InspireMD, Inc.
Form 10-Q
May 07, 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: March 31, 2013

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: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

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

4 Menorat Hamaor St.

Tel Aviv, Israel 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 May 7, 2013: 34,316,864.

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Item 1. Financial Statements

INSPIREMD, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(U.S. dollars in thousands)

	March 31, 2013	June 30, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,514	$ 10,284
Restricted cash	91	37
Accounts receivable:		
Trade, net	2,146	1,824
Other	278	264
Prepaid expenses	91	93
Inventory:		
On hand	1,982	1,744
On consignment		63
Total current assets	7,102	14,309
PROPERTY, PLANT AND EQUIPMENT, net of accumulated depreciation and amortization	467	462
OTHER NON-CURRENT ASSETS:		
Deferred issuance costs	951	961
Funds in respect of employees rights upon retirement	380	282
Royalties buyout	897	
Total other non-current assets	2,228	1,243
Total assets	$ 9,797	$ 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)

	March 31, 2013	June 30, 2012
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 416	$ 441
Other	2,885	2,925
Advanced payment from customers	177	174
Deferred revenues	10	10
Convertible loan	7,385	
Total current liabilities	10,873	3,550
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	495	354
Convertible loan		5,018
Contingently redeemable warrants and others	1,832	1,706
Total long-term liabilities	2,327	7,078
Total liabilities	13,200	10,628
COMMITMENT AND CONTINGENT LIABILITIES		
EQUITY (CAPITAL DEFICIENCY)		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 18,204,796 and 17,040,040 shares issued and outstanding at March 31, 2013 and June 30, 2012, respectively.	2	2
Additional paid-in capital	54,628	49,106
Accumulated deficit	(58,033)	(43,722)
Total equity (capital deficiency)	(3,403)	5,386
Total liabilities and equity (less capital deficiency)	$ 9,797	$ 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 March 31,		Nine months ended March 31,	
	2013	2012	2013	2012
REVENUES	$1,514	$1,138	$3,373	$4,416
COST OF REVENUES	674	574	1,451	2,046
GROSS PROFIT	840	564	1,922	2,370
OPERATING EXPENSES:				
Royalties buyout expenses			918	
Other research and development expenses	907	1,349	3,109	2,730
Selling and marketing	804	445	2,412	1,373
General and administrative	2,340	1,896	6,341	11,780
Total operating expenses	4,051	3,690	12,780	15,883
LOSS FROM OPERATIONS	(3,211)	(3,126)	(10,858)	(13,513)
FINANCIAL EXPENSES (INCOME), net:				
Expenses related to revaluation of contingently redeemable warrants and others, net	402		106	
Expenses related to interest on convertible loan and other financial expenses (income)	1,290	(11)	3,316	136
LOSS BEFORE TAX EXPENSES (INCOME)	(4,903)	(3,115)	(14,280)	(13,649)
TAX EXPENSES (INCOME)	(18)	25	31	7
NET LOSS	$(4,885)	$(3,140)	$(14,311)	$(13,656)
NET LOSS PER SHARE - basic and diluted	$(0.27)	$(0.18)	$(0.81)	$(0.82)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	18,196,083	17,044,737	17,662,175	16,596,379

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)

	9 months ended March 31,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(14,311)	$(13,656)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	146	85
Change in liability for employees right upon retirement	141	35
Financial expenses	2,707	246
Royalties buyout expenses	918	
Share-based compensation expenses	2,730	9,799
Loss (gains) on amounts funded in respect of employee rights upon retirement, net	(3)	5
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	2	(18)
Increase in trade receivables	(322)	(1,428)
Increase in other receivables	(14)	(33)
Decrease in inventory on consignment	63	23
Increase in inventory on hand	(238)	(546)
Decrease in trade payables	(65)	(512)
Increase in deferred revenues		25
Increase (decrease) in other payables and advance payment from customers	(370)	179
Net cash used in operating activities	(8,616)	(5,796)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease (increase) in restricted cash	(54)	304
Purchase of property, plant and equipment	(118)	(176)
Proceeds from sale of property, plant and equipment		12
Amounts funded in respect of employee rights upon retirement	(95)	(31)
Net cash provided by (used in) investing activities	(267)	109
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options and warrants	1,049	1,500
Shares of common stock used to satisfy tax withholding obligations	(20)	
Repayment of long-term loan		(281)
Net cash provided by financing activities	1,029	1,219
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	84	(251)
DECREASE IN CASH AND CASH EQUIVALENTS	(7,770)	(4,719)
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	$2,514	$3,351

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	
Deferred issuance costs included in trade and other payables	$287	

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

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.

On April 16, 2013, the Company consummated an underwritten public offering, pursuant to which it sold a total of 12,500,000 shares of common stock (the "Offering"). The price to the public in the Offering was $2.00 per share, and the aggregate net proceeds of the Offering to the Company were approximately $22.6 million, after the underwriters' commissions and offering expenses. In connection with the Offering, the Company also granted the underwriters a 30-day option to purchase up to an additional 1.875 million shares to cover over-allotments, if any. On April 11, 2013, following the pricing of the Offering, the Company's common stock began trading on the NYSE MKT.

On April 9, 2013, the Company, entered into an exchange and amendment agreement with the holders of the Company's outstanding senior secured convertible debentures (the "Debentures") due April 5, 2014 and as subsequently amended on April 15, 2013 (the "Exchange Agreement"). Pursuant to the Exchange Agreement, simultaneously with the closing of the Offering and in full satisfaction of the Company's obligations under the Debentures, the Company:

- repaid $8,787,234 in cash;
- issued 2,159,574 shares of common stock to the holders of the Debentures, reflecting a conversion price of $2.00 per share for the remaining unpaid portion of the Debentures;
- issued five year warrants to the holders of the Debentures to purchase an aggregate of 659,091 shares of common stock for $3.00 per share;
- amended the securities purchase agreement pursuant to which the Debentures were originally issued to prohibit the Company from issuing securities containing anti-dilution protective provisions; and
- amended the warrants issued in connection with the Debentures to (i) eliminate the automatic incorporation of the terms of any of the Company's securities that are superior to those of such warrants, except with respect to exercise price and warrant coverage and (ii) provide that upon a fundamental transaction, the holders of such warrants will have the right to cause the Company to repurchase the unexercised portion of such warrants at their Black-Scholes value on the date of such fundamental transaction, payable in shares of common stock, rather than in cash as was

previously provided.

The above transactions pursuant to the Exchange Agreement are referred to herein as the “Exchange.”

Pursuant to the terms of the securities purchase agreement that the Company entered into on March 31, 2011 (the “2011 SPA”), as a result of the Offering and the Exchange, the Company issued the purchasers in its March 31, 2011 financing, or their assigns, an aggregate of 755,207 shares of common stock. The related expense has been recorded to “Financial expenses (income), net” within the Consolidated Statements of Operations.

Due to the Offering and the Exchange, the Company believes that it has sufficient cash to continue its operations into 2015. However, depending on the operating results in 2013 and 2014, the Company may need to obtain additional cash in 2015 to continue to fund its operations.

NOTE 2 - BASIS OF PRESENTATION:

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to 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 nine months ended March 31, 2013 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 10(a)).

During the nine months ended March 31, 2013, 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.

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 the 2011 SPA. Pursuant to the 2011 SPA, 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 2011 SPA additional shares of common stock equal to 10% of the number of shares of common stock originally acquired by each such purchaser under the 2011 SPA.

On February 7, 2013 the Company's board of directors approved the appointment of a new Director. In connection with his appointment, the Company issued 124,415 stock options to purchase shares of common stock at an exercise price of $3.4 per share, the closing price of the common stock on the date of grant. The fair value of the above granted shares is approximately $257,000. In calculating the fair value of options granted under share-based remuneration arrangements the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years in each year; expected volatility of 66.8%-68.9%; and risk-free interest rate of 0.96%-1.21%. The options have terms of 10 years from the date of grant and are subject to a three year vesting period, with one-third of such awards vesting each year.

NOTE 3- EQUITY (continued):

On January 3, 2013, in connection with the appointment of a new CEO, the Company granted the CEO a nonqualified stock option to purchase 525,927 shares of the Company's common stock and an incentive stock option to purchase 74,073 shares of the Company's common stock and 400,000 shares of restricted stock (See Note 9).

As of March 31, 2013 there is unrecognized stock based compensation of approximately $3.4 million that will be recognized over a weighted average period of 3 years.

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 nine month periods ended March 31, 2013 and 2012 and the three month period ended March 31, 2013 and 2012, all shares of common stock underlying outstanding options, warrants, convertible loans and restricted stock 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 stock related to outstanding options, warrants and convertible loans that were excluded from the calculations of diluted loss per share were 8,512,041 and 5,036,730 for the nine month periods ended March 31, 2013 and 2012, respectively and 8,512,041 and 5,036,730 for the three month periods ended March 31, 2013 and 2012, respectively.

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.

NOTE 5 - FAIR VALUE MEASURMENT (continued):

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

	Level	March 31 2013	June 30, 2012
		($ in thousands)	
Anti-dilution rights	3	$1,322	
2012 Warrants at fair value	2	$510	$1,706
Embedded derivative	3	30	49
		$1,862	$1,755

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

	Anti-Dilution Rights	Embedded Derivative
	($ in thousands)	
Balance as of July 1, 2012	$-	$ 49
Losses included in earnings - financial expenses , net	1,322	(19)
Balance as of March 31, 2013	$1,322	$ 30

Level 3 liabilities include an embedded derivative related to the Company's former Debentures and anti-dilution rights. 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.

The Company values the Level 3 Anti-Dilution Rights using an internally developed valuation model, whose inputs include potential fund raising amounts, probability of completing successful fund raising during the relevant period and stock prices.

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 March 31, 2013, the Company used the following assumptions: expected term of 4 years; expected volatility of 63.3%; risk-free interest rate of 0.57%; 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 former Debentures at March 31, 2013 approximated 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:

	March 31, 2013	June 30, 2012
	($ in thousands)	
Finished goods	$416	$ 479
Work in process	1,433	1,115
Raw materials and supplies	133	150
	$1,982	$ 1,744

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2013	June 30, 2012
	($ in thousands)	
Employees and employee institutions	$496	$ 438
Accrued vacation and recreation pay	220	272
Accrued clinical trial expenses	399	607
Provision for sales commissions	153	194
Accrued expenses	1,562	1,197
Due to government institutions	8	22
Provision for returns		139
Taxes payable	47	56
	$2,885	$ 2,925

NOTE 8 - FINANCIAL EXPENSES (INCOME), NET:

	Three months ended March 31,		Nine months ended March 31,	
	2013	2012	2013	2012
	($ in thousands)		($ in thousands	
Bank commissions	$ 6	$ 12	$ 23	$ 27
Interest income	(7)	(5)	(22)	(37)
Exchange rate differences	6	(19)	(69)	118
Interest expense (including debt issuance costs)	1,276	1	3,384	28
	411		106	

Change in fair value of warrants, embedded derivatives and anti-dilution rights	$ 1,692	$ (11)	$ 3,422	$ 136

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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.

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. The Company recorded a provision amounting to $66,000.

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 CEO, the Company entered into an Employment Agreement (the “Employment Agreement”) with the CEO. Under the Employment Agreement, the CEO is entitled to an annual base salary of at least $450,000. The 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 “Restricted Stock 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 CEO's continued service with the Company, with one-thirty-sixth (1/36th) of such awards vesting each month.

On April 24, 2013, the Company and the CEO amended each of (i) Employment Agreement and (ii) Restricted Stock Award Agreement in order to change the vesting of the restricted stock awarded to the CEO thereunder from monthly vesting to annual vesting.

The CEO has an option to deliver a number of shares with an aggregate fair market value that equals or exceeds (to avoid the issuance of fractional shares) the required tax withholding payment resulted from the vesting of the restricted stock or from the exercise of the options. As of March 31, 2013, 6,567 shares were withheld by the Company to satisfy tax withholding obligations. The payment, amounting to $20,388, was deducted from equity.

On or before December 31 of each calendar year, the 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.

NOTE 9 - RELATED PARTIES (continued):

If, during the term of the Employment Agreement, the CEO's employment is terminated upon certain conditions as stipulated in the agreement, the CEO will be entitled to receive certain benefits as stipulated in the agreement.

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.

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 was 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.

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 were 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 amortization is calculated using the economic pattern of the Company's estimated future revenues over the

estimated useful life of the royalties' buyout. The amortization is recorded in "Cost of Revenues" in the Consolidated Statements of Operations.

On February 27, 2013, the Company gave a 90 days' notice period as stipulated in the agreement to cancel its lease agreement for the Company's existing production facilities. The production will be moved to the Company's headquarters.

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.

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES (continued):

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 20, 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. As of March 31, 2013, the Company paid the plaintiff $25,000 and the provision was modified to $25,000.

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.

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. Following an evidence hearing on April 29, 2013, the parties agreed to settle all current and future claims against each other in exchange for the Company issuing between $50,000 and $200,000 of shares of its common stock, with the exact amount and current value of the Company's common stock to be determined by the court. After considering the views of its legal counsel as well as other factors, the Company's management believes that the final outcome within the range is not 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. 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.

NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES (continued):

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 possible 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 filed a complaint against InspireMD Ltd., the Company’s former CEO, former President, and Vice President of Research and Development (the ‘‘Managers’’), alleging that InspireMD Ltd. failed to operate its production facilities under a proper business license. InspireMD Ltd. received its required business license on January 31, 2013. On February 13, 2013, all claims against the Managers were dropped and InspireMD Ltd. settled its claim with the State of Israel for less than $2,000.

c. Liens and pledges

As of March 31, 2013, the Company had fixed liens aggregating $91,000 to bank Mizrahi in connection with the Company’s credit cards.

The Company’s obligations under the Debentures were 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. In connection with the Exchange (See Note 1), all of these security interests were terminated.

NOTE 11 - ENTITY WIDE DISCLOSURE:

The Company operates in one operating segment.

Disaggregated financial data is provided below as follows:

(1) Revenues by geographic area and

(2) Revenues from principal customers.

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

	3 months ended March 31,		9 months ended March 31,	
	2013	2012	2013	2012
	($ in thousands)		($ in thousands)	
Russia	$435	$-	$560	$360
Spain	157	105	446	376
Germany	81	150	186	320
Netherlands	39	123	105	144
India	27	120	299	120
Mexico	-	219	5	391
Poland	-	144	3	334
Other	775	277	1,769	2,371
	$1,514	$1,138	$3,373	$4,416

NOTE 11 - ENTITY WIDE DISCLOSURE (continued):

The following is a summary of revenues by principal customers:

	3 months ended March 31,		9 months ended March 31,	
	2013	2012	2013	2012
Customer A	29%	- %	17%	8 %
Customer B	10%	9 %	13%	9 %
Customer C	5 %	13 %	6 %	7 %
Customer D	3 %	11 %	3 %	3 %
Customer E	2 %	11 %	9 %	3 %
Customer F	- %	19 %	- %	9 %
Customer G	- %	13 %	- %	8 %

The majority of tangible long-lived assets are located in Israel.

NOTE 12 - SUBSEQUENT EVENTS:

On November 16, 2011, in connection with the appointment of the Company's Chairman, the Chairman was issued an option to purchase 181,250 shares of common stock at an exercise price of $7.80 per share, which vested and became exercisable on April 11, 2013, when the common stock was listed on the NYSE MKT, a registered national securities exchange.

On April 16, 2013, the Company appointed a new Vice President of Corporate Development. In accordance with the appointment, on April 22, 2013, the Company granted the new Vice President of Corporate Development stock options to purchase 150,000 shares of the Company's common stock. The options have an exercise price of $1.97, which was the fair market value of the Company's common stock on the date of grant. The options are subject to a three-year vesting period with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 66.9%-68.2%; and risk-free interest rate of 0.8%-1.02%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $178,000.

On April 22, 2013, the Company modified the compensation packages of its chief financial officer and its senior vice president of research and development and chief technical officer of InspireMD Ltd., the Company's wholly-owned subsidiary, in order to (i) increase the base salaries of each to $175,000 per annum, (ii) provide that each shall be eligible to receive an annual bonus equal to up to 30% of his base salary, at the sole discretion of the compensation committee of the Company, in consultation with the Company's chief executive officer, and (iii) provide termination benefits as stipulated in the amendments.

On April 25, 2013, the Company granted to the CEO (i) options to purchase 297,447 shares of common stock of Common Stock, with an exercise price of $2.05 per share (the "April Option Grant") and (ii) 179,866 restricted shares of Common Stock (the "April RS Grant"). The April Option Grant vests in three equal annual installments. The April RS Grant is subject to forfeiture until vested. This award vests in three equal annual installments. The fair value of the above 179,866 restricted shares was approximately $369,000.

NOTE 12 - SUBSEQUENT EVENTS (continued):

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 66.9%-68.2%; and risk-free interest rate of 0.82%-1.04%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $368,000.

On May 3, 2013, the board of directors approved the issuance of options to purchase an aggregate of 400,000 shares of the Company's common stock to certain of the Company's independent directors, with the grant date to be the second trading day after the filing of this Quarterly Report on Form 10-Q and the exercise price to be the fair market value of the common stock on such grant date. The options will be subject to a three-year vesting period with one-third of such awards vesting each year.

During April and May 2013, the Company issued a total of 126,928 shares of its common stock in connection with the exercise of 126,928 options. The Company's cash proceeds in connection with such exercises equal the par value of the shares issued.

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.

On April 16, 2013, we consummated an underwritten public offering pursuant to which we sold 12.5 million shares of common stock. The public offering price of our common stock in this offering was $2.00 per share, resulting in aggregate net proceeds to us of approximately $22.6 million, after the underwriters' commissions and offering expenses. We also granted the underwriters in this offering a 30-day option to purchase up to an additional 1.875 million shares of common stock to cover over-allotments, if any. On April 11, 2013, following the pricing of the offering, the Company's common stock commenced trading on the NYSE MKT.

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 March 31, 2013 Compared to Three Months Ended March 31, 2012

Revenues. For the three months ended March 31, 2013, total revenue increased by approximately $0.4 million, or 33.0%, to approximately $1.5 million from approximately $1.1 million during the same period in 2012. The following is an explanation of the approximately $0.4 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately $452,000 and a net decrease in deferred revenues of approximately $77,000.

For the three months ended March 31, 2013, total gross revenue increased by approximately $452,000, or approximately 42.6%, to approximately $1.5 million from approximately $1.1 million during the same period in 2012. This increase in total gross revenue is attributable to an increase in sales volume of approximately $0.5 million, or approximately 47.1%, partially offset by price decreases to our repeat distributors accounting of approximately $54,000, or approximately 5.1%. With respect to regions, the increase in gross revenue was mainly attributable to an increase of approximately $0.4 million in gross revenue from our distributors in Europe, an increase of approximately $0.1 million in gross revenue from our distributor in Israel and an increase of approximately $0.1 million in gross revenue from our distributors in Africa. These increases were partially offset by a decrease of approximately $0.1 million in gross revenue from our distributors in Latin America.

For the three months ended March 31, 2013, we did not recognize past deferred revenue, nor did we defer any of our current revenue, compared to a net recognition of approximately $77,000 of revenue during the same period in 2012. The revenue recognized and deferred during both periods was calculated based on our history of returns, and recognized one year later.

Gross Profit. For the three months ended March 31, 2013, gross profit (revenue less cost of revenues) increased 48.9%, or approximately $0.3 million, to approximately $0.9 million from approximately $0.6 million during the same period in 2012. The increase in gross profit is attributable to an increase in net sales of approximately $0.4 million, partially offset by an increase in cost of goods sold of approximately $0.1 million. Gross margin increased from 49.6% in the three months ended March 31, 2012 to 55.5% in the three months ended March 31, 2013 due to an increase in average sales price as well as a decrease in average cost per unit sold.

Research and Development Expenses. For the three months ended March 31, 2013, research and development expenses decreased 32.8%, or approximately $0.5 million, to approximately $0.9 million, from approximately $1.4 million during the same period in 2012. The decrease in cost resulted primarily from lower clinical trial expenses of approximately $0.4 million, attributable mainly to a timing gap between the pre-clinical phase and the start of the recruitment phase of our planned U.S. Food and Drug Administration trial (causing a decrease of approximately $0.3 million between periods), as well as a decrease of approximately $0.2 million in expenses associated with our MASTER Trial, as we approach the trial's conclusion, partially offset by an increase in expenditures related to a clinical trial for our MGuard Carotid product (increase of approximately $0.1 million). In addition to the decrease in clinical trial expenses, there was a decrease of approximately $0.1 million in share based compensation expenses. Research and development expense as a percentage of revenue decreased to 59.9% for the three months ended March 31, 2013 from 118.5% in the same period in 2012.

Selling and Marketing Expenses. For the three months ended March 31, 2013, selling and marketing expenses increased 80.7%, or approximately $0.4 million, to approximately $0.8 million, from approximately $0.4 million during the same period in 2012. The increase in selling and marketing expenses resulted primarily from an increase of approximately $0.2 million of additional salary expenses as we expanded our sales activities worldwide, an increase of approximately $0.2 million in product promotion expenses, and an increase of approximately $0.1 million in travel expenses. These increases were partially offset by a decrease of approximately $0.1 million in miscellaneous expenses. Selling and marketing expenses as a percentage of revenue increased to 53.1% in the three months ended March 31, 2013 from 39.1% in the same period in 2012.

General and Administrative Expenses. For the three months ended March 31, 2013, general and administrative expenses increased 23.4%, or approximately $0.5 million, to approximately $2.4 million from approximately $1.9 million during the same period in 2012. This increase resulted primarily from an increase in share-based compensation of $0.3 million (which predominately relates to the hiring of our new chief executive officer), an increase in salary expenses of approximately $0.2 million (which predominately relates to the hiring of our new chief executive officer), and an increase of approximately $0.1 million in miscellaneous expenses. This increase was partially offset by a decrease of approximately $0.1 million in rent expense. General and administrative expenses as a percentage of revenue decreased to 154.6% in the three months ended March 31, 2013 from 166.6% in the same period in 2012.

Financial Expenses (Income). For the three months ended March 31, 2013, financial expenses (income) increased approximately $1.7 million to approximately $1.7 million of financial expenses from approximately $11,000 of financial income during the same period in 2012. The increase in expense resulted primarily from approximately $1.3

million of amortization expense pertaining to our convertible debentures and their related issuance costs and approximately $1.3 million of expense pertaining to anti-dilution rights, partially offset by approximately $0.9 million of financial income pertaining to the revaluation of certain of our warrants due to our stock price decreasing to $2.52 on March 31, 2013, from $3.90 on December 31, 2012. Financial expense as a percentage of revenue increased from (1.0)% in the three months ended March 31, 2012, to 111.8% in the same period in 2013.

Tax Expenses (Income). For the three months ended March 31, 2013, tax expenses (income) decreased by approximately $43,000 from approximately $25,000 of tax expenses for the three months ended March 31, 2012, to approximately $18,000 of tax income during the same period in 2013.

Net Loss. Our net loss increased by approximately $1.8 million, or 55.6%, to approximately $4.9 million for the three months ended March 31, 2013 from approximately $3.1 million during the same period in 2012. The increase in net loss resulted primarily from an increase of approximately $1.7 million in financial expenses (see above for explanation) and an increase of approximately $0.4 million in operating expenses (see above for explanation), partially offset by an increase of approximately $0.3 million in gross profit (see above for explanation).

Nine Months Ended March 31, 2013 Compared to Nine Months Ended March 31, 2012

Revenues. For the nine months ended March 31, 2013, total revenue decreased by approximately $1.0 million, or 23.6%, to approximately $3.4 million from approximately $4.4 million during the same period in 2012. The following is an explanation of the approximately $1.0 million decrease in revenue broken down by its main two components, a decrease in gross revenues of approximately $1.1 million, partially offset by a net increase in deferred revenues of approximately $0.1 million.

For the nine months ended March 31, 2013, total gross revenue decreased by approximately $1.1 million, or approximately 24.6%, to approximately $3.3 million from approximately 4.4 million during the same period in 2012. This decrease in total gross revenue is entirely attributable to a decrease in sales volume of approximately $1.1 million, or approximately 24.7%, partially offset by price increases to our repeat distributors of approximately $5,000, or approximately 0.1%. The $1.1 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 distributors in Central and South America, a decrease of approximately $0.3 million in gross revenue from our distributors in Europe, a decrease of approximately $0.2 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 nine months ended March 31, 2013 increased to approximately $83,000 recognized in revenue from approximately $53,000 recognized in revenue during the same period in 2012. 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 nine months ended March 31, 2013, gross profit (revenue less cost of revenues) decreased 18.9%, or approximately $448,000, to approximately $1.9 million from approximately $2.4 million during the same period in 2012. This decrease in gross profit is attributable to a decrease in net sales of approximately $1.0 million, partially offset by a decrease in cost of goods sold of approximately $0.5 million. Gross margin increased from 53.7%

in the nine months ended March 31, 2012 to 57.0% in the nine months ended March 31, 2013.

Royalties' Buyout Expenses. For the nine months ended March 31, 2013, we incurred approximately $0.9 million in royalties' buyout expenses relating to the restructuring of our royalty agreement for the MGuard Prime version of our MGuard Coronary stent. 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 $10.0 million of net sales in the United States and 10% of net sales in the United States above $10.0 million 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 nine months ended March 31, 2012. Royalties' buyout expenses as a percentage of revenue was 27.2% for the nine months ended March 31, 2013.

Research and Development Expenses. For the nine months ended March 31, 2013, research and development expenses increased 13.9%, or approximately $0.4 million, to approximately $3.1 million from approximately $2.7 million during the same period in 2012. The increase in cost resulted primarily from higher clinical trial expenses of approximately $0.3 million attributable mainly to a clinical trial for our MGuard Carotid product (approximately $0.4 million), and miscellaneous clinical trial expenses (approximately $0.1 million), partially offset by delaying expenditures associated with our planned U.S. Food and Drug Administration trial (causing a decrease of approximately $0.1 million between periods), as we awaited approval for our Investigational Device Exemption application with the U.S Food and Drug Administration, as well as a decrease of approximately $0.1 million in expenses associated with our MASTER Trial (as we were concluding the trial). In addition to the increase in clinical trial expenses, there was an increase of approximately $0.1 million in patent expenses. Research and development expense as a percentage of revenue increased to 92.2% for the nine months ended March 31, 2013 from 61.8% in the same period in 2012.

Selling and Marketing Expenses. For the nine months ended March 31, 2013, selling and marketing expenses increased 75.7%, or approximately $1.0 million, to approximately $2.4 million, from approximately $1.4 million during the same period in 2012. The increase in selling and marketing expenses resulted primarily from approximately $0.5 million of additional salary expenses as we expanded our sales activities worldwide, 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, an increase of approximately $0.4 million in product promotional expenses, and an increase of approximately $0.1 million in travel expenses. These increases were partially offset by a decrease of approximately $0.3 million in share based compensation expenses and a decrease of approximately $0.1 million in miscellaneous expenses. Selling and marketing expenses as a percentage of revenue increased to 71.5% in the nine months ended March 31, 2013 from 31.1% in the same period in 2012.

General and Administrative Expenses. For the nine months ended March 31, 2013, general and administrative expenses decreased 46.2%, or approximately $5.4 million, to approximately $6.4 million from approximately $11.8 million during the same period in 2012. This decrease resulted primarily from a decrease in share-based compensation of $6.6 million (which predominately pertained to directors' compensation), partially offset by an increase of approximately $0.5 million in legal fees and other expenses related to our fundraising activities, approximately $0.2 million in additional salaries (which predominately relates to the hiring of our new chief executive officer), an increase of approximately $0.2 million in bad debt expense and an increase of approximately $0.3 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue decreased to 188.0% in the nine months ended March 31, 2013 from 266.8% in the same period in 2012.

Financial Expenses. For the nine months ended March 31, 2013, financial expenses increased 2,416.2% or approximately $3.3 million to approximately $3.4 million from approximately $0.1 million during the same period in 2012. The increase resulted primarily from approximately $3.4 million of amortization expense pertaining to our convertible debentures and their related issuance costs and approximately $1.3 million of expense pertaining to anti-dilution rights expenses, partially offset by approximately $1.2 million of financial income pertaining to the revaluation of certain of our warrants due to our stock price decreasing to $2.52 on March 31, 2013, from $4.24 on June 30, 2012 and approximately $0.1 million for the favorable impact of exchange rate differences for the nine months ended March 31, 2013. Financial expense as a percentage of revenue increased from 3.1% in the nine months

ended March 31, 2013, to 101.5% in the same period in 2013.

Tax Expenses. For the nine months ended March 31, 2013, tax expenses increased by approximately $24,000 from approximately $7,000 for the nine months ended March 31, 2012, to approximately $31,000 during the same period in 2013.

Net Loss. Our net loss increased by approximately $0.6 million, or 4.8%, to approximately $14.3 million for the nine months ended March 31, 2013 from approximately $13.7 million during the same period in 2012. The increase in net loss resulted from an increase of approximately $3.3 million financial expenses (see above for explanation) and a decrease of approximately $0.4 million in gross profit (see above for explanation), partially offset by a decrease of approximately $3.1 million in operating expenses (see above for explanation).

Liquidity and Capital Resources

Due to the underwritten public offering of our common stock and the exchange and amendment agreement that we entered into with the holders of our convertible debentures, we believe that we have sufficient cash to continue our operations into 2015. However, depending on the operating results in 2013 and 2014, we may need to raise additional funds in 2015 to continue financing its operations.

General. At March 31, 2013, we had cash and cash equivalents of approximately $2.5 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 issuing 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 $8.6 million for the nine months ended March 31, 2013 and $5.8 million for the same period in 2012. The principal reasons for the usage of cash in our operating activities for the nine months ended March 31, 2013 include a net loss of approximately $14.3 million and an increase in working capital of approximately $0.9 million, offset by approximately $2.7 million in non-cash financial expenses, approximately $2.7 million in non-cash share-based compensation, 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 miscellaneous expenditures.

Cash used in our investing activities was approximately $267,000 during the nine months ended March 31, 2013, compared to approximately $109,000 of cash generated by investing activities during the same period in 2012. The principal reason for the increase in cash used in investing activities during 2013 was the purchase of property, plant and equipment of approximately $118,000 (primarily new manufacturing equipment), an increase in restricted cash of approximately $54,000 and the funding of employee retirement funds of approximately $95,000.

Cash generated by financing activities was approximately $1.0 million for the nine months ended March 31, 2013, compared to $1.2 million generated from financing activities for the same period in 2012. The principal source of cash from financing activities during the nine months ended March 31, 2013 was funds received for the exercise of options and warrants in the amount of approximately $1.0 million. In contrast, during the nine months ended March 31, 2012, we received approximately $1.5 million from the exercise of options, partially offset by a repayment of a long term loan of approximately $0.3 million.

As of March 31, 2013, our current liabilities exceeded current assets by a multiple of 1.53. Current assets decreased approximately $7.2 million during the nine month period, mainly due to cash used in operations, and current liabilities

increased by approximately $7.3 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 $14.5 million to a working capital deficiency of approximately $3.8 million at March 31, 2013.

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, bore interest at an annual rate of 8% and were 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 were entitled to 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 had the right to 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 had the right to 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.

On April 9, 2013, we entered into an exchange and amendment agreement with the holders of these convertible debentures, pursuant to which, simultaneously with the closing of our underwritten public offering on April 16, 2013, and in full satisfaction of our obligations under the convertible debentures, we:

- repaid $8,787,234 in cash;
- issued 2,159,574 shares of common stock to the holders of the convertible debentures, reflecting a conversion price of $2.00 per share for the remaining unpaid portion of the convertible debentures;
- issued five year warrants to the holders of these convertible debentures to purchase an aggregate of 659,091 shares of common stock for $3.00 per share;
- amended the securities purchase agreement pursuant to which the convertible debentures were originally issued to prohibit us from issuing securities containing anti-dilution protective provisions; and
- amended the warrants issued in connection with the convertible debentures to (i) eliminate the automatic incorporation of the terms of any securities that are superior to those of such warrants, except with respect to exercise price and warrant coverage and (ii) provide that upon a fundamental transaction, the holders of such warrants will have the right to cause us to repurchase the unexercised portion of such warrants at their Black-Scholes value on the date of such fundamental transaction, payable in shares of common stock, rather than in cash as was previously provided.

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 nine months ended March 31, 2013, we amended our license agreement for the use of the stent design for the MGuard Prime version of the MGuard Coronary stent. 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 March 31, 2013, 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 March 31, 2013, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of March 31, 2013.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the nine months ended March 31, 2013 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 Reports on Form 10-Q for the three months ended September 30, 2012 and the six months ending December 31, 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

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. Since we expect to continue incurring negative cash flows from operations, there can be no assurance that we will ever generate sufficient revenues to become profitable.

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 Coronary 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 Coronary 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 Coronary 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 Coronary 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 Coronary 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 Coronary stents.

Finally, the production of our MGuard Coronary 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.

Clinical trials necessary to support our MGuard products may 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 our MGuard products will be expensive and may 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. 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. Significant delays or failures of clinical trials could delay or prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

The clinical trial for our investigational device exemption application with the U.S. Food and Drug Administration may be more costly and burdensome than we currently anticipate, which would limit or delay our ability to complete the trial 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 April 19, 2013, we received an approval with conditions from the U.S. Food and Drug Administration to conduct this pivotal trial in support of our investigational device exemption application. This clinical study, however, may have unanticipated complications and delays, may require the enrollment of additional patients, require longer follow-up periods and may be more costly than we currently anticipate, and/or we may fail to achieve the primary or secondary endpoints. Any unanticipated costs and length of this trial, 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.

Physicians may not widely adopt the MGuard Coronary stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of the MGuard Coronary 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 Coronary stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our MGuard Coronary 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 Coronary 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 Coronary 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 Coronary 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, the U.S. Food and Drug Administration may determine that certain metrics that we utilized in our clinical trials were inappropriate 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 eight 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 Coronary 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.

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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, 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. The legislation levies a 2.3% excise tax, that began on January 1, 2013, on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. If we commence sales of our MGuard 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 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.

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.

The report of our independent auditors contains an explanatory paragraph as to our ability to continue as a going concern, which could result in a negative perception of us from investors, customers, vendors and strategic partners.

Because we had recurring losses and negative cash flows from operating activities, along with significant future commitments as of June 30, 2012. 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 transition 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. This doubt regarding our potential inability to continue as a going concern may result in a negative perception of us from investors, customers, vendors and strategic partners. This negative perception could limit the number and quality of parties willing to engage in transactions with us, which could result in a material adverse effect on our overall business 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 five years; a fine of up to approximately $317,000 to be paid by management of the violating company; and a fine of up to approximately $1,590,000 to be paid by the violating company, any of which penalties could result in a material adverse effect on our operations. We believe that it is unlikely that either we or any individual will be subject to fines or other penalties as a result of these alleged violations.

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

In order to fully realize all of our business objectives, we will need to raise additional capital, 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 our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

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

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately 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 many of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. 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.

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 expose us to competitive disadvantages if former employees go to work for a competitor while in possession of confidential information about our business.

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. InspireMD 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. Under these benefits, InspireMD Ltd. will not be subject to taxation for two years following the exhaustion of its carried forward tax losses and then it will enjoy five to eight years of a reduced tax rate of 10% to 25% of taxable income in Israel. 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 current standard corporate tax rate for Israeli companies is 25% of their taxable income. 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.

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;

- 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.

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, even though our common stock was recently listed on the NYSE MKT, we cannot assure you that we will maintain compliance with all of the requirements for our common stock to remain listed. Furthermore, there can be no assurance that trading of our common stock on the NYSE MKT will be sustained or desirable or that our common stock will enjoy similar levels of liquidity, research coverage and institutional investor following as other stocks listed on a national securities exchange.

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

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

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

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our 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 May 6, 2013, there were 3,308,277 shares of our common stock issuable upon the exercise of our outstanding warrants. In addition, there are 21,466,746 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 and warrant 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.

Item 6. Exhibits

See Index to Exhibits.

SIGNATURES

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

INSPIREMD, INC.

Date: May 7, 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	Employment Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan W. Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.2	Nonqualified Stock Option Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan W. Milinazzo (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.3	Incentive Stock Option Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan W. Milinazzo (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.4	Restricted Stock Award Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan W. Milinazzo (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.5	Separation Agreement and Release, dated January 3, 2013, by and between InspireMD Ltd. and A.S. Paz Management and Investment Ltd., Company No. 514480433 (incorporated by reference to Exhibit 10.6 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)

31.1* Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2* Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1* Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

* Filed herewith.

** 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.