InspireMD, Inc.
Form 10-Q
November 12, 2014

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: September 30, 2014

OR

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

For the transition period from to

Commission file number: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

321 Columbus Avenue

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 ¨	Smaller reporting company x
(Do not check if a smaller reporting company)	

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

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of November 12, 2014: 42,401,311.

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(Unaudited)

September 30, 2014

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INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

September 30, 2014

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The amounts are stated in U.S. dollars

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	September 30, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,978	$ 17,535
Restricted cash		93
Accounts receivable:		
Trade	397	1,855
Other	544	387
Prepaid expenses	138	141
Inventory	1,682	1,593
Total current assets	$ 7,739	21,604
PROPERTY, PLANT AND EQUIPMENT, net	636	652
NON-CURRENT ASSETS:		
Deferred issuance costs	170	310
Funds in respect of employees rights upon retirement	474	434
Long term prepaid expenses	80	114
Royalties buyout	792	852
Total other non-current assets	1,516	1,710
Total assets	$ 9,891	$ 23,966

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

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	September 30, 2014	December 31, 2013
LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 1,548	$ 1,623
Other	4,113	3,141
Advanced payment from customers	180	179
Current maturity of loan	3,710	1,181
Total current liabilities	9,551	6,124
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	719	610
Long term loan	6,002	8,593
Total long-term liabilities	6,721	9,203
COMMITMENTS AND CONTINGENT LIABILITIES (Note 11)		
Total liabilities	16,272	15,327
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 35,107,046 and 33,983,346 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	4	3
Additional paid-in capital	96,236	90,952
Accumulated deficit	(102,621)	(82,316)
Total equity (capital deficiency)	(6,381)	8,639
Total liabilities and equity (less capital deficiency)	$ 9,891	$ 23,966

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

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INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
REVENUES	$273	$1,552	$1,948	$4,566
COST OF REVENUES	349	750	1,558	2,256
GROSS PROFIT (LOSS)	(76)	802	390	2,310
OPERATING EXPENSES:				
Research and development	2,460	1,544	7,485	3,498
Selling and marketing	1,806	830	5,030	2,838
General and administrative	2,139	2,313	7,126	7,285
Total operating expenses	6,405	4,687	19,641	13,621
LOSS FROM OPERATIONS	(6,481)	(3,885)	(19,251)	(11,311)
FINANCIAL EXPENSES, net:				
Interest expense	361		1,072	2,160
Other financial expenses (income)	(48)	57	(21)	10,344
Total financial expenses	313	57	1,051	12,504
LOSS BEFORE INCOME TAXES	(6,794)	(3,942)	(20,302)	(23,815)
TAX EXPENSES (INCOME)	(19)	3	3	(38)
NET LOSS	$(6,775)	$(3,945)	(20,305)	$(23,777)
NET LOSS PER SHARE - basic and diluted	$(0.20)	$(0.12)	$(0.59)	$(0.86)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	34,581,521	33,959,773	34,251,620	27,787,580

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

INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(U.S. dollars in thousands)

	Nine months ended September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(20,305)	$(23,777)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	181	163
Change in liability for employees right upon retirement	109	186
Financial expenses	279	12,231
Share-based compensation expenses	3,151	3,259
Loss (Gains) on amounts funded in respect of employee rights upon retirement, net	15	(3)
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	37	(193)
Decrease (increase) in trade receivables	1,458	(855)
Increase in other receivables	(157)	(235)
Decrease in inventory on consignment		20
Decrease (increase) in inventory	(89)	585
Increase (decrease) in trade payables	(75)	349
Decrease in deferred revenues		(10)
Increase in other payables and advance payment from customers	1,124	507
Net cash used in operating activities	(14,272)	(7,773)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(105)	(195)
Decrease in restricted cash	93	
Amounts funded in respect of employee rights upon retirement, net	(55)	(98)
Net cash used in investing activities	(67)	(293)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes withheld in respect of share issuance	(115)	(27)
Proceeds from issuance of shares	2,229	22,880
Repayment of loan	(290)	
Exercise of options and warrants		8

Induced conversion of convertible debt		(8,787)
Net cash provided by financing activities	1,824	14,074
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(42)	(1)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(12,557)	6,007
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	17,535	5,433
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$4,978	$11,440

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

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. The Company's coronary products combining MicroNet and a bare-metal stent (MGuard™ Prime EPS) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). In October 2014, the Company launched a limited market release of its carotid embolic prevention system (CGuard™ EPS), which combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease. A coronary stent product incorporating a drug-eluting (drug-coated) stent with MicroNet is currently in development. The Company markets its products through distributors in international markets, mainly in Europe, Southeast Asia, India, Latin America and Israel, and through direct sales to hospitals in Europe.

The Company has an accumulated deficit of $103 million as of September 30, 2014, as well as net losses and negative operating cash flows in recent years and the current quarter. The Company expects to continue incurring losses and negative cash flows from operations until its MGuard™ and CGuard™ products reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations for the next twelve months. Therefore, there is substantial doubt about the Company's ability to continue as a going concern.

Management's plans include the continued commercialization of the MGuard™ and CGuard™ products and raising capital through the sale of additional equity securities or debt. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its MGuard™ or CGuard™ products and raising capital, it may need to reduce activities, curtail or cease operations.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

On April 30, 2014, the Company initiated a voluntary field corrective action ("VFA") of its MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime stent dislodgements. On June 18, 2014, the Company received approval from the European regulatory agency to resume the manufacturing of the MGuard Prime stent with a modified stent securement process. The Company also received approval to modify and re-deploy existing MGuard Prime stents that have been sent to us by clinical and commercial sites worldwide. These products have been modified and shipped to direct hospital customers and the majority of its distributor partners, who have begun shipping modified product back into hospital accounts. The Company began shipping products to new customers in the Company's direct markets in Western Europe in October 2014. The VFA had an adverse impact on both the commercial and clinical activities relating to the MGuard Prime EPS from the date of initiation through September 30, 2014.

The expenses associated with the modifications that were performed as a result of the VFA is approximately $320,000 with an additional approximate $76,000 accrued for as of September 30, 2014 which is estimated to be incurred. These expenses were recorded in "Cost of revenues" in the nine months ended September 30, 2014.

On November 7, 2014, the Company sold 6,261,846 shares of its common stock and warrants to purchase 3,130,923 shares of common stock in in a registered direct offering. The common stock was sold at a negotiated purchase price of $1.30 per share, and each purchaser received a warrant to purchase 0.5 of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months and have a term of exercise of 42 months from the date of issuance and an exercise price of $1.75. This offering resulted in net proceeds to the Company of approximately $7.4 million after deducting placement agent fees and other estimated offering expenses.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the six month period ended December 31, 2013, as found in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission on February 26, 2014, as amended by Amendment No. 1 filed with the Securities and Exchange Commission on September 25, 2014. The balance sheet for December 31, 2013 was derived from the Company's audited financial statements for the six month period ended December 31, 2013. The results of operations for the nine months ended September 30, 2014 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 – RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, Financial Accounting Standards Board (the "FASB") issued ASC 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after January 1, 2017. Early adoption is permitted.

In August 2014, the FASB issued Accounting Standards Update ("ASU") 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance under U.S. GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in ASU 2014-15 provide that guidance. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. This new standard requires management to assess the entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective prospectively for annual reporting periods ending after the first annual period ending after December 15, 2016 and interim periods therein. Early application of the standard is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued.

NOTE 4 - EQUITY:

a. During the nine months ended September 30, 2014, the Company granted stock options to employees and directors to purchase a total of 1,826,515 shares of the Company's common stock. The options have exercise prices ranging from $2.38-$3.23 per share, which were the fair market value of the Company's common stock on the date of each respective grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 63.7%-67.9%; and risk-free interest rate of 1.64%-2.18%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $3.3 million.

b. During the nine months ended September 30, 2014, the Company granted a total of 652,757 restricted shares of the Company's common stock to employees. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately $1.9 million.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

c. During the three months ended September 30, 2014, the Company sold 948,000 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with MLV & Co. LLC. These sales resulted in net proceeds to the Company of approximately $2.2 million.

NOTE 5- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, convertible loans and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, convertible loans and restricted stock excluded from the calculations of diluted loss per share were 10,484,017 and 8,180,669 for the nine and three month periods ended September 30, 2014 and 2013, respectively.

NOTE 6 - FAIR VALUE MEASURMENT:

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. As of September 30, 2014, the carrying amount of cash and cash equivalents, accounts receivable, other current assets and accounts payables and accrued expenses approximated their fair values due to the short-term maturities of these instruments. The fair value of the loan received on October 23, 2013 (the “Loan”) approximated its carrying amount.

NOTE 7 - INVENTORY:

	September 30, 2014	December 31, 2013
	($ in thousands)	
Finished goods	$800	$ 1,097
Work in process	585	341
Raw materials and supplies	297	155
	$1,682	$ 1,593

NOTE 8 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	September 30, 2014	December 31, 2013
	($ in thousands)	
Employees and employee institutions	$1,556	$ 1,133
Accrued vacation and recreation pay	405	325
Accrued clinical trial expenses	1,141	622
Accrued expenses	797	886
Provision for sales commissions	207	139
Other	7	36
	$4,113	$ 3,141

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 9 - FINANCIAL EXPENSES, NET:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
	($ in thousands)			
Bank commissions	14	$11	35	$30
Interest income	(2)	(2)	(2)	(14)
Exchange rate differences	(60)	(29)	(7)	(16)
2013 Exchange agreement:				
Induced conversion of convertible debt				9,330
Issuance of warrants				568
Interest expense (including debt issuance costs)	361		1,072	2,160
Change in fair value of warrants, embedded derivatives and other		77	(47)	446
	$313	$57	$1,051	$12,504

NOTE 10 - RELATED PARTIES:

a. During the nine month period ended September 30, 2014, the Company's chief executive officer was granted options to purchase 399,675 shares of common stock at exercise prices ranging from $2.97-$3.10 per share, as well as 182,725 shares of restricted stock. See Note 4.

b. During the nine month period ended September 30, 2014, directors of the Company were granted options to purchase an aggregate of 335,000 shares of common stock at an exercise price of $3.10 per share. See Note 4a.

c. On February 25, 2014, the Company entered into a consulting agreement with a director of the Company, pursuant to which the director agreed to provide the Company with consulting services in exchange for a monthly consultancy fee calculated at the rate of $313 per hour. On July 14, 2014, the Company appointed the director as the new executive vice president and COO and entered into an Employment Agreement with the COO. Under the Employment Agreement, the COO is entitled to an annual base salary of $365,000. The COO is also eligible to receive an annual bonus of at least $225,000 upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with the COO. In accordance with the Employment Agreement, the Company granted the new COO a nonqualified stock option to purchase 335,058 shares of common stock, made pursuant to a Nonqualified Stock Option Agreement, an incentive stock option to purchase 114,942 shares of common stock, made pursuant to an Incentive Stock Option Agreement, and 150,000 shares of restricted stock, made pursuant to a Restricted Stock Award Agreement. The options have an exercise price of $2.61 per share, which was the fair market value of the Company's common stock on the date of grant. Both the options and the restricted stock are subject to a three-year vesting period subject to the COO's continued service with the Company, with one-third (1/3rd) of such awards vesting on the first, second and third anniversary of the grant date. See Note 4.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 11 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Litigation

In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company's former chief executive officer and president for a declaratory and enforcement order that this purported assignee is entitled to options to purchase 83,637 shares of the Company's commons stock at an exercise price of $0.76 per share. After considering the views of its legal counsel as well as other factors, the Company's management believes that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of $193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of $250,000 in the financial statements for the quarter ended December 31, 2012. The Company's management estimates that the ultimate resolution of this matter could result in a loss of up to $80,000 in excess of the amount accrued.

b. Liens and pledges

The Company's obligations under the Loan (as defined in Note 6) were secured by Israeli security agreements and deposit account control agreements on all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd.

NOTE 12 - ENTITY WIDE DISCLOSURE:

The Company operates in one operating segment.

Disaggregated financial data is provided below as follows:

(1) Revenues by geographic area and

(2) Revenues from principal customers.

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
	($ in thousands)			
Germany	72	29	164	172
Malaysia	41		119	
Argentina	40	57	40	100
Middle East	39	57	664	240
Russia		453	3	1,165
Spain	5	162	206	574
Other	76	794	752	2,315
	273	1,552	1,948	4,566

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The following is a summary of revenues by principal customers:

	Three months ended September 30,				Nine months ended September 30,			
	2014		2013		2014		2013	
Customer A	17	%	1	%	6	%	1	%
Customer B	15	%			6	%		
Customer C	15	%	4	%	2	%	2	%
Customer D	14	%	4	%	4	%	5	%
Customer E			29	%			26	%
Customer F	2	%	10	%	11	%	13	%
Customer G					31	%		

All tangible long-lived assets are located in Israel.

NOTE 13 - SUBSEQUENT EVENTS:

As a result of the VFA, the Company suspended enrollment in the MASTER II trial, which had been previously launched to support its investigational device exemption application for MGuard Prime EPS with the U.S. Food and Drug Administration (“FDA”), pending a review by the FDA of the manufacturing improvements to the MGuard Prime EPS. The FDA approved the re-commencement of the MASTER II trial in October 2014.

Notwithstanding FDA approval to re-commence enrollment of the Master II trial, in light of current market conditions moving toward the use of drug-eluting stents (DES) over bare-metal stents, the Company elected not to resume enrollment in the MASTER II trial. As a result of this change, the MASTER II trial will no longer be an FDA registration trial.

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

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

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

Forward-Looking Statements

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- market acceptance of our existing and new products;
- negative clinical trial results or lengthy product delays in key markets;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- our dependence on single suppliers for certain product components and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;

- entry of new competitors and products and potential technological obsolescence of our products;

- our limited manufacturing capabilities and reliance on subcontractors for assistance;

- loss of a key customer or supplier;

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

- product malfunctions;

- adverse economic conditions;

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

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

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

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

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

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

- loss or retirement of key executives and research scientists.

For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading “Part II – Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and the Transition Report on Form 10-KT for the transition period from July 1, 2013 to December 31, 2013, as amended by Amendment No. 1 filed with the Securities and Exchange Commission on September 25, 2014, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. A stent is an expandable “scaffold-like” device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. Our initial MGuard ™ coronary products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

We market and sell our bare-metal based MGuard coronary products in the European Union, Southeast Asia, India, Latin America and Israel. In October 2007, our first generation MGuard coronary product combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union. We subsequently replaced the stainless steel stent with a more advanced cobalt-chromium based stent. Our cobalt-chromium based MGuard coronary product is referred to as the MGuard Prime ™ and, unless otherwise indicated, in this Current Report, references to bare-metal MGuard coronary products are to both our initial stainless steel based MGuard coronary product and our more current cobalt-chromium based MGuard Prime. MGuard Prime received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection.

In October 2014, we launched a limited market release of our CGuard ™ carotid embolic prevention system (EPS) in certain European countries. CGuard EPS combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease. CGuard EPS received CE mark approval in the European Union in March 2013.

We are also developing a pipeline of other products and additional applications by leveraging our MicroNet technology. Among the products in development is a coronary stent product incorporating drug-eluting (drug-coated) stents with MicroNet, for which we anticipate proceeding with animal testing in the fourth calendar quarter of 2014. We also intend to explore possible new applications of our technology in other vascular procedures and interventional medical specialties, specifically peripheral, neurovascular and renal procedures.

Recent Events

On April 30, 2014, we initiated a voluntary field corrective action of our MGuard Prime to address the issue of stent retention following reports of MGuard Prime stent dislodgements. These reported dislodgements have primarily occurred during the preparation of the MGuard Prime, upon removal of the protective sleeve or during withdrawal of the MGuard Prime into the guide catheter. To address this problem, we subsequently modified our manufacturing process of MGuard Prime stents in order to improve stent retention and performance. On June 18, 2014, we received approval from the European regulatory agency to resume the manufacturing of the MGuard Prime stent with a modified stent securement process. We also received approval to modify and re-deploy existing MGuard Prime stents that have been sent back to us by clinical and commercial sites worldwide. These products have been modified and shipped to direct hospital customers and the majority of our distributor partners, who have begun shipping modified products back into hospital accounts. We began shipping products to new customers in our direct markets in Western Europe in October 2014. The voluntary field corrective action had an adverse impact on both the commercial and clinical activities relating to the MGuard Prime EPS from the date of initiation through September 30, 2014. As a result of the voluntary field corrective action, we also suspended enrollment in our MASTER II trial (defined below), which had been previously launched to support our investigational device exemption (IDE) application for MGuard Prime with the U.S. Food and Drug Administration, pending a review by the U.S. Food and Drug Administration of the manufacturing improvements to the MGuard Prime EPS. The U.S. Food and Drug Administration approved the re-commencement of the MASTER II trial in October 2014.

Notwithstanding the U.S. Food and Drug Administration’s approval to re-commence enrollment of the MASTER II trial, in light of current market conditions moving toward the use of drug-eluting stents over bare-metal stents, we elected not to resume enrollment in the MASTER II trial. As a result of this change, the MASTER II trial will no longer be a U.S. Food and Drug registration trial. We intend to devote many of the resources originally planned for the MASTER II trial toward developing a drug-eluting stent coronary product incorporating our MicroNet mesh.

In September 2014, we announced the results of the first clinical trial of CGuard EPS, the CARENET (CARotid Embolic protection study using MicroNET) trial. The CARENET trial was a multi-specialty trial that assessed the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The CARENET trial recruited 30 patients and achieved its primary end point with 0 percent MACE (meaning no death, stroke or myocardial infarction) at 30 days. Additionally, as compared to published historical control groups of non-mesh covered carotid stents, the incidence of new ischemic lesions as assessed by diffusion-weighted magnetic resonance imaging after carotid artery stenting was reduced by almost 50 percent. The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than these historical control groups. The reduction in both the number of new ischemic lesions and the volume of those lesions indicates therapeutic benefits of the MicroNet technology in this patient cohort after 30 days, as compared to the historical control groups.

In October 2014, we launched a limited market release of and received first commercial orders for the CGuard EPS in certain European countries. The full launch of CGuard EPS is scheduled to occur in 2015, concurrently with the full launch of the rapid exchange delivery system for CGuard EPS.

On November 7, 2014, we sold 6,261,846 shares of our common stock and warrants to purchase 3,130,923 shares of our common stock in a registered direct offering. The common stock was sold at a negotiated purchase price of $1.30 per share, and each purchaser received a warrant to purchase one-half of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months after the date of issuance and have a term of exercise of 42 months after the date of issuance and an exercise price of $1.75. This offering resulted in net proceeds to us of approximately $7.4 million after deducting placement agent fees and other estimated offering expenses. Such sales were made pursuant to our effective $75 million shelf registration statement filed with the SEC in October 2013 (File No. 333-191875).

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) the Management's Discussion and Analysis of Financial Condition and Results of Operations section and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Transition Report on Form 10-KT for the transition period from July 1, 2013 to December 31, 2013, as amended by Amendment No. 1 filed with the Securities and Exchange Commission on September 25, 2014. There have not been any material changes to such critical accounting policies since December 31, 2013.

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

Results of Operations

Three months ended September 30, 2014 compared to the three months ended September 30, 2013

Revenues. For the three months ended September 30, 2014, revenue decreased by $1.3 million, or 82.4%, to $0.3 million from $1.6 million during the same period in 2013. This decrease was driven by a decrease in sales volume of $1.3 million, or 82.3%, as well as by price decreases to our repeat distributors of $1,000, or 0.1%. The decrease is due to our voluntary field action (VFA) which resulted in a temporary suspension of MGuard™ Prime EPS sales, our primary commercial product. On June 18, 2014, we received European regulatory approval to modify, redeploy and resume the manufacturing of our MGuard™ Prime EPS, and all distributed products sent back to us has been modified and shipped to direct hospital customers and the majority of our distributor partners, who have begun shipping modified products back into hospital accounts.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of $0.9 million in revenue from our distributors in Europe, $0.2 million in revenue from our distributors in Latin America, $0.1 million in revenue from our distributors in Africa and $0.1 million in revenue from our distributors in the rest of the world.

Gross Profit (Loss). For the three months ended September 30, 2014, we had a gross loss (revenue less cost of revenues) of $0.1 million, as compared to a gross profit of $0.8 million during the same period in 2013, representing a decrease of 109.5%, or $0.9 million. This decrease in gross profit was attributable to the impact of the VFA which included a decrease in revenues of $1.3 million (see above for explanation), partially offset by a decrease in cost of revenues of $0.4 million. Gross margin (gross profits as a percentage of revenue) decreased from 51.7% in the three months ended September 30, 2013 to (27.8)% in the same period in 2014.

Research and Development Expenses. For the three months ended September 30, 2014, research and development expenses increased by 59.3%, or $0.9 million, to $2.5 million, from $1.6 million during the same period in 2013. This increase in research and development expenses resulted primarily from an increase of $0.3 million in related salaries, $0.1 million in related share-based compensation expenses, $0.1 million in miscellaneous expenses and $0.3 million in clinical trial and development expenses associated with our CGuard™ EPS product. In addition, expenditures related to our eMaster post-market registry increased by $0.1 million, and expenditures related to our optical coherence tomography (OCT) clinical study, for which enrollment is expected to begin in the fourth calendar quarter of 2014, increased by $0.1 million. This increase in research and development expenses, however, was partially offset by a decrease of $0.1 million in expenses associated with our MASTER II trial, for which enrollment had been

suspended due to the VFA. Research and development expenses as a percentage of revenue increased to 901.1% for the three months ended September 30, 2014, from 99.5% in the same period in 2013.

Selling and Marketing Expenses. For the three months ended September 30, 2014, selling and marketing expenses increased by 117.6%, or $1.0 million, to $1.8 million, from $0.8 million during the same period in 2013. This increase in selling and marketing expenses resulted primarily from an increase of $0.6 million in salaries and an increase of $0.1 million in share-based compensation as we hired additional sales personnel in an effort to expand our sales activities worldwide, an increase of $0.2 million in expenditures related to the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C. held this year in the third quarter as compared to the fourth quarter in 2013, and an increase of $0.1 million in travel expenses associated with the increased number of our sales force. Much of these sales initiatives were driven by efforts to support the new sales strategies in key European and Latin American countries. Selling and marketing expenses as a percentage of revenue increased to 661.5% in the three months ended September 30, 2014 from 53.5% in the same period in 2013.

General and Administrative Expenses. For the three months ended September 30, 2014, general and administrative expenses decreased by 7.5%, or $0.2 million, to $2.1 million from $2.3 million during the same period in 2013. The decrease in general and administrative expenses resulted primarily from a decrease of $0.1 million in legal expenses and a decrease in travel expenses of $0.1 million. General and administrative expenses as a percentage of revenue increased to 783.5% in the three months ended September 30, 2014 from 149.0% in the same period in 2013.

Financial Expenses. For the three months ended September 30, 2014, financial expenses increased by 449.1%, or $0.2 million, to $0.3 million from $0.1 million during the same period in 2013. The increase in financial expenses partially resulted from an increase of $0.4 million of amortization and interest expenses, partially offset by our incurring $0.1 million of expenses in the three months ended September 30, 2013 pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders and the non-cash revaluations of our warrants. No such expense occurred during the three months ended September 30, 2014. Financial expenses as a percentage of revenue increased to 114.7% in the three months ended September 30, 2014, from 3.7% in the same period in 2013.

Tax Expenses. For the three months ended September 30, 2014, tax expenses decreased by $22,000 from $3,000 in the three months ended September 30, 2013 to $19,000 of tax income during the same period in 2014.

Net Loss. Our net loss increased by $2.8 million, or 71.7%, to $6.8 million for the three months ended September 30, 2014 from $4.0 million during the same period in 2013. The increase in net loss resulted primarily from an increase of $1.7 million in operating expenses primarily associated with research and development and sales and marketing expansion (see above for explanation), a decrease of $0.9 million in gross profit (see above for explanation), and an increase of $0.2 million in financial expenses (see above for explanation).

Nine months ended September 30, 2014 compared to the nine months ended September 30, 2013

Revenues. For the nine months ended September 30, 2014, revenue decreased by $2.6 million, or 57.3%, to $1.9 million from $4.5 million during the same period in 2013. This decrease was driven by a decrease in sales volume of $2.6 million, or 57.4%, partially offset by price increases to our repeat distributors of $4,000, or 0.1%. The decrease is due to our VFA which resulted in a temporary suspension of MGuard™ Prime EPS sales, our primary commercial product. On June 18, 2014, we received European regulatory approval to modify, redeploy and resume the manufacturing of our MGuard™ Prime EPS, and all distributed products sent back to us has been modified and shipped to direct hospital customers and the majority of our distributor partners, who have begun shipping modified products back into hospital accounts.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of $2.4 million in revenue from our distributors in Europe, $0.5 million in revenue from our distributors in Latin America and $0.1 million in revenue from our distributors in Africa, partially offset by an increase of $0.4 million in revenue from our distributors in the Middle East.

Gross Profit. For the nine months ended September 30, 2014, gross profit (revenue less cost of revenues) decreased by 83.1%, or $1.9 million, to $0.4 million from $2.3 million during the same period in 2013. This decrease in gross profit was attributable to the impact of the VFA which included a decrease in revenues of $2.6 million (see above for explanation), partially offset by a decrease in cost of revenues of $0.7 million. The cost of revenues for the nine months ended September 30, 2014 included $0.4 million of costs associated with the VFA, including the costs of modifying and shipping the distributor products sent back to us . Gross margin (gross profits as a percentage of revenue) decreased from 50.6% in the nine months ended September 30, 2013 to 20.0% in the same period in 2014.

Research and Development Expenses. For the nine months ended September 30, 2014, research and development expenses increased by 114.0%, or $4.0 million, to $7.5 million, from $3.5 million during the same period in 2013. This increase in research and development expenses resulted primarily from increases of $0.7 million in related salaries, $0.2 million in related share-based compensation expenses, $0.1 million in related travel expenses, $0.1 million in miscellaneous expenses, $1.8 million in clinical trial expenses associated with our MASTER II trial and $0.7 million in clinical trial and development expenses associated with our CGuard™ EPS product. In addition, expenditures related to product development increased by $0.4 million, expenditures related to our eMaster post-market registry increased by $0.2 million, expenditures related to our OCT clinical study, for which enrollment is expected to begin in the fourth calendar quarter of 2014, increased by $0.1 million and expenditures related to patents increased by $0.1 million. This increase in research and development expenses, however, was partially offset by a decrease of $0.4 million in expenses associated with our MASTER I trial which concluded in 2013. Research and development expenses as a percentage of revenue increased to 384.2% for the nine months ended September 30, 2014, from 76.6% in the same period in 2013.

Selling and Marketing Expenses. For the nine months ended September 30, 2014, selling and marketing expenses increased by 77.2%, or $2.2 million, to $5.0 million, from $2.8 million during the same period in 2013. This increase in selling and marketing expenses resulted primarily from an increase of $1.5 million in salaries and an increase of $0.3 million in share-based compensation, as we hired additional sales personnel in an effort to expand our sales activities worldwide, an increase of $0.2 million in expenditures related to the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C. held this year in the third quarter as compared to the fourth quarter in 2013, an increase of $0.2 million in travel expenses for the increased number of our sales force and an increase of $0.2 million in miscellaneous expenses. Much of these sales initiatives were driven by our increased efforts to support the new sales strategies in key European and Latin American countries. This increase in selling and marketing expenses, however, was partially offset by a decrease of $0.2 million in product promotion expenses. Selling and marketing expenses as a percentage of revenue increased to 258.2% in the nine months ended September 30, 2014 from 62.2% in the same period in 2013.

General and Administrative Expenses. For the nine months ended September 30, 2014, general and administrative expenses decreased by 2.2%, or $0.2 million, to $7.1 million, from $7.3 million during the same period in 2013. This decrease in general and administrative expenses resulted primarily from a decrease of $0.5 million in share-based compensation, partially offset by an increase in salaries of $0.2 million and an increase of $0.1 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue increased to 365.8% in the nine months ended September 30, 2014 from 159.5% in the same period in 2013.

Financial Expenses. For the nine months ended September 30, 2014, financial expenses decreased by 91.6%, or $11.4 million, to $1.1 million from $12.5 million during the same period in 2013. The decrease in financial expenses partially resulted from a decrease of $1.1 million of amortization and interest expenses. In the nine months ended September 30, 2014, we recognized $1.1 million in amortization and interest expense, in contrast to the nine months ended September 30, 2013, during which we recognized $2.2 million of amortization and interest expense pertaining to our previously outstanding senior convertible debentures and their related issuance costs. In addition, we incurred $1.6 million of expense in the nine months ended September 30, 2013 pertaining to our obligation to issue shares of common stock without new consideration to the investors in our March 2011 private placement due to certain anti-dilution rights held by such stockholders and the non-cash revaluations of our warrants, as well as $9.9 million of expense pertaining to the adjustment of the conversion ratio of our convertible debentures prior to their retirement in April 2013. No such expenses occurred during the nine months ended September 30, 2014. This decrease in expenses was partially offset by the absence of any revaluations of our warrants during the nine months ended September 30, 2014. During the nine months ended September 30, 2013, we recognized $1.1 million of financial income pertaining to the revaluation of certain of our warrants due to our stock price decreasing from $3.90 to $2.21 during such period. No such income was recognized during the nine months ended September 30, 2014. Financial expense as a percentage of revenue decreased to 54.0% in the nine months ended September 30, 2014, from 273.9% in the same period in 2013.

Tax Expenses. For the nine months ended September 30, 2014, tax expenses increased $41,000 to $3,000 from $38,000 of tax income during the same period in 2013.

Net Loss. Our net loss decreased by $3.5 million, or 14.6%, to $20.3 million for the nine months ended September 30, 2014 from $23.8 million during the same period in 2013. The decrease in net loss resulted primarily from a decrease of $11.4 million in financial expenses (see above for explanation), partially offset by an increase of $6.0 million in operating expenses primarily associated with research and development and sales and marketing expansion (see above for explanation), and a decrease of $1.9 million in gross profit (see above for explanation).

Liquidity and Capital Resources

We had an accumulated deficit of $102.6 million as of September 30, 2014, as well as net losses and negative operating cash flows in recent years and the current quarter. We expect to continue incurring losses and negative cash flows from operations until our MGuard and CGuard products reach profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we do not have sufficient resources to fund operations for the next twelve months. Therefore, there is substantial doubt about our ability to continue as a going concern.

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

On October 23, 2013, we entered into a loan and security agreement, pursuant to which we received a loan of $10 million, before deduction of issuance costs. Interest on the loan is determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5% plus (B) the prime rate minus 5.5%. Payments under the loan and security agreement are interest only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017. Our obligations under the loan and security agreement are secured by a grant of a security interest in all of our assets (other than our intellectual property). In addition, in connection with the loan and security agreement, we issued the lender a five year warrant to purchase 168,351 shares of our common stock at a per share exercise price of $2.97.

On October 23, 2013, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC (MLV), pursuant to which we may issue and sell shares of our common stock in an aggregate amount up to $40.0 million from time to time in an “at-the-market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, through MLV as our sales agent. On August 15, 2014, we sold 948,000 shares of our common stock, at $2.40 per share, pursuant to the at-the-market issuance sales agreement with MLV. These sales resulted in net proceeds to us of approximately $2.2 million. We paid MLV compensation at a commission rate of 3% of the gross sales. Prior to these sales, we have not made any sales under this “at-the-market” equity offering program, and, as of September 30, 2014, shares of our common stock having an aggregate value of approximately $37.7 million remained available for sale under this offering program. Such sales were made pursuant to our effective $40 million shelf registration statement filed with the SEC in October 2013 (File No. 333-191875). Our securities purchase agreement with purchasers of shares of our common stock and warrants to purchase our common stock, dated November 4, 2014, entered into in connection with the registered direct offering, prohibits us from issuing and selling additional shares of our common stock under this “at-the-market” equity offering program until November 7, 2016.

Nine months ended September 30, 2014 compared to the nine months ended September 30, 2013

General. At September 30, 2014, we had cash and cash equivalents of $5.0 million, as compared to $17.5 million as of December 31, 2013. 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 clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was $14.3 million for the nine months ended September 30, 2014 and $7.8 million for the same period in 2013. The principal reason for the usage of cash in our operating activities for the nine months ended September 30, 2014 was a net loss of $20.3 million, offset by $3.2 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, a decrease in working capital of $2.3 million, $0.3 million of non-cash financial expense and $0.2 million of depreciation and amortization expenses The principal reasons for the usage of cash in our operating activities for the nine months ended September 30, 2013 included a net loss of $23.8 million offset by $12.2 million in non-cash financial expenses, $3.3 million in non-cash share-based compensation, a decrease in working capital of $0.3 million and $0.2 million in depreciation and amortization expenses.

Cash used in our investing activities was $67,000 during the nine months ended September 30, 2014, compared to $293,000 during the same period in 2013. The principal reason for the decrease in cash used in investing activities during 2014 was the $93,000 decrease in restricted cash upon the removal of fixed liens in connection with our credit cards, as well as a decrease of $90,000 in purchases of property, plant and equipment.

Cash provided by financing activities for the nine months ended September 30, 2014 was $1.8 million, compared to $14.1 million during the same period in 2013. The principal source of the cash provided by financing activities during the nine months ended September 30, 2014 relates to funds received from the issuance of ATM shares of approximately $2.2 million, offset by the repayment of a loan of $0.3 million. The principal source of the cash provided by financing activities during the nine months ended September 30, 2013 relates to funds received from the issuance of shares in connection with the underwritten public offering of our common stock of approximately $22.9 million, partially offset by the partial satisfaction of our convertible debentures for approximately $8.8 million.

As of September 30, 2014, our current liabilities exceeded our current assets by a multiple of 1.2. Current assets decreased by $13.8 million during the period, mainly due to cash used in operations, and current liabilities increased by $3.4 million during the period. As a result, our working capital surplus decreased by $17.2 million to a working capital deficit of $1.8 million at September 30, 2014.

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Codification 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 January 1, 2017. Early adoption is permitted.

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-15, Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Continuation of a reporting entity as a going concern is presumed as the basis for preparing financial statements unless and until the entity's liquidation becomes imminent. Preparation of financial statements under this presumption is commonly referred to as the going concern basis of accounting. Currently, there is no guidance under accounting principles generally accepted in the U.S. about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern or to provide related footnote disclosures. The amendments in Accounting Standards Update 2014-15 provide that guidance. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. This new standard requires management to assess the entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period including interim periods, (3) provide principles for considering the mitigating effect of management's plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). Accounting Standards Update 2014-15 will be effective prospectively for annual reporting periods ending after the first annual period ending after December 15, 2016 and interim periods therein. Early application of the standard is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued.

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of September 30, 2014, 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 September 30, 2014.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

Item 1A. Risk Factors

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Quarterly Report on Form 10-Q and the Transition Report on Form 10-KT for the six month period ended December 31, 2013, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business

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

To date, we have experienced net losses. A substantial portion of the expenses associated with our manufacturing facilities are fixed in nature (i.e., depreciation) and will reduce our operating margin until such time, if ever, as we are able to increase utilization of our capacity through increased sales of our products. The clinical trials necessary to support our anticipated growth will be expensive and lengthy. In addition, our strategic plan will require a significant investment in clinical trials, product development and sales and marketing programs, which may not result in the accelerated revenue growth that we anticipate. Because we expect to continue incurring negative cash flows from operations, there can be no assurance that we will ever generate sufficient revenues to become profitable.

Our financial statements for the quarter ended September 30, 2014 contain an explanatory paragraph in the footnotes, as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Accordingly, the footnotes to our financial statements for the quarter ended September 30, 2014 include an explanatory paragraph as to our potential inability to continue as a going concern. Additionally, 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 November 7, 2014 offering of 6,261,846 shares of our common stock and warrants to purchase 3,130,923 shares of our common stock are expected to be sufficient to enable us to continue operations for only a short period of time. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transaction we will need to raise additional capital in the first half of 2015, which may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- developing CGuard, a drug-eluting stent with MicroNet, PVGuard and any additional products;

- pursuing growth opportunities, including more rapid expansion;

- acquiring complementary businesses;

- making capital improvements to improve our infrastructure;

- hiring qualified management and key employees;

- developing new services, programming or products;

- 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. 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 and any future recalls and/or product withdrawals due to product defects or product enhancements and modifications, could 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. As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

- although we received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process and have modified all existing MGuard Prime EPS returned to us, the suspension of shipments has and will continue to adversely impact revenue until we and our distributor

partners have completed shipping all of the modified products back to our customers, and there is no assurance that our revenue will return to the level prior to the suspension of shipments;

- we are more susceptible to claims such as products 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;

- the direct and indirect costs associated with the voluntary field action and re-launch of our product are difficult to predict and will likely divert significant managerial, financial and other resources, which could have an adverse effect on our financial condition and operating results and could hinder our ability to carry out initiatives relating to other new products or product enhancements; and

- our decision to implement the voluntary field action and discontinue shipments, and any future action, 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, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

In addition to the foregoing, since we initiated our voluntary field action we have received a demand from one distributor that we refund approximately $160,000 in lieu of receiving refitted product and a demand from a second distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action, related costs and any third claims. We do not believe that these distributors are entitled to any compensation or refunds due to the voluntary field action and we intend to defend ourselves against any such claims.

We expect to derive our revenue from sales of our MGuard and CGuard stent products and other products we may develop. 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 and CGuard stent products and other products we may develop. Future sales of these products, if any, will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. Even if we are successful in development of DES-MicroNet product or any other products we may develop, there can be no assurance that the product will gain market acceptance or prove to be commercially successful. If we fail to generate such revenues, 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 U.S. 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 U.S. 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 U.S.

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 protections to, or may make it more difficult to effect the enforcement of, proprietary rights as in the U.S., a risk that may be exacerbated if we move our manufacturing to certain counties 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.

We have limited manufacturing capabilities and manufacturing personnel, and 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 and CGuard products at our facility in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production of MGuard. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard or CGuard 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 or CGuard 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.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our stents in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or "scale up," the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities will require the investment of substantial funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If unable to do so, we may not be able to meet potential future demand. If we are unable to manufacture a sufficient supply of our MGuard or CGuard stents, our revenues, business and financial prospects would be adversely affected and we may suffer reputational harm, which could further adversely affect our revenues, business and financial prospects. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.

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 or CGuard 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 stent 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 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. It will 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.

For example, we decided to discontinue our MASTER II trial notwithstanding the resources we had spent on the trial due to the change in market demand and the delay in the U.S. Food and Drug Administration review process following the voluntary field corrective action. With respect to the drug-eluting stent incorporating MicroNet, it will take more than a year to complete the clinical trials, if required for CE mark approval, and submit the DES-MicroNet product for CE mark approval and begin to commercialize the product, even if the trials are successful.

Physicians may not widely adopt our stents 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.

We believe that physicians will not widely adopt our stents 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, including coronary artery bypass grafting balloon angioplasty, bare-metal stents and other drug-eluting stents, provided by Boston Scientific Corporation, Medtronic Inc., Abbott Laboratories and others, to carotid endarterectomy or using conventional stenting for carotid artery disease.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that our stents are an attractive alternative to other procedures. 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 stents 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 stents will vary. Clinical trials conducted with our stents have involved procedures performed by physicians who are technically proficient and are high-volume stent users. 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 stents 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 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. While physicians currently consider drug-eluting stents to be the industry standard for treatment of coronary artery disease, none of our stent products incorporates drug-eluting stents. Although we are in the process of developing a product incorporating a drug-eluting stent and MicroNet, there is no assurance that we will complete the development and commercialize the DES-MicroNet 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, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the 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 9 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 U.S., 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 product for which we obtain marketing approval in the U.S., along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the U.S. Food and Drug Administration and other regulatory bodies. In particular, we and our suppliers will be required to comply with the U.S. Food and Drug Administration's Quality System Regulation for the manufacture of our MGuard stent, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval in the U.S. The U.S. Food and Drug Administration enforces the Quality System Regulation through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the U.S. Food and Drug Administration and will have to successfully complete such inspections before we receive U.S. regulatory approval for our products. Failure by us or one of our suppliers to comply with statutes and regulations administered by the U.S. Food and Drug Administration and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving, or refusal to approve, our products;
- withdrawal or suspension of approval by the U.S. Food and Drug Administration or other regulatory bodies;
- product recall or seizure;
- orders for physician notification or device repair, replacement or refund;
- interruption of production;
- operating restrictions;

- injunctions; and

- criminal prosecution.

If any of these actions were to occur, it could harm our reputation and could cause our product sales and profitability to suffer. Furthermore, key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval of a product is granted in the U.S., the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the U.S. Food and Drug Administration determines that our promotional materials, training or other activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Moreover, any modification to a device that has received U.S. Food and Drug Administration approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new approval from the U.S. Food and Drug Administration. If the U.S. Food and Drug Administration disagrees with any determination by us that new approval is not required, we may be required to cease marketing or to recall the modified product until approval is obtained. In addition, we could also be subject to significant regulatory fines or penalties.

Additionally, we may be required to conduct costly post-market testing and surveillance to monitor the safety or efficacy of our products, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, such as Quality System Regulation, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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.

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 U.S. 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 in the U.S. and internationally in connection with our current product 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 Medical Corporation, Covidien Ltd., Cordis Corporation 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. For example, we are aware of one public company that is pursuing patent protection directed to layered materials disposed over a particular stent configuration. 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, 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 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 product 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 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, we depend on QualiMed Innovative Medizinprodukte GmbH, which manufactures the body of the stent, MeKo Laserstrahl-Materialbearbeitung for the laser cutting of the stent, Natec Medical Ltd. and Creganna-Tactx Medical, Ireland 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.

Our relationship with our strategic partners in connection with the DES-MicroNet product development may not prove successful.

We plan to develop the DES-MicroNet product with two strategic partners who would supply FDA-approved or CE-marked drug-eluting stents. Our successful development of the DES-MicroNet product will depend, among other things, on our partners' ability to supply drug-eluting stents that we may require. Our partners may not be able to supply us with drug-eluting stents due to bankruptcy, insolvency, liquidation, or reorganization; a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims filed against them; or failure to comply with ongoing regulatory requirements. If our partners are unable to produce sufficient quantities of drug-eluting stents for use in our current and planned clinical trials, or if their manufacturing process yields substandard stents, our development and commercialization efforts would be delayed and could increase our costs.

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 clinical trials. We may also be exposed to product liability claims based on the sale of any such products 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. We also have liability insurance for our ongoing clinical trials. 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.

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 manufacture 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;

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- 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. 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 product candidates 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 product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates 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 currently under development and limit our ability to sell our product candidates 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 U.S. and in the European Union, our business could be significantly and adversely affected by recent 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 U.S. in March 2010. Certain provisions of these acts will not be fully implemented until 2018 for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts 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 or CGuard stent in the U.S., this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include 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. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the U.S., 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 U.S.

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.

Our strategic business plan may not produce the intended growth in revenue and operating income.

Our strategies include making significant investments in sales and marketing programs to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected.

In addition, as part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the operations, technologies, services and products of the acquired companies and the diversion of management's attention from other business concerns. Although we will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We may have violated Israeli securities law.

We may have violated section 15 of the Israeli Securities Law of 1968. Section 15 of the Israeli Securities Law of 1968 requires the filing of a prospectus with the Israel Securities Authority and the delivery thereof to offerees in connection with an offer or sale of securities to more than 35 offerees (where for the purpose of calculating such number, offerees of the type listed on the First Addendum of the Israeli Securities Law of 1968 shall not be taken into account) during any 12-month period. We allegedly issued securities to more than 35 offerees during certain 12-month periods, ending in October 2008. Our wholly-owned subsidiary, InspireMD Ltd., a private company incorporated under the laws of the State of Israel, applied for a no-action determination from the Israel Security Authority on February 14, 2011 in connection with the foregoing. To date, the Israel Securities Authority has not responded to InspireMD Ltd.'s application for no-action determination and we are unable to predict when a response will be received. The maximum penalties for violating section 15 of the Israeli Securities Law of 1968 are as follows: imprisonment of five years; a fine of up to approximately $317,000 to be paid by management of the violating company; and a fine of up to approximately $1,590,000 to be paid by the violating company, any of which penalties could result in a material adverse effect on our operations. We believe that it is unlikely that either we or any individual will be subject to fines or other penalties as a result of these alleged violations.

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, some 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.

Some 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 officers or key 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 U.S. to enforce any judgments obtained against us or some of our directors or officers.

The majority of our assets 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 U.S. 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 2014 is 26.5% 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 Common Stock

Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock has been and is 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;

- sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;

- limited availability of freely-tradable "unrestricted" shares of our common stock to satisfy purchase orders and demand;

- 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 price of our common stock.

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. We are also subject to certain restrictions pursuant to our loan and security agreement with Hercules Technology Growth Capital, Inc., which prohibits us from paying dividends or distributions on our common stock. 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.

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

On March 31, 2011, we became 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. It also requires an independent registered public accounting firm to test our internal control over financial reporting and report on the effectiveness of such controls. 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 of 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 U.S. 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, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or equity markets for capital.

Delaware law, our corporate charter and bylaws and our stockholder rights plan, or poison pill, 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.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

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. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Risks Related to our Indebtedness

Our obligations under our $10 million principal term loan are secured by substantially all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.

The lender under our $10 million principal term loan has a security interest in substantially all of our assets and those of InspireMD Ltd., our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders.