedies for fraud and abuse, adding transparency requirements, and decreasing healthcare costs, among others. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies, pricing and the market for our products, and the healthcare industry in general. The Affordable Care Act includes provisions affecting the Medicare program, such as value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Judicial challenges as well as legislative initiatives to modify, limit, or repeal the Affordable Care Act have been initiated and continue, including a recent Executive Order signed by the U.S. president directing executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of provisions of the Affordable Care Act that would impose a fiscal or regulatory burden on individuals and certain entities to the maximum extent permitted by law. The challenges to the Affordable Care Act and efforts to repeal or replace the legislation may increase in light of the change in presidential administrations and U.S. Congress. We cannot predict what healthcare programs and regulations will be implemented or changed at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework governing medical devices in the European Union. These proposals are currently being reviewed by the European Parliament and the Council and may undergo significant amendments as part of the legislative process. If adopted by the European Parliament and the Council in their present form, these proposed revisions would, among other things, impose stricter requirements on medical device manufacturers and strengthen the supervising competences of the competent authorities of European Union Member States and the notified bodies. As a result, if and when adopted, the proposed new legislation could prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis. The regulation of advanced therapy medicinal products is also in continued development in the European Union, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis. Any of these regulatory changes and events could limit our ability to form collaborations and our ability to continue to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

Risks Related to Operating in Israel

We anticipate being subject to fluctuations in currency exchange rates because we expect a substantial portion of our revenues will be generated in Euros and U.S. dollars, while a significant portion of our expenses will be incurred in New Israeli Shekels.

We expect a substantial portion of our revenues will be generated in U.S. dollars and Euros, while a significant portion of our expenses, principally salaries and related personnel expenses, is paid in New Israeli Shekels, or NIS. As a result, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the NIS in relation to the Euro or the U.S. dollar, or that the timing of this devaluation will lag behind inflation in Israel. Because inflation has the effect of increasing the dollar and Euro costs of our operations, it would therefore have an adverse effect on our dollar-measured results of operations. The value of the NIS, against the Euro, the U.S. dollar, and other currencies may fluctuate and is affected by, among other things, changes in Israel's political and economic conditions. Any significant revaluation of the NIS may materially and adversely affect our cash flows, revenues and financial condition. Fluctuations in the NIS exchange rate, or even the appearance of instability in such exchange rate, could adversely affect our ability to operate our business.

If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.

Our sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In July 2014, Israel launched an additional operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching rockets at Israel. Recent political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

In addition, many of our officers or key employees may be called to active duty at any time under emergency circumstances for extended periods of time. See "— Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service."

Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service.

Many of our officers and employees reside in Israel and may be required to perform annual military reserve duty. Currently, all male adult citizens and permanent residents of Israel under the age of 40 (or older, depending on their position with the Israeli Defense Forces reserves), unless exempt, are obligated to perform military reserve duty annually and are subject to being called to active duty at any time under emergency circumstances. Our operations could be disrupted by the absence for a significant period of one or more of our key officers and employees due to military service. Any such disruption could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to enforce covenants not-to-compete under current Israeli law.

We have non-competition agreements with most of our employees, many of which are governed by Israeli law. These agreements generally prohibit our employees from competing with us or working for our competitors for a specified period following termination of their employment. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for relatively brief periods of time in restricted geographical areas and only when the employee has unique value specific to that employer's business and not just regarding the professional development of the employee. Any such inability to enforce non-compete covenants may cause us to lose any competitive advantage resulting from advantages provided to us by such confidential information.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our Israeli employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Israeli Patent Law"), inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Israeli Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "C&R Committee"), a body constituted under the Israeli Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. The C&R Committee (decisions of which have been upheld by the Israeli Supreme Court) has held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. Further, the C&R Committee has not yet set specific guidelines regarding the method for calculating this remuneration or the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. We generally enter into intellectual property assignment agreements with our employees pursuant to which such employees assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

It may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers.

The majority of our assets other than cash are located outside the U.S. In addition, certain of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the U.S. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

The tax benefits that are currently available to us under Israeli law require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to pay increased taxes and would likely be denied these benefits in the future.

InspireMD Ltd. has been granted a "Beneficiary Enterprise" status by the Investment Center in the Israeli Ministry of Industry Trade and Labor, and we are therefore eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The main benefit is a two-year exemption from corporate tax, commencing when we begin to generate net income derived from the beneficiary activities in facilities located in Israel, and a reduced corporate tax rate for an additional five years, depending on the level of foreign investment in each year. In addition, under the January 1, 2011 amendment to the Israeli Law for the Encouragement of Capital Investments, 1959, a uniform corporate tax rate of 16% applies to all qualifying income of "Preferred Enterprise," which we may be able to apply as an alternative tax benefit.

The tax benefits available to a Beneficiary Enterprise or a Preferred Enterprise are dependent upon the fulfillment of conditions stipulated under the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which include, among other things, maintaining our manufacturing facilities in Israel. If we fail to comply with these conditions, in whole or in part, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. If we are no longer eligible for these tax benefits, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2016 is 25% and in 2017 is 24% of taxable income. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

In addition to losing eligibility for tax benefits currently available to us under Israeli law, if we do not maintain our manufacturing facilities in Israel, we will not be able to realize certain tax credits and deferred tax assets, if any, including any net operating losses to offset against future profits.

The tax benefits available to Beneficiary Enterprises may be reduced or eliminated in the future. This would likely increase our tax liability.

The Israeli government may reduce or eliminate in the future tax benefits available to Beneficiary Enterprises and Preferred Enterprises. Our Beneficiary Enterprise status and the resulting tax benefits may not continue in the future at their current levels or at any level. The 2011 amendment regarding Preferred Enterprise may not be applicable to us or may not fully compensate us for the change. The termination or reduction of these tax benefits would likely increase our tax liability. The amount, if any, by which our tax liability would increase will depend upon the rate of any tax increase, the amount of any tax benefit reduction, and the amount of any taxable income that we may earn in the future.

Risks Related to Our Organization and Our Common Stock, Preferred Stock and Warrants

The market prices of our common stock and our publicly traded warrants are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors.

The market prices of our common stock and our Series A Warrants and Series B Warrants have been and are likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market prices of our common stock and our publicly traded warrants.

A continued low trading price could lead the NYSE MKT to take actions toward delisting our common stock, including immediately suspending trading in our common stock.

Pursuant to Section 1003(f)(v) of the NYSE MKT Company Guide (the "Company Guide"), the NYSE MKT could take action to delist our common stock in the event that our common stock trades at levels viewed as abnormally low for a substantial period of time. In addition, the NYSE MKT has advised us that its policy is to immediately suspend trading in shares of, and commence delisting procedures with respect to, a listed company if the market price of its shares falls below $0.06 per share at any time during the trading day. For much of the several months prior to the 1-for-25 reverse stock split of our common stock which became effective as of October 7, 2016, our common stock had traded at prices less than $1.00. Our stock has traded at prices less than $1.00 for much of the past month, and there is no assurance that our stock will not trade at levels viewed as abnormally low for a substantial period of time and lead the NYSE MKT to immediately suspend trading in our common stock.

There is no public market for our preferred stock.

There is no established trading market for our preferred stock. A trading market for our preferred stock is not expected to develop, and even if a market develops for our preferred stock, it may not provide meaningful liquidity. The absence of a trading market or liquidity for our preferred stock may adversely affect their value.

The certificate of designation for the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock. Sales of these shares will dilute the interests of other security holders and may depress the price of our common stock.

The respective certificate of designation for our Series B Convertible Preferred Stock and Series C Convertible Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the applicable conversion price, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings. In accordance with this anti-dilution price protection, because the effective common stock purchase price in the March 2017 offering was below the then current Series B Convertible Preferred Stock conversion price, we reduced the Series B Convertible Preferred Stock conversion price upon closing of the March 2017 offering. If in the future, while any of our Series B Convertible Preferred Stock or Series C Convertible Preferred Stock is outstanding, we issue securities at an effective common stock purchase price of less than the applicable conversion price of our Series B Convertible Preferred Stock or Series C Convertible Preferred Stock, as then in effect, we will be required, subject to certain limitations and adjustments as provided in the respective certificate of designation for the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock, to reduce the relevant conversion price, which will result in a greater number of shares of common stock being issuable upon conversion of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock, which in turn will have a greater dilutive effect on our shareholders. In addition, as there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion. As such, it is possible that we will not have a sufficient number of available shares to satisfy the conversion of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock if we enter into a future transaction that reduces the applicable conversion price. If we do not have a sufficient number of available shares for any Series B Convertible Preferred Stock or Series C Convertible Preferred Stock conversions, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive. The potential for such additional issuances may depress the price of our common stock regardless of our business performance. We may find it more difficult to raise additional equity capital while any of our Series B Convertible Preferred Stock or Series C Convertible Preferred Stock is outstanding.

We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

The Series B Convertible Preferred Stock provides for the payment of dividends in cash or in shares of our common stock, and we may not be permitted to pay such dividends in cash, which will require us to have shares of common stock available to pay the dividends.

Each share of the Series B Convertible Preferred Stock is entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Convertible Preferred Stock. The dividends are payable, at our discretion, in cash, out of any funds legally available for such purpose, or in pay-in-kind shares of common stock calculated based on the conversion price, subject to adjustment as provided in the certificate of designation for the Series B Convertible Preferred Stock. The conversion price is subject to reduction if in the future we issue securities for less than the conversion price of our Series B Convertible Preferred Stock, as then in effect. As there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion or in connection with the dividend. It is possible that we will not have a sufficient number of available shares to pay the dividend in common stock, which would require the payment of the dividend in cash. We will not be permitted to pay the dividend in cash unless we are legally permitted to do so under Delaware law, which requires cash to be available from surplus or net profits, which may not be available at the time payment is due. In light of our recurring losses and negative cash flows from operating activities, we do not expect to have cash available to pay the dividends on our Series B Convertible Preferred Stock or to be permitted to make such payments under Delaware law, and will be relying on having available shares of common stock to pay such dividends, which will result in dilution to our shareholders. If we do not have such available shares, we may not be able to satisfy our dividend obligations.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us and adversely affect how our stock trades. This could in turn negatively affect our ability to access equity markets for capital.

Delaware law and our corporate charter and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our publicly traded securities to decline.

Sales of a significant number of shares of our common stock or our warrants in the public market could harm the market prices of our common stock or warrants and make it more difficult for us to raise funds through future offerings of common stock or warrants. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock or our publicly traded warrants in the public market. In addition, we will be required to issue additional shares of common stock to the holders of our Series B Convertible Preferred Stock upon conversion of shares of our Series B Convertible Preferred Stock and the payment of the dividends thereunder in common stock and to the holders of our Series C Convertible Preferred Stock upon conversion of shares of our Series C Convertible Preferred Stock, as a result of the full ratchet anti-dilution price protection in the respective certificate of designation for the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock, if the effective common stock purchase price in a subsequent offering is less than the respective then current conversion price of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock, which in turn will increase the number of shares of common stock available for sale. See "Risk Factors — Risks Related to Our Organization and Our Common Stock, Preferred Stock and Warrants— The certificate of designation for the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock. Sales of these shares will dilute the interests of other security holders and may depress the price of our common stock."

In addition, the fact that our stockholders, option holders and warrant holders can sell substantial amounts of our common stock or our publicly traded warrants in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

No industry analyst publishes research about our business.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Because no industry analyst publishes research about us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Aspects of the tax treatment of the securities may be uncertain.

The tax treatment of our preferred stock and our warrants is uncertain and may vary depending upon whether you are an individual or a legal entity and whether or not you are domiciled in the United States. In the event you are a non-U.S. investor, you should consult your tax advisors as to the consequences, under the tax laws of the country where you are resident for tax purposes, of acquiring, holding and disposing of our preferred stock and our warrants.

Item 5. Other Information

Not applicable

Item 6. Exhibits

See Index to Exhibits.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSPIREMD, INC.

Date: May 9, 2017

By: */s/ James Barry, Ph.D.*
Name: James Barry, Ph.D
Title: President and Chief Executive Officer

Date: May 9, 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)
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 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.

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Barry, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 9, 2017

/s/ James Barry
James Barry, Ph.D.
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Craig Shore, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

May 9, 2017

/s/ Craig Shore
Craig Shore
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended March 31, 2017 of InspireMD, Inc. (the "Company"). I, James Barry, the Chief Executive Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: May 9, 2017

By: */s/ James Barry*
Name: James Barry, Ph.D.
Title: Chief Executive Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended March 31, 2017, of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: May 9, 2017

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a)s and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.