InspireMD, Inc.
Form 10-Q
February 04, 2013

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: December 31, 2012

OR

o 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: 000-54335

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

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

4 Menorat Hamaor St.

Tel Aviv, Israel 67448
(Address of principal executive offices)
(Zip Code)

972-3-691-7691
(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 o

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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of February 4, 2013: 18,604,709.

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Item 1. Financial Statements

INSPIREMD, INC.

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

December 31, 2012

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The amounts are stated in U.S. dollars

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INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	December 31, 2012	June 30, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,433	$10,284
Restricted cash	93	37
Accounts receivable:		
Trade, net	1,273	1,824
Other	212	264
Prepaid expenses	94	93
Inventory:		
On hand	1,977	1,744
On consignment	20	63
Total current assets	9,102	14,309
PROPERTY, PLANT AND EQUIPMENT, net of accumulated depreciation and amortization	479	462
OTHER NON-CURRENT ASSETS:		
Deferred debt issuance costs	776	961
Funds in respect of employees rights upon retirement	335	282
Royalties buyout	905	
Total other non-current assets	2,016	1,243
Total assets	$ 11,597	$16,014

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)

	December 31, 2012	June 30, 2012
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 501	$441
Other	2,376	2,925
Advanced payment from customers	184	174
Deferred revenues	10	10
Convertible loan	6,461	
Total current liabilities	9,532	3,550
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	451	354
Convertible loan		5,018
Contingently redeemable warrants	1,410	1,706
Total long-term liabilities	1,861	7,078
Total liabilities	11,393	10,628
EQUITY		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 18,026,680 and 17,040,040 shares issued and outstanding at December 31, 2012 and June 30, 2012, respectively.	2	2
Additional paid-in capital	53,349	49,106
Accumulated deficit	(53,147)	(43,722)
Total equity	204	5,386
Total liabilities and equity	$ 11,597	$16,014

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

INSPIREMD, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three months ended December 31,		Six months ended December 31,	
	2012	2011	2012	2011
REVENUES	$1,350	$1,292	$1,859	$3,278
COST OF REVENUES	547	671	777	1,472
GROSS PROFIT	803	621	1,082	1,806
OPERATING EXPENSES:				
Royalties buyout expenses	918		918	
Other research and development expenses	1,256	834	2,202	1,381
Selling and marketing	1,206	626	1,608	928
General and administrative	1,789	7,398	4,001	9,884
Total operating expenses	5,169	8,858	8,729	12,193
LOSS FROM OPERATIONS	(4,366)	(8,237)	(7,647)	(10,387)
FINANCIAL EXPENSES (INCOME), net:				
Expenses (income) related to revaluation of Contingently redeemable warrants, net	(3,569)		(296)	
Expenses related to interest on convertible loan and other financial expenses	1,081	39	2,026	147
LOSS BEFORE TAX EXPENSES	(1,878)	(8,276)	(9,377)	(10,534)
TAX EXPENSES	42	(43)	49	(18)
NET LOSS	$(1,920)	$(8,233)	$(9,426)	$(10,516)
NET LOSS PER SHARE - basic and diluted	$(0.11)	$(0.49)	$(0.54)	$(0.64)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	17,727,815	16,674,356	17,401,025	16,374,636

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)

	6 months ended December 31,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(9,426)	$(10,516)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	95	51
Change in liability for employees right upon retirement	97	(12)
Financial expenses (income)	1,241	249
Royalties buyout	918	
Share-based compensation expenses	1,431	8,611
Loss (gains) on amounts funded in respect of employee rights upon retirement, net	(3)	5
Changes in operating asset and liability items:		
Increase in prepaid expenses	(1)	(1)
Decrease (increase) in trade receivables	551	(1,670)
Decrease in other receivables	52	53
Decrease (increase) in inventory on consignment	43	(28)
Increase in inventory on hand	(233)	(590)
Increase (decrease) in trade payables	60	(31)
Decrease in other payables and advance payment from customers	(624)	(338)
Net cash used in operating activities	(5,799)	(4,217)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease (increase) in restricted cash	(56)	252
Purchase of property, plant and equipment	(87)	(97)
Proceeds from sale of property, plant and equipment		12
Amounts funded in respect of employee rights upon retirement	(50)	(10)
Net cash provided by (used in) investing activities	(193)	157
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options and warrants	1,049	1,500
Repayment of long-term loan		(187)
Net cash provided by financing activities	1,049	1,313
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	92	(229)
DECREASE IN CASH AND CASH EQUIVALENTS	(4,851)	(2,976)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	10,284	8,070
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$5,433	$5,094

Purchasing of property, plant and equipment on credit and in consideration of share-based payment	$62
Royalties buyout in consideration of shares and waiver	$930

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. (formerly Saguaro Resources, Inc.), a Delaware corporation (the "Company"), was formed on February 29, 2008. On March 28, 2011, the Company changed its name to InspireMD, Inc. in connection with a share exchange transaction between the Company, InspireMD Ltd., a limited company incorporated under the laws of the State of Israel in April 2005, and the shareholders of InspireMD Ltd.

On December 19, 2012, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a one-for-four reverse stock split of its common stock (the "Reverse Stock Split"), which decreased the number of issued and outstanding shares of common stock from approximately 72.1 million shares to approximately 18.0 million shares. The Company's authorized common stock was not affected by the Reverse Stock Split. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

The Company has had recurring losses and negative cash flows from operating activities and has significant future commitments. For the six months ended December 31, 2012, the Company had losses of approximately $9.4 million and negative cash flows from operating activities of approximately $5.8 million. The Company's management believes that its financial resources as of December 31, 2012 should enable it to continue funding the negative cash flows from operating activities through the three months ended September 30, 2013. Furthermore, commencing October 2013, the Company's senior secured convertible debentures (the "2012 Convertible Debentures") are subject to a non-contingent redemption option that could require the Company to make a payment of $13.3 million, including accrued interest. Since the Company expects to continue incurring negative cash flows from operations and in light of the cash requirement in connection with the 2012 Convertible Debentures, there is substantial doubt about the Company's ability to continue operating as a going concern. These financial statements include no adjustments of the values of assets and liabilities and the classification thereof, if any, that will apply if the Company is unable to continue operating as a going concern.

The Company will need to raise further capital at some future point in time, through the sale of additional equity securities or debt. The Company's future capital requirements and the adequacy of the Company's available funds will depend on many factors, including the Company's ability to successfully commercialize the Company's MGuard™ products, development of future products, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement the Company's product offerings. However, the Company may be unable to raise sufficient additional capital when the Company needs it or with favorable terms. The terms of any securities issued by the Company in future financings 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 the Company's securities then outstanding. If the Company is unable to obtain adequate funds on reasonable terms, the Company will need to curtail operations significantly, including possibly postponing or halting the Company's Unites States of America ("U.S.") Food and Drug Administration clinical trials or entering into financing agreements with unattractive terms.

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 present fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended June 30, 2012, as found in the Company's amended Transition Report on Form 10-KT/A, filed with the Securities and Exchange Commission on January 3, 2013. The balance sheet for June 30, 2012 was derived from the Company's audited financial statements for the year ended June 30, 2012. The results of operations for the six months ended December 31, 2012 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3- EQUITY:

On August 1, 2012, the Company issued a consultant options with certain market conditions to purchase 50,000 shares of common stock at an exercise price of $4.72 per share, the closing price of the common stock on the date of grant.

On August 27, 2012, the Company issued options to purchase 60,871 shares of common stock at an exercise price of $5.80 per share, the closing price of the common stock on the date of grant, to a consultant who was an immediate family member of the Company's CEO at the time of grant.

On August 27, 2012, the Company extended the term of an option to purchase 30,435 shares of common stock previously granted to a consultant who was an immediate family member of the Company's CEO at the time of the extension. Following the extension, the options can be exercised until September 30, 2014.

On October 20, 2012, the Company issued 215,000 shares of common stock to pursuant to an agreement with a licensor (See Note 9(a)).

During the six months ended December 31, 2012, the Company issued a total of 771,640 shares of common stock in connection with the exercise of 771,640 options and warrants. The Company received aggregate cash proceeds equal to approximately $1 million in connection with such exercises.

On December 21, 2012, the Company amended its Umbrella Plan to increase the total number of shares of common stock issuable under such plan by 1.25 million shares and to permit the awarding of incentive stock options pursuant to the U.S. portion of the plan.

NOTE 4- EARNINGS 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 shares of common stock, as the effect is anti-dilutive. Potential shares of common stock are comprised of incremental shares of common stock issuable upon the exercise of stock options, warrants and convertible loans.

For the six month periods ended December 31, 2012 and 2011, all shares of common stock underlying outstanding options, warrants and convertible loans have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive. The total number of shares of common stcok related to outstanding options, warrants and convertible loans that were excluded from the calculations of diluted loss per share were 7,362,598 and 5,406,613 for the six month periods ended December 31, 2012 and 2011, respectively.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 5 - FAIR VALUE MEASURMENT:

a. Financial Assets and Liabilities Measured at Fair Value.

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The following table summarizes the balances for those financial liabilities where fair value measurements are estimated utilizing Level 2 and Level 3 inputs:

	December 31	June 30

	Level	2012	2012
		($ in thousands)	
2012 Warrants at fair value	2	$1,410	$1,706
Embedded derivative	3	40	49
		$1,450	$1,755

The following table summarizes the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

	Embedded Derivative ($ in thousands)
Balance as of July 1, 2012	$ 49
Losses included in earnings - financial expenses , net	(9)
Balance as of December 31, 2012	$ 40

Level 3 liabilities include an embedded derivative related to the Company’s 2012 Convertible Debentures. The Company values the Level 3 embedded derivative using an internally developed valuation model, whose inputs include recovery rates, credit spreads, stock prices, and volatilities, as described below.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 5 - FAIR VALUE MEASURMENT (continued):

The fair value of the warrants included in Level 2 is estimated using the Black Scholes model.

In calculating the fair value of warrants at December 31, 2012, the Company used the following assumptions: expected term of 4.26 years; expected volatility of 70.64%; risk-free interest rate of 0.59%; and dividend yield of 0%.

b. Financial Assets and Liabilities Not Measured at Fair Value Method

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. The carrying amount of the Company's other financial long-term assets approximate their fair value.

The fair value of the Company's 2012 Convertible Debentures approximates the carrying amount (after considering the beneficial conversion feature). If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy.

NOTE 6 - INVENTORY ON HAND:

	December 31, 2012	June 30, 2012
	($ in thousands)	
Finished goods	$378	$479

Work in process	1,484	1,115
Raw materials and supplies	115	150
	$1,977	$1,744

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	December 31, 2012	June 30, 2012
	($ in thousands)	
Employees and employee institutions	$394	$438
Accrued vacation and recreation pay	278	272
Accrued clinical trial expenses	552	607
Provision for sales commissions	155	194
Accrued expenses	841	1,197
Due to government institutions		22
Provision for returns	53	139
Taxes payable	103	56
	$2,376	$2,925

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 8 - FINANCIAL EXPENSES (INCOME), NET:

	Three months ended December 31,		Six months ended December 31,	
	2012	2011	2012	2011
	($ in thousands)		($ in thousands)	
Bank commissions	$ 8	$ 8	17	$ 16
Interest income	(6)	(11)	(15)	(32)
Exchange rate differences	(81)	32	(75)	138
Interest expense (including debt issuance costs)	1,120	10	2,108	25
Change in fair value of warrants and embedded derivatives	(3,529)		(305)	
	$ (2,488)	$ 39	$ 1,730	$ 147

NOTE 9 - RELATED PARTIES:

On July 2, 2012, effective August 1, 2012, InspireMD Ltd. (a wholly-owned subsidiary of the Company) entered into a consultancy agreement (the "First Consultancy Agreement") with a member of the immediate family of the Company's former CEO at the time, pursuant to which the consultant was to provide sales consulting services. Pursuant to the agreement, the consultant was entitled to a fixed fee of $625 (2,500 NIS) for each full working day and a bonus of up to $10,000 (40,000 NIS) upon the achievement of set objectives. The First Consultancy Agreement was terminated on September 30, 2012.

On August 27, 2012, InspireMD Ltd. entered into a revised consultancy agreement (the "Second Consultancy Agreement") with this consultant, pursuant to which the consultant is entitled to options to purchase 60,871 shares of common stock at an exercise price of $5.80 per share. The revised agreement also extended the term of options to purchase 30,435 shares of common stock that were scheduled to expire upon the termination of the First Consultancy Agreement to September 2014.

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Commitment

In March 2010, the Company entered into a license agreement to use a stent design ("MGuard Prime™"). Pursuant to the agreement, the licensor is entitled to receive royalty payments of 7% of net sales outside the United States and, for sales within the United States, royalty payments as follows: 7% of net sales for the first $10,000,000 of net sales and 10% of net sales for net sales exceeding $10,000,000.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES (continued):

On October 20, 2012, the Company, InspireMD Ltd. and the licensor entered into the First Amendment to License Agreement, which amended the license agreement described above. Pursuant to the amendment, amongst other things, the licensor agreed to reduce the royalty owed with respect to sales of MGuard PrimeTM to 2.9% of all net sales both inside and outside the U.S. in exchange for (i) InspireMD Ltd. waiving $85,000 in regulatory fees for the CE Mark that are owed by the licensor to InspireMD Ltd., (ii) InspireMD Ltd. making full payment of royalties in the amount of $205,587 due to the licensor as of September 30, 2012 and (iii) 215,000 shares of the Company's common stock, that were valued at the closing price of the common stock on October 19, 2012 at $8.20 per share. The total amount paid to the licensor was valued at $1,848,000, inclusive of the shares issued as well as the $85,000 waiver, and was allocated as follows: $930,000 was allocated to royalties buyout and $918,000 was allocated to "research and development" expenses based on the MGuard PrimeTM registration status in the various territories. The royalties buyout will be amortized over the estimated useful lives of the royalties buyout to "Cost of Revenues" in the Consolidated Statements of Operations.

b. Litigation

In February 2011, a third party threatened to seek damages from the Company in connection with certain finders' fees that it claimed were owed. The claimant is seeking approximately $1 million. To date, no lawsuit has been filed and the Company has not accrued an expense in connection with this matter because the Company's management, after considering the views of its legal counsel as well as other factors, believes that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

In February 2011, a service provider filed a claim against the Company for $327,000 in the Magistrate's Court in Tel Aviv, claiming a future success fee and commission for assistance in finding the Company's distributor in Brazil. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of $327,000 in the financial statements in the first quarter of 2011. The related expense has been recorded to "General and administrative" within the Consolidated Statements of Operations. On October 5, 2011, the Company filed a counter claim against the plaintiff in the amount of $29,000. Following the first court evidence hearing held on January 20th, 2013, the parties reached a settlement agreement which provides that in consideration of the mutual

waiver by the parties of all their claims against each other and their shareholders, officers and employees, the Company shall pay to the plaintiff $50,000. Accordingly, as of December 31, 2012, the provision was modified to $50,000.

In August 2011, a former senior employee submitted to the Regional Labor Court in Tel Aviv a claim against the Company for (i) compensation of $118,000 and (ii) a declaratory ruling that he is entitled to exercise 121,742 options to purchase shares of the Company's common stock at an exercise price of $0.004 per share, of which, 20,290 options were not disputed by the Company. On October 21, 2012, the former senior employee exercised 20,290 options. 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 November 2011, a former service provider of InspireMD Ltd. filed a claim with the Magistrate Court in Tel Aviv against the Company, InspireMD Ltd. and the Company's former President and former CEO for a declaratory ruling that it is entitled to convert options to purchase 13,650 of InspireMD Ltd.'s ordinary shares at an exercise price of $3.67 per share into options to purchase 27,696 shares of the Company's common stock at an exercise price of $1.80 per share, and to convert options to purchase 4,816 of InspireMD Ltd.'s ordinary shares at an exercise price of $10 per share into options to purchase 9,772 shares of the Company's common stock at an exercise price of $4.92 per share. On July 30, 2012, the parties held a mediation which resulted in a settlement agreement, pursuant to which the Company paid $7,000 plus value added taxes to the plaintiff and the plaintiff waived all of his claims to any options and agreed to the irrevocable dismissal of the above mentioned claim. On August 5, 2012, the court approved the settlement and dismissed the claim.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES (continued):

In December 2011, a statement of claim against the Company was submitted by an alleged finder of the Company, regarding options to purchase 146,089 shares of the Company's common stock. The Company filed its defense in this case on March 11, 2012. Mediation procedures have not resulted in a settlement agreement between the parties. A court hearing to hear the evidences in this case is set for February 27, 2013. 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 July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company's former CEO and former President for a declaratory and enforcement order that it is entitled to options to purchase 83,637 shares of the Company's common stock at an exercise price of $0.76 per share. A first hearing of this claim was set for February 21, 2013. 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 related expense has been recorded to "General and administrative" within the Consolidated Statements of Operations. 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.

In December 2012, the State of Israel issued a criminal complaint to InspireMD Ltd., the Company's former CEO, former President, and Vice President of Research and Development, alleging that the Company failed to operate its production facilities under an appropriate business license. On January 31, 2013, the Company received the business license and is currently seeking a dismissal of the criminal complaint. The Company does not expect that this action

by the State of Israel will result in any material liability to either the Company or the named individuals.

c. Liens and pledges

As of December 31, 2012, the Company had fixed liens aggregating $93,000 to bank Mizrahi and bank Leumi in connection with the Company's credit cards.

The Company's obligations under the 2012 Convertible Debentures are secured by a first priority perfected security interest in all of the assets and properties of the Company and InspireMD Ltd., including the stock of InspireMD Ltd. and InspireMD GmbH.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 11 - ENTITY WIDE DISCLOSURE:

The Company operates in one reportable 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:

	3 months ended December 31,		6 months ended December 31,	
	2012	2011	2012	2011
	($ in thousands)		($ in thousands)	
India	$272		$272	
Spain	188	38	289	270
Brazil	176	194	181	398
Russia	98	231	125	360
Israel	40	251	115	355
Poland	3	194	3	194
Other	573	384	874	1,701
	$1,350	$1,292	$1,859	$3,278

The following is a summary of revenues by principal customers:

	3 months ended December 31,		6 months ended December 31,	
	2012	2011	2012	2011
Customer A	20%		15%	
Customer B	14%	3 %	16%	8 %
Customer C	13%	15 %	10%	12 %
Customer D	7 %	18 %	7 %	11 %
Customer E	3 %	19 %	6 %	11 %
Customer F		15 %		6 %

All tangible long-lived assets are located in Israel.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 12 - SUBSEQUENT EVENTS:

1) On January 3, 2013, the Company's CEO at the time resigned as CEO (the "Former CEO"). The Former CEO will continue to serve as a member of the Company’s board of directors. In accordance with the terms of a Separation Agreement and Release, the Company will continue to pay the Former CEO $21,563 for six months.

On January 3, 2013 and in connection with the Former CEO’s resignation, the Company appointed a new CEO.

In connection with the appointment of the new CEO, the Company entered into an Employment Agreement (the “Employment Agreement”) with the new CEO. The Employment Agreement has an initial term that ends on January 1, 2016 and will automatically renew for additional one-year periods on January 1, 2016 and on each January 1 thereafter unless either party gives the other party written notice of its election not to extend such employment at least six months prior to the next January 1 renewal date. If a change in control occurs when less than two full years remain in the initial term or during any renewal term, the Employment Agreement will automatically be extended for two years from the change in control date and will terminate on the second anniversary of the change in control date.

Under the Employment Agreement, the new CEO is entitled to an annual base salary of at least $450,000. Such amount may be reduced only as part of an overall cost reduction program that affects all senior executives of the Company and does not disproportionately affect him, so long as such reductions do not reduce the base salary to a rate that is less than 90% of the amount set forth above (or 90% of the amount to which it has been increased). The base salary will be reviewed annually by the board for increase as part of its annual compensation review. The new CEO is also eligible to receive an annual bonus of at least $275,000 upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors. In accordance with the Employment Agreement, on January 3, 2013, the Company granted the new CEO a nonqualified stock option to purchase 525,927 shares of the Company’s common stock, made pursuant to a Nonqualified Stock Option Agreement, an incentive stock option to purchase 74,073 shares of the Company’s common stock, made pursuant to an Incentive Stock Option Agreement, and 400,000 shares of restricted stock, which are subject to forfeiture until the vesting of such shares, made pursuant to a Restricted Stock Award Agreement. The options have an exercise price of $4.05, 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 new CEO's continued service with the Company, with one-thirty-sixth (1/36th) of such awards vesting each month. On or before December 31 of each calendar year, the new CEO will be eligible to receive an additional grant of equity awards equal, in the aggregate, to up to 0.5% of the Company’s actual outstanding shares of common stock on the date of grant, provided that the actual amount of the grant will be based on his achievement of certain performance objectives as established by the board, in its reasonable discretion, for each such calendar year.

If, during the term of the Employment Agreement, the new CEO's employment is terminated upon certain conditions as stipulated in the agreement, the new CEO will be entitled to receive, in addition to other unpaid amounts owed to him (e.g., for base salary and accrued vacation): (i) the pro rata amount of any bonus for the fiscal year of such termination (assuming full achievement of all applicable goals under the bonus plan) that he would have received had his employment not been terminated; (ii) a one-time lump sum severance payment equal to 200% of his base salary; (iii) vesting of 50% of all unvested stock options, restricted stock, stock appreciation rights or similar stock based rights, and lapse of any forfeiture included in such restricted or other stock grants; (iv) an extension of the term of any outstanding stock options or stock appreciation rights until the earlier of (a) two (2) years from the date of termination, or (b) the latest date that each stock option or stock appreciation right would otherwise expire by its original terms; (v) to the fullest extent permitted by the Company’s then-current benefit plans, continuation of health, dental, vision and life insurance coverage; and (vi) a cash payment of $35,000, which the new CEO may use for executive outplacement services or an education program.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 12 - SUBSEQUENT EVENTS (continued):

In addition, the new CEO has no specific right to terminate the Employment Agreement or right to any severance payments or other benefits solely as a result of a change in control. However, if within 24 months following a change in control, (a) the new CEO terminates his employment for good reason, or (b) the Company terminates his employment without cause, the lump sum severance payment to which he is entitled will be increased from 200% of his base salary to 250% of his base salary and all stock options, restricted stock units, stock appreciation rights or similar stock-based rights granted to him will vest in full and be immediately exercisable and any risk of forfeiture included in restricted or other stock grants previously made to him will immediately lapse.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.04-6.5 years; expected volatility of 68.5%-70.3%; and risk-free interest rate of 0.72%-1.07%.

The fair value of the above 525,927 and 74,073 options, using the Black-Scholes option-pricing model, was approximately $1.47 million.

The fair value of the above 400,000 restricted shares was approximately $1.62 million.

2) On January 8, 2013, due to the failure of the Company’s common stock to be listed on a national securities exchange on or before December 31, 2012, the Company issued 178,029 shares of common stock to the purchasers, or their assignees, under a Securities Purchase Agreement, dated as of March 31, 2011 as amended, between the Company and the purchasers thereunder. Pursuant to the Securities Purchase Agreements, in the event that the Company’s common stock was not listed on a national securities exchange on or before December 31, 2012, the Company was required to issue the purchasers under the Securities Purchase Agreement additional shares of common stock equal to 10% of the number of shares of common stock originally acquired by each such purchaser under the Securities Purchase Agreement.

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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;
- our ability to complete clinical trials as anticipated and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- disputes over ownership of intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

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

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

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

- loss of a key customer or supplier;

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

- adverse economic conditions;

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

- price increases for supplies and components;

- inability to carry out research, development and commercialization plans; and

- loss or retirement of key executives and research scientists.

For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading “Part II – Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in our Transition Report on Form 10-KT for the six month period ended June 30, 2012 (the “Transition Report”), 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 stent platform technology, MGuard. MGuard provides embolic protection in stenting procedures by placing a micron mesh

sleeve over a stent. Our initial products are marketed for use mainly in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

Recent Developments

On December 19, 2012, we effectuated a one-for-four reverse stock split of our outstanding shares of common stock. Our authorized shares of common stock were not adjusted as a result of this reverse stock split. All share and related option and warrant information presented in the following discussion and analysis of our financial condition and results of operations and the accompanying consolidated interim financial statements have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

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 Note 2 of the Notes to the Consolidated Financial Statements included in our Transition Report and are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Transition Report. There have not been any material changes to such critical accounting policies since June 30, 2012.

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 December 31, 2012 Compared to Three Months Ended December 31, 2011

Revenues. For the three months ended December 31, 2012, total revenue increased approximately $0.1 million, or 4.5%, to approximately $1.4 million from approximately $1.3 million during the same period in 2011. The following is an explanation of the approximately $0.1 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $34,000, and a net increase in deferred revenues of approximately $24,000.

For the three months ended December 31, 2012, total gross revenue increased by approximately $35,000, or approximately 2.6%, to approximately $1.4 million from approximately $1.3 million during the same period in 2011. This increase in total gross revenue is attributable to an increase in both sales volume and price, with increased sales volume accounting for approximately $17,000, or approximately 1.3%, and price increases to our repeat distributors accounting for the remaining approximately $17,000, or approximately 1.3%. With respect to regions, the increase in gross revenue was mainly attributable to an increase of approximately $0.3 million in gross revenue from our distributors in Asia and an increase of approximately $0.1 million in gross revenue from our distributors in Europe. These increases were partially offset by a decrease of approximately $0.2 million in gross revenue from our distributor in Israel and a decrease of approximately $0.1 million in gross revenue from our distributors in Africa.

Net deferred revenue during the three months ended December 31, 2012 increased approximately $24,000, or approximately 116.2% to approximately $3,000 recognized in revenue from approximately $(21,000) deferred from revenue during the same period in 2011. The revenue recognized and deferred during both periods related to our provision for returns, which is calculated based on our history of returns, and recognized one year later.

Gross Profit. For the three months ended December 31, 2012, gross profit (revenue less cost of revenues) increased 29.3%, or approximately $0.2 million, to approximately $0.8 million from approximately $0.6 million during the same period in 2011. The increase in gross profit is attributable to both an increase in net sales of approximately $0.1 million, as well as a decrease in cost of goods sold of approximately $0.1 million. Gross margin increased from 48.1% in the three months ended December 31, 2011 to 59.5% in the three months ended December 31, 2012.

Royalties' Buyout Expenses. For the three months ended December 31, 2012, we incurred approximately $0.9 million in royalties' buyout expenses relating to the restructuring of our royalty agreement for MGuard Prime. In connection with the restructuring of this agreement, the licensor of the stent design used for this product agreed to reduce the royalty from 7% of net sales outside of the United States, 7% of the first $10,000,000 of net sales in the United States and 10% of net sales in the United States above $10,000,000 to 2.9% of all net sales both inside and outside the United States in exchange for (i) us waiving $85,000 in regulatory fees owed to us, (ii) us making full payment of royalties owed as of September 30, 2012 in the amount of $205,587 and (iii) $1,763,000, payable in 215,000 shares of our common stock that were valued at $8.20 per share. There was no such expense during the three months ended December 31, 2011. Royalties' buyout expenses as a percentage of revenue was 68.0% for the three months ended December 31, 2012.

Research and Development Expenses. For the three months ended December 31, 2012, research and development expenses increased 50.6%, or approximately $0.4 million, to approximately $1.3 million, from approximately $0.9 million during the same period in 2011. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.4 million, attributable mainly to our planned U.S. Food and Drug Administration trial (approximately $0.2 million), and a clinical trial for our MGuard Carotid product (approximately $0.2 million). Research and development expense as a percentage of revenue increased to 93.0% for the three months ended December 31, 2012 from 64.6% in the same period in 2011.

Selling and Marketing Expenses. For the three months ended December 31, 2012, selling and marketing expenses increased 92.7%, or approximately $0.6 million, to approximately $1.2 million, from approximately $0.6 million during the same period in 2011. The increase in selling and marketing expenses resulted primarily from an increase of approximately $0.4 million in expenditures related to the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Miami, Florida, where we announced our successful MASTER trial results and approximately $0.2 million of additional salaries expense as we expanded our sales activities worldwide. Selling and marketing expenses as a percentage of revenue increased to 89.3% in 2012 from 48.5% in 2011.

General and Administrative Expenses. For the three months ended December 31, 2012, general and administrative expenses decreased 75.8%, or approximately $5.6 million, to approximately $1.8 million from approximately $7.4 million during the same period in 2011. This decrease resulted primarily from a decrease in share-based compensation of $6.0 million (which predominately pertained to directors' compensation), partially offset by an increase of approximately $0.4 million in legal fees. General and administrative expenses as a percentage of revenue decreased to 132.5% in 2012 from 572.6% in 2011.

Financial Expenses (Income). For the three months ended December 31, 2012, financial expense (income) decreased to approximately $2.5 million of financial income from approximately $39,000 of financial expense during the same period in 2011. The decrease in expense resulted primarily from approximately $3.5 million of financial income pertaining to the revaluation of certain of our warrants due to our stock price decreasing to $3.90 on December 31, 2012, from $9.08 on September 30, 2012 and approximately $0.1 million for the favorable impact of exchange rate differences in the three months ended December 31, 2012, partially offset by approximately $1.1 million of amortization expense pertaining to our convertible debentures and their related issuance costs for the three months ended December 31, 2012. Financial expense as a percentage of revenue decreased from 3.0% in 2011, to (184.3)% in 2012.

Tax Expenses. For the three months ended December 31, 2012, tax expense increased by approximately $0.1 million from approximately $(43,000) for the three months ended December 31, 2011, to approximately $42,000 during the same period in 2012.

Net Loss. Our net loss decreased by approximately $6.3 million, or 76.7%, to approximately $1.9 million for the three months ended December 31, 2012 from approximately $8.2 million during the same period in 2011. The decrease in net loss resulted primarily from a decrease of approximately $3.7 million in operating expenses (see above for explanation), a decrease of approximately $2.5 million in financial expenses (see above for explanation), an increase of approximately $0.2 million in gross profit and an increase of approximately $0.1 million in tax expenses.

Six Months Ended December 31, 2012 Compared to Six Months Ended December 31, 2011

Revenues. For the six months ended December 31, 2012, total revenue decreased approximately $1.4 million, or 43.3%, to approximately $1.9 million from approximately $3.3 million during the same period in 2011. The following is an explanation of the approximately $1.4 million decrease in revenue broken down by its main two components, a decrease in gross revenues of approximately $1.5 million, and a net increase in deferred revenues of approximately $0.1 million.

For the six months ended December 31, 2012, total gross revenue decreased by approximately $1.5 million, or approximately 46.2%, to approximately $1.8 million from approximately $3.3 million during the same period in 2011. This increase in total gross revenue is entirely attributable to a decrease in sales volume of approximately $1.5 million, or approximately 46.6%, partially offset by price increases to our repeat distributors of approximately $14,000, or approximately 0.4%. The $1.5 million decrease was attributable primarily to activities in anticipation of the release of our MASTER trial results at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Miami, Florida, which included evaluating and appointing new distributors in some territories, as well as replacing third party distributors with direct sales channels in key European countries where end user average selling prices and the lack of strong distributors have limited sales. Broken out by region, the decrease in gross revenue was mainly attributable to a decrease of approximately $0.8 million in gross revenue from our distributor in Europe, a decrease of approximately $0.6 million in gross revenue from our distributors in Central and South America, a decrease of approximately $0.3 million in gross revenue from our distributors in Israel and a decrease of approximately $0.1 million in gross revenue from our distributors in Africa. These decreases were partially offset by an increase of approximately $0.3 million in gross revenue from our distributors in Asia.

Net deferred revenue during the six months ended December 31, 2012 increased to approximately $83,000 recognized in revenue from approximately $(24,000) deferred from revenue during the same period in 2011. The revenue recognized and deferred during both periods related to our provision for returns, which is calculated based on our history of returns, and recognized one year later. The reason for the increase in the six months ended December 31, 2012, compared to the same period in 2011, is the decrease in sales between periods, as well as our reassessment of the provision for returns during the six months ended December 31, 2012. Our reassessment of the provision for returns of approximately $55,000 was based on a comparison of our history of returns against the percentage of sales we had been recording in the provision.

Gross Profit. For the six months ended December 31, 2012, gross profit (revenue less cost of revenues) decreased 40.1%, or approximately $0.7 million, to approximately $1.1 million from approximately $1.8 million during the same period in 2011. The decrease in gross profit is attributable to a decrease in net sales of approximately $1.4 million, partially offset by a decrease in cost of goods sold of approximately $0.7 million. Gross margin increased from 55.1% in the six months ended December 31, 2011 to 58.2% in the six months ended December 31, 2012.

Royalties' Buyout Expenses. For the six months ended December 31, 2012, we incurred approximately $0.9 million in royalties' buyout expenses relating to the restructuring of our royalty agreement for MGuard Prime (see above for explanation). There was no such expense during the six months ended December 31, 2011. Royalties' buyout expenses as a percentage of revenue was 49.4% for the six months ended December 31, 2012.

Research and Development Expenses. For the six months ended December 31, 2012, research and development expenses increased 59.4%, or approximately $0.8 million, to approximately $2.2 million from approximately $1.4 million during the same period in 2011. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.7 million, attributable mainly to a clinical trial for our MGuard Carotid product (approximately $0.3 million), our planned U.S. Food and Drug Administration trial (approximately $0.2 million) and the MASTER Trial (approximately $0.2 million). In addition to the increase in clinical trial expenses, there was an increase of approximately $0.1 million in salaries and share-based compensation related to the hiring of additional clinical trial personnel. Research and development expense as a percentage of revenue increased to 118.5% for the six months ended December 31, 2012 from 42.1% in the same period in 2011.

Selling and Marketing Expenses. For the six months ended December 31, 2012, selling and marketing expenses increased 73.3%, or approximately $0.7 million, to approximately $1.6 million, from approximately $0.9 million during the same period in 2011. The increase in selling and marketing expenses resulted primarily from an increase of approximately $0.4 million in expenditures related to the Transcatheter Cardiovascular Therapeutics (TCT) meeting in Miami, Florida, where we announced our successful MASTER trial results, approximately $0.2 million of additional salaries expense as we expanded our sales activities worldwide, and approximately $0.1 million of additional travel expense. Selling and marketing expenses as a percentage of revenue increased to 86.5% in 2012 from 28.3% in 2011.

General and Administrative Expenses. For the six months ended December 31, 2012, general and administrative expenses decreased 59.5%, or approximately $5.9 million, to approximately $4.0 million from approximately $9.9 million during the same period in 2011. This decrease resulted primarily from a decrease in share-based compensation of $6.8 million (which predominately pertained to directors' compensation), partially offset by an increase of approximately $0.4 million in legal fees, an increase of approximately $0.2 million in bad debt expense, an increase of approximately $0.1 million in rent expense and an increase of approximately $0.2 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue decreased to 215.2% in 2012 from 301.5% in 2011.

Financial Expenses. For the six months ended December 31, 2012, financial expenses increased 1,076.9%, or approximately $1.6 million to approximately $1.7 million from approximately $0.1 million during the same period in 2011. The increase resulted primarily from approximately $2.1 million of amortization expense pertaining to our convertible debentures and their related issuance costs, partially offset by approximately $0.3 million of financial income pertaining to the revaluation of certain of our warrants due to our stock price decreasing to $3.90 on December 31, 2012, from $4.24 on June 30, 2012 and approximately $0.1 million for the favorable impact of exchange rate differences for the six months ended December 31, 2012. Financial expense as a percentage of revenue increased from 4.5% in 2011, to 93.1% in 2012.

Tax Expenses. For the six months ended December 31, 2012, tax expense increased by approximately $0.1 million from approximately $(18,000) for the six months ended December 31, 2011, to approximately $49,000 of during the same period in 2012.

Net Loss. Our net loss decreased by approximately $1.1 million, or 10.4%, to approximately $9.4 million for the six months ended December 31, 2012 from approximately $10.5 million during the same period in 2011. The decrease in net loss resulted primarily from a decrease of approximately $3.5 million in operating expenses (see above for explanation), partially offset by an increase of approximately $1.6 million in financial expenses (see above for explanation), a decrease of approximately $0.7 million in gross profit and an increase of approximately $0.1 million in tax expenses.

Liquidity and Capital Resources

We have had recurring losses and negative cash flows from operating activities and have significant future commitments. For the six months ended December 31, 2012, we had losses of approximately $9.4 million and negative cash flows from operating activities of approximately $5.8 million. We believe that our financial resources as of December 31, 2012 should enable us to continue funding the negative cash flows from operating activities through the three months ended September 30, 2013. Further, commencing October 2013, our senior convertible debentures are subject to a non-contingent redemption option that could require us to make a payment of approximately $13.3 million, including accrued interest. Since we expect to continue incurring negative cash flows from operations and in light of the potential cash requirement in connection with our convertible debentures, there is substantial doubt about our ability to continue operating as a going concern.

We will need to raise further capital at some future point in time, through the sale of additional equity securities or debt. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our MGuard products, our development of future products and competing technological and market developments. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. In addition, the terms of any securities we issue in future financings 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. If we are unable to obtain adequate funds on reasonable terms, we will need to curtail operations significantly, including possibly postponing or halting our planned U.S. Food and Drug Administration clinical trial or entering into financing agreements with unattractive terms.

General. At December 31, 2012, we had cash and cash equivalents of approximately $5.4 million, as compared to $10.3 million as of June 30, 2012. The decrease is attributable primarily to our net loss, excluding non-cash financial expenses. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales

activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately $5.8 million for the six months ended December 31, 2012 and $4.2 million for the same period in 2011. The principal reasons for the usage of cash in our operating activities for the six months ended December 31, 2012 include a net loss of approximately $9.4 million and an increase in working capital of approximately $0.2 million, offset by approximately $1.4 million in non-cash share-based compensation, approximately $1.2 million in non-cash financial expenses, approximately $0.9 million in a non-cash royalties buyout, approximately $0.1 million in depreciation and amortization expenses and approximately $0.2 million of all other miscellaneous expenditures.

Cash used in our investing activities was approximately $193,000 during the six months ended December 31, 2012, compared to approximately $157,000 of cash generated by investing activities during the same period in 2011. The principal reason for the decrease in cash flow from investing activities during 2012 was the purchase of approximately $87,000 of new manufacturing equipment, an increase in restricted cash of approximately $56,000 and the funding of employee retirement funds of approximately $50,000.

Cash generated by financing activities was approximately $1.0 million for the six months ended December 31, 2012, compared to $1.3 million generated from financing activities for the same period in 2011. The principal source of cash from financing activities during the six months ended December 31, 2012 was funds received for the exercise of options and warrants in the amount of approximately $1.0 million. In contrast, during the six months ended December 31, 2011, we received approximately $1.5 million from the exercise of options, partially offset by a repayment of a long term loan of approximately $0.2 million.

As of December 31, 2012, our current liabilities exceeded current assets by a multiple of 1.05. Current assets decreased approximately $5.2 million during the six month period, mainly due to cash used in operations, and current liabilities increased by approximately $6.0 million during the same period, mainly due to the liability associated with our convertible debentures. As a result, our working capital surplus decreased by approximately $11.2 million to a working capital deficiency of approximately $0.4 million at December 31, 2012.

Convertible Debentures

On April 5, 2012, we issued senior secured convertible debentures due April 5, 2014 in the original aggregate principal amount of $11,702,128 and five-year warrants to purchase an aggregate of 835,866 shares of our common stock at an exercise price of $7.20 per share in exchange for aggregate gross proceeds of $11.0 million, with corresponding net proceeds of approximately $9.9 million. The convertible debentures were issued with a 6% original issuance discount, bear interest at an annual rate of 8% and are convertible at any time into shares of common stock at an initial conversion price of $7.00 per share. Upon conversion of the convertible debentures, investors will receive a conversion premium equal to 8%, per annum, with a limit of 12% for the term of the convertible debentures, of the principal amount being converted. In addition, the investors may require us to redeem the convertible debentures at any time after October 5, 2013 (18 months after the date of issuance) for 112% of the then outstanding principal amount, plus all accrued interest, and we may prepay the convertible debentures after six months for 112% of the then outstanding principal amount, plus all accrued interest. In connection with this financing, we paid placement agent fees of $848,750 and issued placement agents warrants to purchase 78,078 shares of common stock, with terms identical to the warrants issued to the investors.

Recently Issued Accounting Pronouncements

None

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Contractual Obligations and Commitments

During the six months ended December 31, 2012, we amended our license agreement for the use of the stent design for MGuard Prime. Pursuant to the amendment, among other things, the licensor of the stent design used for this product agreed to reduce the royalty from 7% of net sales outside of the United States, 7% of the first $10,000,000 of net sales in the United States and 10% of net sales in the United States above $10,000,000 to 2.9% of all net sales both inside and outside the United States in exchange for (i) us waiving $85,000 in regulatory fees owed to us, (ii) us making full payment of all royalties owed as of September 30, 2012 in the amount of $205,587 and (iii) $1,763,000, payable in 215,000 shares of our common stock that were valued at $8.20 per share.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest Rate Exposure

Our exposure to market risk relates primarily to short-term investments, including funds classified as cash equivalents. As of December 31, 2012, all excess funds were invested in time deposits and other highly liquid investments, therefore our interest rate exposure is not considered to be material.

Foreign Currency Exchange Rate Exposure

Our foreign currency exchange rate exposure continues to evolve as we grow internationally. Our exposure to foreign currency transaction gains and losses is the result of certain revenues and expenses being denominated in currencies other than the U.S. dollar, primarily the Euro and the NIS. We do not currently engage in hedging or similar transactions to reduce these risks. Fluctuations in currency exchange rates could impact our results of operations, financial position, and cash flows.

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of December 31, 2012, 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 December 31, 2012.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the six months ended December 31, 2012 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, in our Quarterly Report on Form 10-Q for the three months ended September 30, 2012 and in our Transition Report on Form 10-K/T for the six month period ended June 30, 2012, 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. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. 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

The report of our independent auditors contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Further, the report of Kesselman & Kesselman C.P.A.s (Isr.), our independent registered public accounting firm, with respect to our financial statements at June 30, 2012, December 31, 2011 and 2010, and for the six month period ended June 30, 2012, and the years ended December 31, 2011, 2010 and 2009 contains an explanatory paragraph as to our potential inability to continue as a going concern. Additionally, this may adversely affect our ability to obtain new financing on reasonable terms or at all.

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. Furthermore, we have significant future commitments with respect to our convertible debentures. Since we expect to continue incurring negative cash flows from operations and in light of the potential cash expenditures that may be required to satisfy our convertible debentures, there can be no assurance that we will ever generate sufficient revenues to become profitable.

We expect to derive our revenue from sales of our MGuard stent products and other products we may develop. If we fail to generate revenue from this source, 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 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. 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 United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States. The laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the United States, and many companies have encountered significant difficulties in protecting, enforcing, and defending such rights in certain foreign jurisdictions. 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 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 stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard stent 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 stent 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 MGuard stent 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 stent, 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 facilities or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce MGuard stents.

Finally, the production of our MGuard stent 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.

The U.S. Food and Drug Administration may not approve our investigational device exemption application for a pivotal trial of our MGuard Coronary with bio-stable mesh, which would prevent us from conducting our clinical trials in the United States, and even if the U.S. Food and Drug Administration does grant such approval, our clinical trials may be more costly and burdensome than we currently anticipate, which would limit or delay our ability to complete clinical trials and ultimately market our MGuard Coronary with bio-stable mesh in the United States.

In connection with our efforts to seek approval of our MGuard Coronary with bio-stable mesh by the U.S. Food and Drug Administration, we filed an investigational device exemption application with the U.S. Food and Drug Administration during the summer of 2012 to conduct a pivotal trial. On August 29, 2012, the U.S. Food and Drug Administration issued us a letter disapproving our investigational device exemption application due to insufficient data to support the initiation of a human clinical study. More specifically, the U.S. Food and Drug Administration cited numerous deficiencies in our application which may require, amongst other things, new and/or repeated testing in order to resolve. On December 17, 2012, we sent a letter in response to the U.S. Food and Drug Administration that addressed the issues cited in the disapproval letter. In addition, we substantially changed the design of the planned trial at that time. On January 18, 2013, the U.S. Food and Drug Administration issued us a second letter disapproving our investigational device exemption application. The U.S. Food and Drug Administration noted that although our December 17, 2012 letter addressed some of the issues cited in the August 29, 2012 disapproval letter, there remained additional comments to be addressed to support the initiation of a human clinical study. More specifically, the U.S. Food and Drug Administration cited numerous deficiencies in our application which may require, amongst other things, additional analysis, the submission of additional materials or new and/or repeated testing in order to resolve. There can be no assurance that we will be able to resolve these deficiencies and secure approval of our investigational device exemption application from the U.S. Food and Drug Administration.

If the U.S. Food and Drug Administration does not approve our investigational device exemption application, we would be unable to conduct a pivotal trial of our MGuard Coronary with bio-stable mesh, thereby preventing us from marketing MGuard Coronary with bio-stable mesh in the United States. Not being able to market MGuard Coronary with bio-stable mesh in the United States would have an adverse effect on our business. Moreover, even if the U.S. Food and Drug Administration approves an investigational device exemption application to conduct a pivotal trial, the clinical study we conduct may have unanticipated complications and delays, may be more costly than we currently anticipate, and/or may fail to achieve the primary or secondary endpoints. The U.S. Food and Drug Administration may approve our investigational device exemption application with conditions relating to the scope or design of our clinical trials for which we have not planned. These conditions may require us to collect additional data, enroll more patients, spend more time and expend more resources than we currently anticipate, and these conditions may make a clinical trial in the United States more costly and time consuming than we currently plan. Any unanticipated costs and length of U.S. clinical trials, along with our failure to achieve primary or secondary endpoints would delay, if not prevent, our ability to market our MGuard Coronary with bio-stable mesh in the United States, which would harm our business.

Clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such 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.

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard stent will be expensive and 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. Clinical trials supporting a pre-market approval applications for the Cypher stent developed by Johnson & Johnson and the Taxus Express2 stent developed by Boston Scientific Corporation, which were approved by the U.S. Food and Drug Administration and are currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. In some trials, a greater number of patients and a longer follow up period may be required. The U.S. Food and Drug Administration may require us to submit data on a greater number of patients or for a longer follow-up period than those for pre-market approval applications for the Cypher stent and the Taxus Express2 stent. 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 products 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.

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

We believe that physicians will not widely adopt the MGuard stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our MGuard stent 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 Johnson & Johnson, Boston Scientific Corporation, Medtronic Inc., Abbott Laboratories and others.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the MGuard stents are an attractive alternative to other procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug-eluting stents or bare-metal stents that have received regulatory approval and that are available on the market, our ability to successfully market the MGuard stent 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 MGuard stent will vary. Clinical trials conducted with the MGuard Coronary stent 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 MGuard Coronary stent 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.

In addition, currently, physicians consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. While we believe that the MGuard Coronary stent is a safe and effective alternative, it is not a drug-eluting stent, which may further hinder its support and adoption by physicians.

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

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

Any product for which we obtain marketing approval in the United States, 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 United States. 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 United States, 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 intend to market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from those obtained in the United States and Europe. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE Mark or U.S. Food and Drug Administration approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE Mark or U.S. Food and Drug Administration approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE Mark 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 United States 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 Cordis Corporation, a subsidiary of Johnson & Johnson, Boston Scientific Corporation, Guidant, Medtronic, Inc., Abbott Vascular Devices, Terumo 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 MGuard stent based on one or more of these patents. It is also 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. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. 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, Johnson & Johnson 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.

If we fail to maintain or establish satisfactory agreements with 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. 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. 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 MGuard stent for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the U.S. Food and Drug Administration or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

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

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in 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 an ongoing clinical trial in Europe. Insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverages, or expand our insurance coverage to include future clinical trials or the sale of products incorporating our licensed technology if marketing approval is obtained for such products, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

We may implement a product recall or voluntary market withdrawal due to product defects or product enhancements and modifications, which would significantly increase our costs.

The manufacturing and marketing of our MGuard stent products involves an inherent risk that our products may prove to be defective. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall of one of our products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and safety.

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 our research and manufacturing facilities 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;
- 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.

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 United States 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 United States 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 in the United States were enacted into law in March 2010. Certain provisions of these acts will not be effective 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. Beginning on January 1, 2013, the legislation levies a 2.3% excise tax on 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 Coronary stent in the United States, this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of 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 starting 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 United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

In the European Union, on September 26, 2012, the European Commission proposed a revision of the legislation currently governing medical devices. If adopted by the European Parliament and the Council in their present form, these proposals, which may apply from 2015 or 2016, will impose stricter requirements on medical device manufacturers. Moreover, the supervising competences of the competent authorities of the EU Member States and the notified bodies will be strengthened. 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 purchasers in connection with an offer or sale of securities to more than 35 parties during any 12 month period. We allegedly issued securities to more than 35 investors 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 5 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.

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 stockholders' ownership interests.

We will need to raise additional capital in the future, 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 MGuard Carotid, MGuard Peripheral and MGuard Coronary with a drug eluting bio-absorbable mesh 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 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 we 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.

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 principal executive offices and 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. 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.

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

Many of our executive officers and key 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 many of our employees, most 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.

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

All of our assets are located outside the United States and we do not currently maintain a permanent place of business within the United States. In addition, three of our directors and most of our officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. 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 available to us require us to continue meeting various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

The tax benefits that are available to us require us to continue meeting various conditions and may be terminated or reduced in the future, which could increase our costs and taxes. Inspire Ltd. has been granted a "Beneficiary Enterprise" status by the Investment Center in the Israeli Ministry of Industry Trade and Labor which made us eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. In order to remain eligible for the tax benefits of a "Beneficiary Enterprise", we must continue to meet certain conditions stipulated in the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which may include, among other things, making specified investments in fixed assets and equipment, financing a percentage of those investments with our capital contributions, filing certain reports with the Investment Center, complying with provisions regarding intellectual property and the criteria set forth in the specific certificate of approval issued by the Investment Center or the Israel Tax Authority. If we do not meet these requirements, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. Further, in the future, these tax benefits may be reduced or discontinued. If these tax benefits are cancelled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2011 was 24% of their taxable income, was increased to 25% in 2012 and remains at such a rate in 2013. In the future, we may not be eligible to receive additional tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

Risks Related to Our Organization and Our Common Stock

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

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, 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.

Because we became public by means of a "reverse merger," we may not be able to attract the attention of major brokerage firms.

There may be risks associated with us becoming public through a "reverse merger" with a shell company. Although the shell company did not have recent or past operations or assets and we performed a due diligence review of the shell company, there can be no assurance that we will not be exposed to undisclosed liabilities resulting from the prior operations of the shell company. Securities analysts of major brokerage firms and securities institutions may also not provide coverage of us because there were no broker-dealers who sold our stock in a public offering that would be incentivized to follow or recommend the purchase of our common stock. The absence of such research coverage could limit investor interest in our common stock, resulting in decreased liquidity. No assurance can be given that established brokerage firms will, in the future, want to cover our securities or conduct any secondary offerings or other financings on our behalf.

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 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 may be subject to penny stock rules which will make the shares of our common stock more difficult to sell.

We may be subject to the Securities and Exchange Commission's "penny stock" rules. Penny stocks generally are equity securities with a per share price of less than $5.00. The penny stock rules require broker-dealers to deliver a standardized risk disclosure document prepared by the Securities and Exchange Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information must be given to the customer orally or in writing prior to completing the transaction and must be given to the customer in writing before or with the customer's confirmation.

In addition, the penny stock rules require that prior to a transaction the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. The penny stock rules are burdensome and may reduce purchases of any offerings and reduce the trading activity for shares of our common stock. To the extent our shares of common stock are subject to

the penny stock rules, the holders of such shares of common stock may find it more difficult to sell their securities.

There has been a limited market for our common stock and we cannot ensure investors that an active market for our common stock will be sustained.

There has been limited trading in our common stock and there can be no assurance that an active trading market in our common stock will be maintained. Due to the illiquidity, the market price may not accurately reflect our relative value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. Because our common stock is so thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price and investors may not be able to liquidate their investment in us at all or at a price that reflects the value of the business. In addition, our common stock currently trades on the OTC Bulletin Board, which generally lacks the liquidity, research coverage and institutional investor following of a national securities exchange like the NYSE MKT, the New York Stock Exchange or the Nasdaq Stock Market. While we have applied to list our common stock on a national securities exchange, we cannot assure you that our common stock will be accepted for listing on any national securities exchanges or that we will maintain compliance with all of the requirements for our common stock to remain listed. Additionally, if our common stock is accepted for listing on a national securities exchange, there can be no assurance that trading of our common stock on such market will be sustained or desirable.

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

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders.

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

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. As of February 4, 2013, there were 4,432,673 shares of our common stock issuable upon the conversion of our outstanding convertible debentures and the exercise of our outstanding warrants, all of which are currently registered for resale. In addition, there are 17,235,692 shares of our common stock currently saleable under Rule 144. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

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

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

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

Risks Related to our Convertible Debentures

Our obligations to the holders of our convertible debentures are secured by all of our assets, so if we default on those obligations, the convertible debenture holders could foreclose on our assets.

The holders of our convertible debentures have a security interest in all of our assets and those of our subsidiaries. As a result, if we default under our obligations to the convertible debenture holders, the convertible debenture holders could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

Our convertible debentures and the associated securities purchase agreement contain covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

The terms of our convertible debentures could have negative consequences to us, such as:

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;
- we may be unable to refinance our indebtedness on terms acceptable to us, or at all; and
- we may be more vulnerable to economic downturns and limit our ability to withstand competitive pressures.

Additionally, covenants in our convertible debentures and the associated securities purchase agreement impose operating and financial restrictions on us. These restrictions prohibit or limit our ability, and the ability of our subsidiaries, to, among other things:

- pay cash dividends to our stockholders;
- redeem, repurchase or otherwise acquire more than a de minimis number of shares of our common stock or common stock equivalents;
- incur additional indebtedness;
- permit liens on assets or conduct sales of assets;
- cease making public filings under the Securities Exchange Act of 1934, as amended;
- engage in transactions with affiliates; and
- amend our charter documents in a way that would materially and adversely affect any holder of our convertible debentures.

These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities. Moreover, additional debt financing we may seek may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

The conversion of our convertible debentures and the exercise of the warrants issued to the purchasers of our convertible debentures would have a dilutive impact on our existing stockholders.

As of February 4, 2013, there were 1,783,487 shares of common stock underlying our convertible debentures and 913,944 shares of common stock underlying warrants that were issued to purchasers and placement agents in connection with the issuance of the convertible debentures, for a total of 2,697,431shares of common stock. If and

when issued, these additional 2,697,431 shares of common stock will equal approximately 12.7% of our then outstanding shares of common stock, and would immediately dilute our current stockholders in terms of ownership percentage and voting power. The terms of the convertible debentures and related warrants contain provisions that restrict the amount of shares a holder can receive upon conversion or exercise to 4.99% of the then outstanding number of shares of our common stock. However, these restrictions do not prevent the holders from selling some of their holdings and then receiving additional shares. In this way, the holders could sell more than these limits while never holding more than the limits. As a result, even with the restrictions, the holders of these convertible debentures and warrants could ultimately convert and exercise, and then sell, the full amount issuable upon conversion and exercise of the convertible debentures and warrants, respectively, in which case our current stockholders would suffer the full amount of dilution.

The holders of our convertible debentures might be able to exert substantial influence over us in the event that Sol J. Barer, Ph.D. ceases to remain our chairman.

Under the terms of the securities purchase agreement pursuant to which our convertible debentures were sold, if Sol J. Barer, Ph.D. ceases to serve as our chairman due to Dr. Barer's resignation following a material adverse change to the condition of Dr. Barer or any member of Dr. Barer's immediate family or the vote or written consent of independent stockholders, we would be required to appoint two persons to our board of directors designated by Genesis Capital Advisors LLC, the investment advisor to our lead investors in the convertible debenture offering, and support the election of such persons until the convertible debentures are either repaid or converted in full. In addition, in the event that Dr. Barer ceases to serve as our chairman for any other reason while the convertible debentures are outstanding, it would be an event of default under the convertible debentures, which could result in the acceleration of our convertible debentures at the election of the holders of 60% of the outstanding principal of the convertible debentures, an amount that Genesis Capital Advisors LLC presently controls. As a result, Genesis Capital Advisors LLC, or its assigns, have the potential to exert substantial influence over our management and governance in the event Dr. Barer ceases to serve as our chairman and they may exert such influence in a manner that is not consistent with the best interests of our common stockholders.

We may default upon our obligations under our convertible debentures.

The holders of our convertible debentures may require us to redeem our convertible debentures after October 5, 2013 or upon the occurrence of an event of a default under our convertible debentures for 112% of the then outstanding principal amount, plus all accrued interest. In the event that we are required to redeem some or all of our convertible debentures, we may not have sufficient resources to do so and we may have to seek additional debt or equity financing to cover the costs of redeeming our convertible debentures. Any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. Because our obligations under our convertible debentures are secured by a security interest in substantially all of our assets and properties, if we cannot repay our obligations under our convertible debentures, the holders of our convertible debentures may have claims against, and ultimately may foreclose upon and take possession of, substantially all of our assets and properties. In such an event, the holders of our convertible debentures would have control of us.

Item 6. Exhibits

See Index to Exhibits.

SIGNATURES

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

INSPIREMD, INC.

Date: February 4, 2013 By: /s/ Alan W. Milinazzo
Name: Alan W. Milinazzo
Title: President and Chief Executive Officer

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer, Secretary and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
2.1	Share Exchange Agreement, dated as of December 29, 2010, by and among InspireMD Ltd., Saguaro Resources, Inc., and the Shareholders of InspireMD Ltd. that are signatory thereto (incorporated by reference to Exhibit 10.1 to Saguaro Resources, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2011)
2.2	Amendment to Share Exchange Agreement, dated February 24, 2011 (incorporated by reference to Exhibit 2.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011
2.3	Second Amendment to Share Exchange Agreement, dated March 25, 2011 (incorporated by reference to Exhibit 2.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2012)
10.1	First Amendment to License Agreement, dated as of October 20, 2012, by and among Svelte Medical Systems, Inc., InspireMD, Inc. and InspireMD Ltd. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 23, 2012)
10.2	Second Amendment to the InspireMD, Inc. Amended and Restated 2011 UMBRELLA Option Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 26, 2012)
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended December 31, 2012, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

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* Filed herewith.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.