

InspireMD, Inc.  
Form 10-Q  
November 14, 2011

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: September 30, 2011

OR

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

For the transition period from      to

Commission file number: 333-162168

InspireMD, Inc.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

26-2123838  
(I.R.S. Employer  
Identification No.)

3 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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting  
company)

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

The number of shares of the registrant’s common stock \$0.0001 par value, outstanding as of November 14, 2011:  
65,278,946

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
CONSOLIDATED BALANCE SHEETS  
(Unaudited)  
(U.S. dollars in thousands)

	September 30, 2011	December 31, 2010
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 7,485	\$ 636
Restricted cash	40	250
Accounts receivable:		
Trade	1,778	852
Other	117	75
Prepaid expenses	103	3
Inventory:		
On hand	1,905	1,704
On consignment	102	371
T o t a l current assets	11,530	3,891
PROPERTY, PLANT AND EQUIPMENT, net of accumulated depreciation and amortization	346	282
<b>OTHER NON-CURRENT ASSETS:</b>		
Deferred debt issuance costs	5	15
Funds in respect of employees rights upon retirement	189	167
T o t a l other non-current assets	194	182
T o t a l assets	\$ 12,070	\$ 4,355

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

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
CONSOLIDATED BALANCE SHEETS  
(Unaudited)  
(U.S. dollars in thousands)

	September 30, 2011	December 31, 2010
<b>LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of long-term loans	\$ 183	\$355
Accounts payable and accruals :		
Trade	562	1,103
Other	2,337	1,509
Advanced payment from customers	516	559
Loans from shareholders		20
Deferred revenues		398
T o t a l current liabilities	3,598	3,944
<b>LONG-TERM LIABILITIES:</b>		
Long term loan		75
Liability for employees rights upon retirement	257	206
Convertible loan		1,044
T o t a l long-term liabilities	257	1,325
<b>COMMITMENTS AND CONTINGENT LIABILITIES (note 10)</b>		
T o t a l liabilities	3,855	5,269
<b>EQUITY (CAPITAL DEFICIENCY):</b>		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 65,278,946 shares issued and outstanding at September 30, 2011 and 49,863,801 shares issued and outstanding at December 31, 2010	6	5
Additional paid-in capital	36,617	21,057
Accumulated deficit	(28,408 )	(21,976 )
T o t a l equity (capital deficiency)	8,215	(914 )
T o t a l liabilities and equity (capital deficiency)	\$ 12,070	\$4,355

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

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

	3 months ended		9 months ended		Year ended
	September 30		September 30		December 31
	2011	2010	2011	2010	2010
REVENUES	\$1,986	\$1,223	\$4,712	\$4,228	\$4,949
COST OF REVENUES	801	561	2,340	2,377	2,696
GROSS PROFIT	1,185	662	2,372	1,851	2,253
OPERATING EXPENSES:					
Research and development	547	196	1,640	969	1,338
Selling and marketing	302	279	1,347	916	1,236
General and administrative	2,486	904	4,877	2,016	2,898
Total operating expenses	3,335	1,379	7,864	3,901	5,472
LOSS FROM OPERATIONS	(2,150 )	(717 )	(5,492 )	(2,050 )	(3,219 )
FINANCIAL EXPENSES, net	108	121	895	150	154
LOSS BEFORE TAX EXPENSES	(2,258 )	(838 )	(6,387 )	(2,200 )	(3,373 )
TAX EXPENSES	25	9	45	39	47
NET LOSS	\$(2,283 )	\$(847 )	\$(6,432 )	\$(2,239 )	\$(3,420 )
NET LOSS PER SHARE - basic and diluted	\$(0.04 )	\$(0.02 )	\$(0.11 )	\$(0.05 )	\$(0.07 )
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	64,300,685	49,490,460	59,667,655	49,072,828	49,234,528

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

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CAPITAL DEFICIENCY)  
(Unaudited)  
(U.S. dollars in thousands)

	Ordinary shares				Total equity (capital deficiency)
	Number of shares	Par value	Additional paid-in capital	Accumulated deficit	
BALANCE AT JANUARY 1, 2011	\$49,863,801	\$5	\$ 21,057	\$(21,976 )	\$(914 )
CHANGES DURING 9 MONTHS OF 2011:					
Net loss				(6,432 )	(6,432 )
Employee and non-employee share-based compensation			4,834		4,834
Issuance of ordinary shares, net of \$185 issuance costs	896,651	*	805		805
Issuance of ordinary shares and warrants, net of \$2,835 issuance costs.	12,992,269	1	7,653		7,654
Exercise of options	1,000,000	*	1,500		1,500
Conversion of convertible loans	526,225	*	768		768
BALANCE AT SEPTEMBER 30, 2011	\$65,278,946	\$6	\$ 36,617	\$(28,408 )	\$8,215
BALANCE AT JANUARY 1, 2010	\$48,338,380	\$5	\$ 17,212	\$(18,556 )	\$(1,339 )
CHANGES DURING 9 MONTHS OF 2010:					
Net loss				(2,239 )	(2,239 )
Employee and non-employee share-based compensation			1,796		1,796
Issuance of ordinary shares, net of \$73 issuance costs	1,152,080	*	1,345		1,345
BALANCE AT SEPTEMBER 30, 2010	\$49,490,460	\$5	\$ 20,353	\$(20,795 )	\$(437 )
BALANCE AT JANUARY 1, 2010	\$48,338,380	\$5	\$ 17,212	\$(18,556 )	\$(1,339 )
CHANGES DURING 2010:					
Net loss				(3,420 )	(3,420 )
Employee and non-employee share-based compensation			1,640		1,640
Issuance of warrants, net of \$23 issuance costs			424		424
Issuance of ordinary shares, net of \$97 issuance costs	1,525,421	*	1,781		1,781
BALANCE AT DECEMBER 31, 2010	\$49,863,801	\$5	\$ 21,057	\$(21,976 )	\$(914 )

\* Represents an amount less than \$1,000

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

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

	9 months ended September 30		Year ended December 31,
	2011	2010	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$(6,432 )	\$(2,239 )	\$(3,420 )
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	52	85	91
Loss from sale of property, plant and equipment	15		
Change in liability for employees right upon retirement	45	3	42
Financial expenses	852	96	94
Share-based compensation expenses	2,817	1,352	1,620
Loss (Gains) on amounts funded in respect of employee rights upon retirement, net	7	38	(11 )
Changes in operating asset and liability items:			
Decrease (increase) in prepaid expenses	(100 )	28	36
Decrease (increase) in trade receivables	(926 )	508	337
Decrease (increase) in other receivables	(50 )	(35 )	9
Decrease in inventory on consignment	269	829	722
Increase in inventory on hand	(201 )	(518 )	(758 )
Increase (decrease) in trade payables	(541 )	(231 )	196
Decrease in deferred revenues	(398 )	(1,783 )	(1,577 )
Increase (decrease) in other payable and advance payment from customers	740	(287 )	(91 )
Net cash used in operating activities	(3,851 )	(2,154 )	(2,710 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Decrease in restricted cash	210	52	52
Purchase of property, plant and equipment	(98 )	(64 )	(81 )
Proceeds from sale of property, plant and equipment	29		
Amounts funded in respect of employee rights upon retirement	(21 )	(41 )	(17 )
Net cash provided by (used in) investing activities	120	(53 )	(46 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of shares and warrants, net of issuance costs of \$1,014 and \$25 in the nine months ended September 30, 2011 and 2010, respectively and \$78 in the year ended December 31, 2010	10,564	1,789	2,245
Exercise of options	1,500		
Repayment of convertible loan	(1,000 )		
Repayment of long term loan	(281 )	(188 )	(281 )
Proceeds from convertible loan at fair value through profit or loss, net of \$60 issuance costs		1,073	1,073
Repayment of loans from shareholders	(20 )		
Net cash provided by financing activities	10,763	2,674	3,037



EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(183 )	13	(21 )
INCREASE IN CASH AND CASH EQUIVALENTS	6,849	480	260
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	636	376	376
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$7,485	\$856	\$636

- (\*) During the 9 month period ended September 30, 2011:
- a. a convertible loan in the amount of \$668,000 was converted into shares of the Company's common stock.
  - b. 93,785 shares were issued in relation to services provided.

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

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 1 - DESCRIPTION OF BUSINESS

InspireMD, Inc., formerly Saguaro Resources, Inc. (the “Company”), a public company, is a Delaware corporation formed on February 29, 2008. On March 28, 2011, the Company changed its name to InspireMD, Inc.

On December 29, 2010, the Company entered into a Share Exchange Agreement (the “Exchange Agreement”) by and among the Company and InspireMD Ltd., a limited company incorporated under the laws of the State of Israel in April 2005. Subsequent to the date of execution of the Exchange Agreement, shareholders of InspireMD Ltd., holding 91.7% of InspireMD Ltd.’s issued and outstanding ordinary shares, executed a joinder to the Exchange Agreement and became parties thereto (the “InspireMD Shareholders”). Pursuant to the Exchange Agreement, on March 31, 2011, the InspireMD Ltd. Shareholders transferred all of their ordinary shares in InspireMD Ltd. to the Company in exchange for 46,471,907 newly issued shares of common stock of the Company (the “Initial Share Exchange”). In addition, the remaining holders of InspireMD Ltd.’s ordinary shares separately transferred all of their ordinary shares of InspireMD Ltd. to the Company, in exchange for an aggregate of 4,194,756 newly issued shares of common stock of the Company (the “Follow Up Share Exchange” and, together with the Initial Share Exchange, the “Share Exchange”). As a result of the Share Exchange, InspireMD Ltd. became a wholly owned subsidiary of the Company.

The Share Exchange is being accounted for as a reverse recapitalization, equivalent to the issuance of stock by InspireMD Ltd., for the net monetary assets of the Company. Accordingly, the historical financial statements of the Company reflect the historical operations and financial statements of InspireMD Ltd.

The Company, together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary stent platform technology, MGuard™. MGuard™ provides embolic protection in stenting procedures by placing a micron mesh sleeve over a stent. The Company’s initial products are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). The Company markets its products through distributors in international markets, mainly in Europe and Latin America.

In addition, the Company operates in Germany through its wholly-owned subsidiary InspireMD GmbH, a German limited liability company incorporated in November 2007, where the Company subcontracts the manufacturing of its stents.

The Company believes that it has sufficient cash to continue its operations into 2013. However, depending on the operating results in 2011 and 2012, the Company may need to obtain additional cash in 2013 to continue to fund operations.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited condensed 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 InspireMD Ltd.’s audited financial statements for the year ended December 31, 2010. The balance sheet for December 31, 2010 was derived from InspireMD Ltd.’s audited financial statements for the year ended December 31, 2010. The results of operations for the nine months ended September 30, 2011 are not

necessarily indicative of results that could be expected for the entire fiscal year.

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 3 - RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

In October 2009, the FASB issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and require companies to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, the amendments eliminate the residual method for allocating arrangement considerations. The adoption of the new guidance did not have a material impact on the Company's consolidated financial statements.

In May 2011, the FASB issued amended guidance and disclosure requirements for fair value measurements. These changes will be effective January 1, 2012 on a prospective basis. Early application is not permitted. These amendments are not expected to have a material impact to the consolidated financial results.

NOTE 4 – DEFERRED REVENUE

As of September 30, 2011, there is no deferred revenue in the balance sheet since, as of this date, the rate of returns can be reliably estimated and is recorded based on historical experience in “Accounts Payable and Accruals – Other.”

NOTE 5 - FACTORING OF RECEIVABLES

During the nine month period ended September 30, 2011, the Company entered into a factoring agreement amounting to \$1.2 million with a certain banking institution on a non-recourse basis. The factoring of trade receivables under this agreement was accounted for as a sale. Under the terms of this factoring agreement, the Company transferred ownership of eligible trade receivables without recourse to the banking institution in exchange for cash. Proceeds on the transfer reflected the face value of the account less a discount. The discount, amounting to \$12,000 during the nine month period ended September 30, 2011 was recorded to “financial expenses - net” within the Condensed Consolidated Statements of Operations.

The receivables sold pursuant to this factoring agreement are excluded from trade receivables on the Condensed Consolidated Balance Sheets and are reflected as cash provided by operating activities on the Condensed Consolidated Statements of Cash Flows. The banking institution had no recourse to the Company’s assets for failure of debtors to pay when due.

The related commissions on the sales of trade receivables sold under these factoring agreements amounting to \$22,000 were recorded to “financial expenses - net” within the Condensed Consolidated Statements of Operations.

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

## NOTE 6 - CERTAIN TRANSACTIONS

During the first quarter of 2011 and prior to the Share Exchange, InspireMD Ltd. raised approximately \$990,000 and issued approximately 803,000 ordinary shares through private placements.

During the first quarter of 2011 and prior to the Share Exchange, InspireMD Ltd. granted 600,294 stock options to employees and consultants at a cash exercise price of \$1.23 per share. The options had terms of four to ten years.

On January 4, 2011, InspireMD Ltd. entered into a convertible loan agreement with its distributor in Israel (the "Lender"), in the amount of \$100,000 subject to the following conditions:

- the convertible loan did not bear annual interest;
- in the event of a share exchange or similar transaction, the Lender would have, at its sole discretion, the option to convert the loan into either (i) shares of the Company's common stock at a price of \$1.23 per share (\$10 as relates to InspireMD Ltd.), or (ii) the Company's product at a price of 400 euro per unit (which represents the market price for the Lender);
- in the event that the Company did not close a share exchange or similar transaction by June 1, 2011, the Lender had the right to extend the loan and its terms for up to an additional 6 months (as noted in Note 1, the Exchange Agreement was closed on March 31, 2011); and
  - in no event was cash required to be repaid by the Company.

On June 1, 2011, the Lender surrendered \$100,000 of the convertible loan in exchange for 81,161 shares of common stock of the Company.

On February 20, 2011, the Company received a tax pre-ruling from the Israeli tax authorities according to section 103 of the Israeli tax law, with regards to the Share Exchange. According to the tax pre-ruling, the exchange of shares and options of InspireMD Ltd. For shares and options of the Company pursuant to the Share Exchange will not result in an immediate tax event for InspireMD Ltd.'s former shareholders, but a deferred tax event, subject to certain conditions as stipulated in the tax pre-ruling. The main condition of the tax pre-ruling is a restriction on the exchanged shares for two years from December 31, 2010 for shareholders holding over of 5%.

In March 2011, the Company granted a new fixed lien of \$40,000 to Bank Mizrahi.

Pursuant to the Exchange Agreement, the Company assumed all of InspireMD Ltd.'s obligations under InspireMD Ltd.'s outstanding stock options. Immediately prior to the Share Exchange, InspireMD Ltd. had outstanding stock options to purchase an aggregate of 937,256 ordinary shares, which outstanding options became options to purchase an aggregate of 7,606,770 shares of common stock of the Company after giving effect to the Share Exchange. In addition, three-year warrants to purchase up to 125,000 ordinary shares of InspireMD Ltd. at an exercise price of \$10 per share were assumed by the Company and converted into warrants to purchase 1,014,500 shares of the Company's common stock at an exercise price of \$1.23 per share.

In connection with the closing of the Share Exchange, the Company sold 6,454,002 shares of its common stock at a purchase price of \$1.50 per share and five-year warrants to purchase up to 3,226,999 shares of common stock at an exercise price of \$1.80 per share in a private placement to accredited investors (the "Private Placement"). As part of the Private Placement, certain holders of the 8% convertible debentures, in an aggregate principal amount of \$1,580,000

(the “Bridge Notes”), surrendered \$667,596 of outstanding principal and interest due under such Bridge Notes in exchange for 445,064 shares of common stock and warrants to purchase an aggregate of 225,532 shares of common stock (the “Debt Conversions”). The number of shares of common stock and warrants issued in connection with the Debt Conversions are included in the aggregate figures for the Private Placement.

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

NOTE 6 - CERTAIN TRANSACTIONS (continued)

As a result, the Company received aggregate cash proceeds of \$9,013,404 in the Private Placement. In addition, as a result of the Debt Conversions, there was \$1,000,000 of unpaid principal outstanding under the Bridge Notes, which was repaid by the Company in May 2011.

In connection with the Private Placement, the Company paid placement agent fees of approximately \$300,000 and issued five-year warrants to purchase 373,740 shares of the Company's common stock at an exercise price of \$1.80 per share to the placement agent for this Private Placement. The fair value of the warrants is \$212,000.

In connection with the Share Exchange, the Company also entered into a stock escrow agreement with certain stockholders, pursuant to which these stockholders deposited 1,015,622 shares of common stock held by them into escrow. These shares will be released to the Company for cancellation or surrender to an entity designated by the Company should the Company have \$10 million in consolidated revenue, as certified by the Company's independent auditors, during the first 12 months following the closing of the Private Placement, yet fail, after a good faith effort, to have the Company's common stock approved for listing on a national securities exchange. On the other hand, should the Company fail to record at least \$10 million in consolidated revenue during the first 12 months following the closing of the Private Placement or have its common stock listed on a national securities exchange within 12 months following the closing on the Private Placement, these escrowed shares shall be released back to the stockholders.

The shares of the Company's common stock issued to the InspireMD Ltd. shareholders in connection with the Exchange Agreement and the shares of common stock issued to the investors in the Private Placement were not registered under the Securities Act of 1933, as amended. These securities may not be offered or sold in the U.S. absent registration or an applicable exemption from the registration requirements. Certificates representing these shares contain a legend stating the restrictions applicable to such shares.

On March 31, 2011, the Company issued certain consultants five-year warrants to purchase up to an aggregate of 2,500,000 shares of common stock at an exercise price of \$1.50 per share in consideration for consulting services related to the Share Exchange, which warrants have a fair value of \$1,500,000. The expenses related to the issuance of the warrants are recorded as share-based compensation and treated as issuance costs.

On April 18, 2011, the Company issued 666,667 shares of its common stock and five-year warrants to purchase 333,333 shares of the Company's common stock at an exercise price of \$1.80 per share, for an aggregate purchase price of \$1,000,000 in a private placement.

On April 18, 2011, the Company issued 283,334 shares of its common stock and five-year term warrants to purchase 141,667 shares of the Company's common stock at an exercise price of \$1.80 per share, for an aggregate purchase price of \$425,000 in a private placement.

In connection with the above-referenced transactions from April 18, 2011, the Company paid placement agent fees of approximately \$471,000 which were recorded as issuance costs and five-year term warrants to purchase 57,000 shares of the Company common stock at an exercise price of \$1.80 per share to the placement agent in this private placement. The fair value of those warrants amounting to \$67,000 is estimated using the Black-Scholes valuation model.

On April 21, 2011, the Company issued 33,333 shares of its common stock, and five-year term warrants to purchase 16,667 shares of the Company's common stock at an exercise price of \$1.80 per share, for an aggregate purchase price of \$50,000 in a private placement.



INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

## NOTE 6 - CERTAIN TRANSACTIONS (continued)

During the nine month period ended September 30, 2011, the Company entered into investor relations consulting agreements (the "Consulting Agreements") with investor relations companies (the "Advisors") to provide investor relations services. Pursuant to the Consulting Agreements, in addition to monthly fees in a range of \$3,000 - \$15,000, the Company issued to the Advisors:

- a one-year warrant to purchase 81,161 shares of common stock of the Company at an exercise price of \$1.23 per share, valued at \$21,000
- 50,000 restricted shares of the Company's common stock, valued at \$62,000, and a five-year warrant to purchase 50,000 shares of common stock of the Company at an exercise price of \$1.50 per share, valued at \$30,000.
  - 25,000 shares of the Company's common stock, valued at \$68,750.

The Company recorded share-based compensation expenses of \$181,750 related to these issuances, during the nine month period ended September 30, 2011.

During the three month period ended June 30, 2011, the Company granted 1,087,225 stock options to employees and consultants at cash exercise prices of \$1.23-\$2.75 per share. The options had terms of five years. 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 2.85-5 years in each year; expected volatility of 63%-71%; and risk-free interest rate of 0.19%-3.39%.

During the three month period ended September 30, 2011, the Company cancelled 200,000 stock options of an employee that had a cash exercise price of \$2.75 per share, and in exchange, issued, to the same employee, 200,000 shares of stock options at cash exercise prices of \$1.93 per share. The options had a term of five years, continuing from the original grant date. For accounting purposes, the above mentioned transaction was treated as a modification to the original grant. The Fair Value of the modification was \$36,000 and used the following assumptions: dividend yield of 0% and expected term of 3-4 years in each year; expected volatility of 67%-70%; and risk-free interest rate of 0.33%-0.65%

In addition to the above mentioned stock option grant, the Company granted an additional 95,000 stock options to employees and consultants at cash exercise prices of \$1.93-\$2.00 per share during the three month period ended September 30, 2011. 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 3-4 years in each year; expected volatility of 67%-70%; and risk-free interest rate of 0.33%-0.68%.

On March 28, 2011, the board of directors and stockholders of the Company adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan (the "Umbrella Plan"). Under the Umbrella Plan, the Company reserved 9,468,100 shares of the Company's common stock as awards to the employees, consultants, and service providers to the Company and its subsidiaries and affiliates worldwide. At a special meeting of stockholders of the Company held on October 31, 2011, the stockholders approved an amendment to the Umbrella Plan to add an additional 5,531,900 shares of common stock.

The Umbrella Plan currently consists of three components, the primary plan document that governs all awards granted under the Umbrella Plan, and two appendices: (i) Appendix A, designated for the purpose of grants of stock

options and restricted stock to Israeli employees, consultants, officers and other service providers and other non-U.S. employees, consultants, and service providers, and (ii) Appendix B, which is the 2011 U.S. Equity Incentive Plan, designated for the purpose of grants of stock options and restricted stock awards to U.S. employees, consultants, and service providers who are subject to the U.S. income tax.

INSPIREMD, INC.  
(FORMERLY SAGUARO RESOURCES, INC.)  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

## NOTE 6 - CERTAIN TRANSACTIONS (continued):

The Umbrella Plan is administered by the compensation committee of the board of directors. Unless terminated earlier by the board of directors, the Umbrella Plan will expire on March 27, 2021.

U.S. federal income tax consequences relating to the transactions described under the Umbrella Plan are set forth in Section 409A, which was added to the Internal Revenue Code of 1986, as amended (the "Code") and treasury regulations in 2004 to regulate all types of deferred compensation. If the requirements of Section 409A of the Code are not satisfied, deferred compensation and earnings thereon will be subject to tax as it vests, plus an interest charge at the underpayment rate plus 1% and a 20% penalty tax. Certain stock options and certain types of restricted stock are subject to Section 409A of the Code.

Israel income tax consequences of awards of options under the Umbrella Plan is general and does not purport to be complete. Pursuant to the current Section 102 of the Ordinance, which came into effect on January 1, 2003, options may be granted through a trustee (i.e., Approved 102 Options) or not through a trustee (i.e., Unapproved 102 Options).

On July 11, 2011, the board of directors of the Company appointed a new director, ("Director A"), with a term expiring at the Company's 2012 annual meeting of stockholders. In connection with his appointment, Director A was granted an option to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$1.50 per share, (the "\$1.50 Option"). The \$1.50 Option was exercisable immediately and expired on September 30, 2011. 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 0.11 years in each year; expected volatility of 53%; and risk-free interest rate of 0.17%.

In addition, in connection with his appointment, Director A was granted an option to purchase 500,000 shares of common stock at an exercise price of \$2.50 per share, the closing price of the common stock on the date of grant (the "\$2.50 Option"), subject to the terms and conditions of the 2011 U.S. Equity Incentive Plan, a sub-plan of the Company's 2011 new Option Plan approved on March 28, 2011 ("2011 Umbrella Option Plan"). The \$2.50 Option vests and becomes exercisable in three equal annual installments beginning on the one-year anniversary of the date of grant, provided that in the event that Director A is either (i) not reelected as a director at the Company's 2012 annual meeting of stockholders, or (ii) not nominated for reelection as a director at the Company's 2012 annual meeting of stockholders, the option vests and becomes exercisable on the date Director A fails to be reelected or nominated. The \$2.50 Option has a term of 10 years from the date of grant. 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 years in each year; expected volatility of 62%-63%; and risk-free interest rate of 1.67%-1.85%.

The fair value of the options granted to the above-mentioned new director, using the Black-Scholes option-pricing model was approximately \$1,700,000.

On September 28, 2011, Director A, exercised the \$1.50 Option to purchase 1,000,000 shares of common stock, resulting in gross proceeds to the Company of \$1,500,000.



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NOTE 6 - CERTAIN TRANSACTIONS (continued):

On August 5, 2011 and effective August 8, 2011, the Board appointed another two new directors (“Director B” and “Director C”). Director B was appointed for with a term expiring at the Company’s 2012 annual meeting of stockholders and Director C was appointed for a term expiring at the Company’s 2013 annual meeting of stockholder. In connection with their appointment, the directors were each granted an option to purchase shares of Common Stock at an exercise price of \$1.95 per share, the closing price of the Common Stock on the date of grant (the “\$1.95 Options”). The grant to Director B was for 100,000 shares and is subject to the terms and conditions of the 2011 U.S. Equity Incentive Plan, a sub-plan of the Company’s 2011 Umbrella Option Plan. The grant to Director C was for 25,000 shares and is subject to the 2006 Employee Stock Option Plan, a sub-plan of the Company’s 2011 Umbrella Option Plan. The \$1.95 Options vests and become exercisable in two equal annual installments beginning on the one-year anniversary of the date of grant. In the case of Director B’s option, in the event that the Director B is either (i) not reelected as a director at the Company’s 2012 annual meeting of stockholders, or (ii) not nominated for reelection as a director at the Company’s 2012 annual meeting of stockholders, the option vests and becomes exercisable on the date of Director B’s failure to be reelected or nominated. In the case of Director C’s option, in the event that Director C is required to resign from the Board due to medical reasons, the option vests and becomes exercisable on the date of Director C’s resignation for medical reasons. The \$1.95 Options have terms of 10 years from the date of grant.

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 3-4 years in each year; expected volatility of 67%-70%; and risk-free interest rate of 0.45%-0.78%.

The fair value of the options granted to the above-mentioned new directors, using the Black-Scholes option-pricing model is approximately \$118,000.

In addition, on August 5, 2011, 324,644 stock options were granted to former directors at a cash exercise price of \$1.23 per share replacing 324,644 stock options held by former directors that expired during the second quarter of 2011. The options had terms of five years. 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 years in each year; expected volatility of 62%; and risk-free interest rate of 1.23%.

The fair value of the options granted to the above-mentioned former directors, using the Black-Scholes option-pricing model is approximately \$445,000.

On July 20, 2011, Mizrahi Tefahot Bank approved the release of a fixed lien in the amount of \$300,000. Following the approval, \$300,000 of Restricted Cash was classified to cash and cash equivalents.

NOTE 7 - FAIR VALUE MEASUREMENT:

- a. 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:



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## NOTE 7 - FAIR VALUE MEASUREMENT (continued):

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.

b. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value. In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The convertible loan was recorded at a fair value of \$1,044 as of December 31, 2010, then subsequently remeasured at fair value with the increase in fair value of \$624 included in the Consolidated Statements of Operations as of March 31, 2011. This security was measured at fair value on a recurring basis and classified in the "Significant Unobservable inputs (Level 3)" category.

c. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and other accrued liabilities approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. The carrying amount of the Group's other financial long-term assets and other financial long-term liabilities approximate their fair value.

## NOTE 8 - INVENTORY ON HAND:

	September 30 2011	December 31, 2010
	(\$ in thousands)	
Finished goods	\$ 445	\$ 957
Work in process	1,222	573
Raw materials and supplies	238	174
	\$ 1,905	\$ 1,704

## NOTE 9 - RELATED PARTIES TRANSACTIONS

In July 2010, the Company's board of directors approved new agreements for the Company's President and CEO. The agreements were approved at the Company's shareholders meeting in March 2011, and are effective from April 1, 2011.

Pursuant to these agreements, the above mentioned executives are entitled to a set monthly fee, as well as a minimum bonus. If their employment is terminated without cause, they are entitled to at least six months' prior notice and will be

paid their monthly fee during such notice period. If their employment is terminated without cause, they will also be entitled to certain severance payments equal to the total amount that has been contributed to and accumulated in their severance payment funds. No further contributions are provided for by these agreements.



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## NOTE 10 - COMMITMENT AND CONTINGENT LIABILITIES:

a. Commitment

In March 2010, the Company entered into a license agreement to use a stent design (“MGuard Prime”). Pursuant to the agreement, the licensor is entitled to receive royalty payments of 7% of net sales outside the United States and, for sales within the United States, royalty payments as follows: 7% of net sales for the first \$10,000,000 of net sales and 10% of net sales for net sales exceeding \$10,000,000. The Company began manufacturing the MGuard Prime during the fourth quarter of 2010 and began selling the MGuard Prime in the first quarter of 2011.

b. Litigation

The Company is a party to various claims arising in the ordinary course of its operations in the aggregate amount of \$10,000. The Company has not recorded an expense related to damages in connection with these matters because management, after considering the views of its legal counsel as well as other factors, is of the opinion that a loss to the Company is neither probable nor is an amount or range of loss that is estimable.

In February 2011, representatives of a third party have indicated that they intend to seek damages from the Company in connection with certain finders’ fees that they claim are owed to them. The claimants’ demand was for approximately \$1 million. The claimants’ most recent settlement demand, conveyed in April 2011, was for a total of \$250,000 in cash and 250,000 shares of the company common stock. 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, is of the opinion a loss to the Company is neither probable nor is an amount or range of loss that is estimable.

In March 2009, a service provider submitted a claim against the Company in the amount of \$150,000 in the Magistrate’s Court in Tel Aviv, claiming a success fee for assistance in locating potential investors and lenders with respect to a loan agreement entered into with a bank. On April 11, 2011, the Company received a court ruling directing the Company to pay the service provider an amount of \$105,000. Since both parties had claims against the court ruling, they renegotiated and on June 5, 2011, signed a settlement agreement according to which the Company shall pay \$96,000 and shall issue 18,785 shares of common stock valued at \$51,000.

The Company has recorded an expense of \$147,000 for the nine months ended September 30, 2011. The expenses have been recorded to “General and administrative” within the Condensed Consolidated Statements of Operations.

In November 2010, a former senior employee submitted a claim against the Company in the total amount of \$430,000 and options to purchase 2,029,025 shares of the Company at an exercise price of \$0.001 per share in the Magistrate’s Court in Tel Aviv, claiming unpaid back wages and commissions. The fair value of those options was valued using the Black-Scholes valuation model at \$2.5 million as of the period he claimed to be entitled to the options. The Company’s management after considering the views of its legal counsel as well as other factors has recorded a provision of \$20,000 in the financial statements in 2009 and is of the opinion an additional loss to the Company is neither probable nor is an amount or range of loss that is estimable.







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## NOTE 11 - TAXES ON INCOME (continued):

The tax rates at company level, under the Law:

Years	Development Zone A		Other Areas in Israel	
<b>"Preferred enterprise":</b>				
2011-2012	10	%	15	%
2013-2014	7	%	12.5	%
2015 and thereafter	6	%	12	%
<b>"Special Preferred Enterprise"</b>				
commencing 2011	5	%	8	%

The benefits granted to the preferred enterprises will be unlimited in time, unlike the benefits granted to special preferred enterprises, which will be limited for a period of 10 years. The benefits shall be granted to companies that will qualify under criteria set in the amendment; for the most part, those criteria are similar to the criteria that were set in the law prior to its amendment.

Under the transitional provisions of the amendment, a company will be allowed to continue and enjoy the tax benefits available under the Law prior to its amendment until the end of the period of benefits, as defined in the Law. The Company will be allowed to set the "year of election" no later than tax year 2012, provided that the minimum qualifying investment commenced not later than the end of 2010. On each year during the period of benefits, the Company will be able to opt for application of the amendment, thereby making available to itself the tax rates as above. A company may not revoke its election for application of the Amendment.

In accordance with income taxes (Topic 740) the measurement of current and deferred tax liabilities and assets is based on provisions of the enacted tax law at balance sheet date. The amendment was "enacted" at the first quarter of 2011 and did not have an impact on the Company's consolidated financial statements.

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## NOTE 12 - ENTITY WIDE DISCLOSURE

The Company operates in one reportable segment.

Disaggregated financial data is provided below as follows:

- (1) Revenues by geographic area and  
(2) Revenues from principal customers.

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

	3 months ended		9 months ended		Year ended
	September 30		September 30		December 31,
	2011	2010	2011	2010	2010
	(\$ in thousands)				
Israel	\$ 124	\$ 109	\$ 479	\$ 109	\$ 119
Spain	233	122	523	308	343
Germany	119	428	257	467	497
India	-	-	1,083	-	-
Brazil	204	-	312	360	360
Poland	-	-	74	1,446	1,446
Argentina	234	60	353	115	150
Other	1,072	504	1,631	1,423	2,034
	\$ 1,986	\$ 1,223	\$ 4,712	\$ 4,228	\$ 4,949

By principal customers:

	3 months ended		9 months ended		Year ended
	September 30		September 30		December 31,
	2011	2010	2011	2010	2010
Customer A	6 %	9 %	10 %	3 %	2 %
Customer B	12 %	10 %	11 %	7 %	7 %
Customer C	6 %	35 %	5 %	11 %	10 %
Customer D	-	-	23 %	-	-
Customer E	10 %	-	7 %	9 %	7 %
Customer F	-	-	2 %	34 %	29 %
Customer G	12 %	5 %	7 %	3 %	3 %

All tangible long lived assets are located in Israel.

NOTE 13 - SUBSEQUENT EVENTS

On October 31, 2011, the stockholders approved the authorization of the board of directors, in its discretion, to amend the Amended and Restated Certificate of Incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio of one-for-two to one-for-four, such ratio to be determined by the board of directors (the "Reverse Stock Split"), which approval will allow the board of directors to effect the Reverse Stock Split any time prior to the Company's annual meeting of stockholders in 2012.

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NOTE 13 - SUBSEQUENT EVENTS (continued)

On October 31, 2011, the stockholders approved the amendment of the Umbrella Plan to increase the number of shares of the Company's common stock available for issuance pursuant to awards under the Umbrella Plan by 5,531,900 shares to a total of 15,000,000 shares, which would provide an incentive to attract and retain employees, consultants, and service providers.

On November 13th, 2011, a previous finder of InspireMD Ltd. (the "Subsidiary") submitted to the Magister Court in Tel Aviv a claim against the Company, the Subsidiary and the Company's President and CEO for a declaratory ruling that it is entitled to convert 13,650 options to purchase the Subsidiary's ordinary shares in an exercise price of USD3.67 per option into 110,785 of the Company's common stock at an exercise price of \$0.45 per option, and to convert 4,816 options to purchase the Subsidiary's ordinary shares in an exercise price of USD10 per option into 39,087 of common stock at an exercise price of \$1.23 per option. The statement of claims in such proceedings was served to the Company today, the 14th of November, 2011. After consulting with its legal advisor and due to the lack of time to review all the materials related to this claim the Company is unable to assess the probable outcome of this claim.



## 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” for periods prior to the closing of the share exchange on March 31, 2011 refer to InspireMD Ltd., a privately held Israeli limited company that is now our wholly-owned subsidiary, and references to the “Company,” “InspireMD,” “we,” “our” and “us” for periods subsequent to the closing of the share exchange on March 31, 2011, refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.

### Forward-Looking Statements

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

- adverse economic conditions and/or intense competition;
  - loss of a key customer or supplier;
  - entry of new competitors and products;
- adverse federal, state and local government regulation, in the U.S., Europe or Israel;
  - failure to adequately protect our intellectual property;
    - inadequate capital;
  - technological obsolescence of our products;
  - technical problems with our research and products;
  - price increases for supplies and components;
- inability to carry out research, development and commercialization plans;
- loss or retirement of key executives and research scientists and other specific risks; and
- the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives.

You should review carefully “Part II – Item 1A. Risk Factors” of this Form 10-Q for a discussion of these and other risks that relate to our business and investing in shares of our common stock.

## 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).

On March 31, 2011, we completed a series of share exchange transactions pursuant to which we acquired all of the capital stock of InspireMD Ltd., a company formed under the laws of the State of Israel, in exchange for an aggregate of 50,666,663 shares of our common stock. As a result of these share exchange transactions, InspireMD Ltd. became our wholly-owned subsidiary, we discontinued our former business and succeeded to the business of InspireMD Ltd. as our sole line of business.

The share exchange transactions are being accounted for as a recapitalization. InspireMD Ltd. is the acquirer for accounting purposes and we are the acquired company. Accordingly, the historical financial statements presented and the discussion of financial condition and results of operations herein are those of InspireMD Ltd., retroactively restated for, and giving effect to, the number of shares received in the share exchange transactions, and do not include the historical financial results of our former business. The accumulated earnings of InspireMD Ltd. were also carried forward after the share exchange transactions and earnings per share have been retroactively restated to give effect to the recapitalization for all periods presented. Operations reported for periods prior to the share exchange transactions are those of InspireMD Ltd.

## Recent Events

At the special meeting of our stockholders held on October 31, 2011, our stockholders approved the authorization of the board of directors, in its discretion, to amend our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio of one-for-two to one-for-four, such ratio to be determined by the board (the “Reverse Stock Split”), which approval will allow the board of directors to effect the Reverse Stock Split any time prior to our annual meeting of stockholders in 2012.

On October 4, 2011, InspireMD Ltd., our wholly-owned subsidiary, entered into a clinical trial services agreement with Harvard Clinical Research Institute, Inc. (“Harvard”), pursuant to which Harvard will conduct a study entitled “MGuard Stent System Clinical Trial in Patients with Acute Myocardial Infarction” on our behalf. We will pay Harvard an estimated fee of \$6,994,456 for conducting the study, subject to adjustment dependent upon changes in the scope and nature of the study, which is expected to last 37 months, as well as other costs to be determined by the parties.

## Critical Accounting Policies

### Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to revenue recognition including provision for returns, legal contingencies and estimation of the fair value of share-based compensation and convertible debt.



## Functional currency

The currency of the primary economic environment in which our operations are conducted is the United States dollar (“\$” or “dollar”). Accordingly, the functional currency of us and of our subsidiaries is the dollar.

The dollar figures are determined as follows: transactions and balances originally denominated in dollars are presented in their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. The resulting translation gains or losses are recorded as financial income or expense, as appropriate. For transactions reflected in the statements of operations in foreign currencies, the exchange rates at transaction dates are used. Depreciation and changes in inventories and other changes deriving from non-monetary items are based on historical exchange rates.

## Fair value measurement

Fair value is defined as 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.

In determining fair value, we use various valuation approaches, including market, income and/or cost approaches. Hierarchy for inputs is used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the reliability of inputs.

## Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash, cash equivalents and restricted cash which are deposited in major financial institutions in Germany and Israel, and trade accounts receivable. Our trade accounts receivable are derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers’ financial condition and, generally, require no collateral from our customers. We also have a credit insurance policy for some of our customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount our management reasonably believes will be collected. To mitigate risks, we deposit cash and cash equivalents with high credit quality financial institutions. Provisions for doubtful debts are netted against “Accounts receivable-trade.”

## Inventory

Inventories include finished goods, work in process and raw materials. Inventories are stated at the lower of cost (cost is determined on a “first-in, first-out” basis) or market value. Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, in our opinion, factors indicate that impairment has occurred, we establish a reserve against the inventories’ carrying value. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. Although we make every effort to ensure the

accuracy of forecasts of future product demand, any significant unanticipated decreases in demand could have a material impact on the carrying value of our inventories and reported operating results. To date, inventory adjustments have not been material. In respect to inventory on consignment, see “Revenue recognition” below.

## Revenue recognition

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title and risks and rewards for the products are transferred to the customer, collection is reasonably assured and when product returns can be reliably estimated. When product returns can be reliably estimated a provision is recorded, based on historical experience, and deducted from sales. The provision for sales returns and related costs are included in “Accounts payable and accruals - Other” under “current liabilities”, and “Inventory on consignment”, respectively.

When returns cannot be reliably estimated, both revenues and related direct costs are eliminated, as the products are deemed unsold. Accordingly, both related revenues and costs are deferred, and presented under “Deferred revenues” and “Inventory on consignment”, respectively.

We recognize revenue net of value added tax (VAT).

## Research and development costs

Research and development costs are charged to the statement of operations as incurred.

## Share-based compensation

Employee option awards are classified as equity awards and accounted for using the grant-date fair value method. The fair value of share-based awards is estimated using the Black-Scholes valuation model, which is expensed over the requisite service period, net of estimated forfeitures. We estimate forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation expensed for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

We account for equity instruments issued to third party service providers (non-employees) by recording the fair value of the options granted using an option pricing model, at each reporting period, until rewards are vested in full. The expense is recognized over the vesting period using the accelerated multiple option approach. The expense relates to options granted to third party service providers with respect to successful investor introductions that are recorded at their fair value in equity, as issuance costs.

## Uncertain tax and VAT positions

We follow a two-step approach to recognizing and measuring uncertain tax and VAT positions. The first step is to evaluate the tax and VAT position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax and VAT benefit as the largest amount that is more than 50% and 75%, respectively, likely of being realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. Our policy is to include interest and penalties related to unrecognized tax benefits within financial expenses.

## Results of Operations

Three months Ended September 30, 2011 Compared to Three months Ended September 30, 2010

Revenues. For the three months ended September 30, 2011, total revenue increased approximately \$0.8 million, or 62.4%, to approximately \$2.0 million from approximately \$1.2 million during the same period in 2010. The \$0.8 million increase was due to an increase in volume of approximately \$0.7 million, or approximately 55.9%, and by an increase of prices of approximately \$0.1 million, or approximately 6.5%. The following is an explanation of the approximately \$0.8 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately \$1.0 million offset by a net decrease in deferred revenues of approximately \$0.2 million.



For the three months ended September 30, 2011, total gross revenue increased by approximately \$0.9 million, or 87.8%, to approximately \$2.0 million as compared to approximately \$1.1 million during the same period in 2010. This increase in total gross revenue is predominantly volume based, accounting for approximately \$0.8 million or approximately 80.3%, and an increase of prices of approximately \$0.1 million, or approximately 7.5%. In general, we focused on opening new markets, such as Russia and the Ukraine, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuard™. With respect to individual markets, this increase in gross revenue is mainly attributable to an increase of approximately \$0.2 million of gross revenue from our distributor in Brazil, an increase of approximately \$0.2 million of gross revenue from our distributor in Argentina, an increase of approximately \$0.1 million of gross revenue from our new distributor in Russia, an increase of approximately \$0.1 million of gross revenue from our new distributor in the Ukraine, an increase of approximately \$0.1 million of gross revenue from our distributor in Mexico, an increase of approximately \$0.1 million of gross revenue from our distributor in Italy, an increase of approximately \$0.1 million of gross revenue from our distributor in Spain and an increase of approximately \$0.1 million of gross revenue from our distributor in Israel. This increase was partially offset by a decrease of approximately \$0.3 million in gross revenue from our distributor in Germany and a decrease of approximately \$0.1 million from our distributor in Romania. We also shipped and recognized gross revenue for approximately \$0.3 million more from our remaining distributors during the three months ended September 30, 2011, as compared to the same period in 2010.

For the three months ended September 30, 2011, net deferred revenue recognized during the period decreased by approximately \$0.2 million, or 102.1%, to approximately \$(4,000) and from approximately \$0.2 million during the same period in 2010. The decrease was volume based. Revenue recognition out of deferred income had less of an impact in 2011 as compared to 2010 due to the fact that we deferred mainly shipments in 2008 and 2009 that were recognized in 2010. In 2010, no customers had revenues deferred until the three months ended September 30, 2011.

For the three months ended September 30, 2011, our net deferred revenue of \$(4,000) consisted of only a provision for sales return included in "accounts payable and accrual - other." For the three months ended September 30, 2010, net deferred revenue of approximately \$0.2 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Israel of approximately \$0.1 million and our distributor in Poland of approximately \$50,000.

**Gross Profit.** For the three months ended September 30, 2011, gross profit (revenue less cost of revenues) increased approximately 79.0%, or approximately \$0.5 million, to approximately \$1.2 million from approximately \$0.7 million during the same period in 2010. Gross margin increased from 54.1% in the three months ended September 30, 2010 to 59.7% in the three months ended September 30, 2011. We were able to improve our gross margin because of reduced production cost per stent driven by economies of scale, as well as an increase in average price per stent. For the three months ended September 30, 2011, our average selling price per stent recognized in revenue was \$624, and we recognized the sale of 3,186 stents, compared to an average price of \$577 per stent and 2,120 stents recognized in revenue for the same period in 2010. The higher average price per stent for the three months ended September 30, 2011 was driven by sales of MGuard Prime, which was launched in 2011 and is priced on average \$171 more versus the average price of MGuard per stent. Our cost of goods sold per stent decreased from an average of \$265 per stent recognized in revenue for the three months ended September 30, 2010 to an average of \$251 per stent for the same period in 2011.

**Research and Development Expense.** For the three months ended September 30, 2011, research and development expense increased 179.1% to approximately \$0.5 million from approximately \$0.2 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately \$0.2 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately \$0.1 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately \$0.1 million), and an increase in R&D related salaries of approximately \$0.2 million relating to the above mentioned clinical studies. Research and development expense as a percentage of revenue increased to 27.5% for the three months ended September 30, 2011

from 16.0% in the same period of 2010.

**Selling and Marketing Expense.** For the three months ended September 30, 2011, selling and marketing expense increased 8.2% to approximately \$0.3 million, from approximately \$0.28 million during the same period in 2010. The increase in cost resulted primarily from approximately \$0.16 million of additional salaries and share based compensation of predominately newly hired sales personnel as we expand our sales activities worldwide. This increase was partially offset by a decrease of approximately \$0.1 million in advertising, travel and other related expenses. Selling and marketing expense as a percentage of revenue decreased from 22.8% in 2010 to 15.2% in 2011.

**General and Administrative Expense.** For the three months ended September 30, 2011, general and administrative expense increased 175.0% to approximately \$2.5 million from \$0.9 million during the same period in 2010. The increase in cost resulted primarily from an increase in share based compensation of \$1.3 million, which predominately pertains to directors' compensation, approximately \$0.2 million in legal fees related primarily to compliance with Securities and Exchange Commission standards, an increase in investor related activities of approximately \$0.1 million due to us having been public during the three months ended September 30, 2011, but not during the same period in 2010, and an increase of \$0.1 million in miscellaneous expenses. This increase was partially offset by a decrease of approximately \$0.1 million in audit and related expenses. General and administrative expense as a percentage of revenue increased to 125.2% in 2011 from 73.9% in 2010.

**Financial Expense.** Financial expense remained relatively flat at \$108,000 for the three months ended September 30, 2011, as compared to \$121,000 during the same period in 2010. Our financial expenses reflect primarily changes in exchange rates, as well as interest related expenses. Financial expense as a percentage of revenue decreased to 5.4% in 2011, from 9.9% in 2010.

**Tax Expense.** Tax expense remained relatively flat at \$25,000 for the three months ended September 30, 2011, as compared to \$9,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

**Net Loss.** Our net loss increased by approximately \$1.5 million, or 169.5%, to \$2.3 million for the three months ended September 30, 2011 from \$0.8 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately \$2.0 million (see above for explanations) and is partially offset by an increase of approximately \$0.5 million in gross profit (see above for explanation).

#### Nine months Ended September 30, 2011 Compared to Nine months Ended September 30, 2010

**Revenues.** For the nine months ended September 30, 2011, total revenue increased approximately \$0.5 million, or 11.4%, to approximately \$4.7 million from approximately \$4.2 million during the same period in 2010. The \$0.5 million increase was due to an increase in volume of approximately \$0.6 million or approximately 14.2%, offset by an approximately \$0.1 million decrease, or approximately 2.7%, due to price decreases. The following is an explanation of the approximately \$0.5 million increase in revenue broken down by its main two components, an increase in gross revenues of approximately \$2.0 million offset by a net decrease in deferred revenues of approximately \$1.5 million.

For the nine months ended September 30, 2011, total gross revenue increased by approximately \$2.0 million, or 85.3%, to approximately \$4.4 million from approximately \$2.4 million during the same period in 2010. This increase in total gross revenue is predominantly volume based, accounting for approximately \$2.0 million or approximately 87.3%, with price decreases accounting for the remaining approximately \$45,000, or approximately 2.0%. In general, we focused on opening new markets, such as India, and also increasing sales in existing markets by presenting clinical data at conferences and individual presentations to doctors about the merits of MGuard™. With respect to individual markets, this increase in gross revenue is mainly attributable to the first time shipment of approximately \$1.2 million to our distributor in India during the first nine months of 2011, an increase of approximately \$0.3 million of gross revenue from our distributor in Argentina, an increase of approximately \$0.2 million of gross revenue from our distributor in Brazil, an increase of approximately \$0.2 million of gross revenue from our distributor in Spain, an increase of approximately \$0.2 million of gross revenue from our distributor in Israel, an increase of approximately \$0.1 million of gross revenue from our new distributor in Russia, an increase of approximately \$0.1 million of gross revenue from our new distributor in the Ukraine, an increase of approximately \$0.1 million of gross revenue from our distributor in Mexico and approximately \$0.1 million of gross revenue from our new distributor in the Netherlands. This increase was partially offset by a decrease of approximately \$0.4 million in gross revenue from our distributor in Poland, a decrease of approximately \$0.2 million in gross revenue from our distributor in Germany, a

decrease of approximately \$0.2 million from our distributor in Pakistan, and a decrease of approximately \$0.1 million in gross revenue to our distributor in Kazakhstan. We also shipped and recognized gross revenue for approximately \$0.4 million more from our remaining distributors during the nine months ended September 30, 2011, as compared to the same period in 2010.

For the nine months ended September 30, 2011, net deferred revenue recognized during the period decreased by approximately \$1.5 million, or 81.0%, to approximately \$0.4 million from approximately \$1.9 million during the same period in 2010. The key driver of this decrease was volume based, accounting for approximately \$1.4 million or approximately 77.4%, with the remaining approximately \$0.1 million, or 3.6%, being driven by price decreases. Revenue recognition out of deferred income had less of an impact in 2011 as compared to 2010 due to the fact that we deferred mainly shipments in 2008 and 2009 that were recognized in 2010. In 2010, only a small set of customers had a large portion of their revenues deferred until 2011.

For the nine months ended September 30, 2011, our net deferred revenue consisted of approximately \$0.2 million attributable to our distributor in Israel, approximately \$0.1 million to our distributor in Brazil, approximately \$0.1 million to our distributor in Poland, and approximately \$0.05 million to our distributor in Italy, offset by approximately \$0.1 million deferred for a shipment to our distributor in India. Our distributor in Israel had a contractual right to return all purchases to us within 18 months of the purchase date. Due to our inability to accurately estimate the amount of future returns, all sales to this distributor were deferred until this 18 month return period elapsed. On May 9, 2011, our distributor in Israel agreed to revoke its previous rights to return purchases, resulting in all future sales being final. The deferred revenue of approximately \$0.2 million recognized during the nine months period ended September 30, 2011 accounted for all previous purchases by the distributor that the distributor no longer had a contractual right to return and were not yet recognized as revenues. Our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. Due to our inability to accurately estimate the amount of future returns by our distributor in Brazil, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately \$0.1 million recognized during the nine months period ended September 30, 2011 accounted for purchases made in December 2010 that were not returned by the Brazilian distributor and were not yet recognized as revenues.

For the first nine months of 2010, net deferred revenue of approximately \$1.9 million was comprised mainly of shipments from 2008 and 2009 to our distributor in Poland of approximately \$1.3 million, to our distributor in Brazil of approximately \$0.4 million, to our distributor in Sri Lanka of approximately \$0.1 million and approximately \$0.1 million to miscellaneous distributors. For the nine months ended September 30, 2010, our distributor in Poland, subject to our sole discretion, had the right to return our products. Because we were unable to develop estimates for the level of returns, the \$1.3 million worth of shipments made to the distributor in Poland that we recorded as deferred revenues was only recognized during the first nine months of 2010 as revenues. As noted above, our distributor in Brazil has a contractual right to return all purchases for up to six months from the delivery date. As also noted above, due to our inability to accurately estimate the rate of return by this distributor, all sales made to it were also deferred until the six month return period elapsed. The deferred revenue of approximately \$0.4 million recognized during the nine months period ended September 30, 2010 accounted for purchases made in December 2009 that were not returned and were not yet recognized as revenues.

**Gross Profit.** For the nine months ended September 30, 2011, gross profit (revenue less cost of revenues) increased 28.1%, or approximately \$0.5 million, to approximately \$2.4 million from approximately \$1.9 million during the same period in 2010. Gross margin increased from 43.8% in the nine months ended September 30, 2010 to 50.3% in the nine months ended September 30, 2011. In addition to an increase in sales, we were able to improve our gross margin because of reduced production cost per stent driven by economies of scale. For the nine months ended September 30, 2011, our average selling price per stent recognized in revenue was \$570, and we recognized the sale of 8,261 stents, compared to an average price of \$643 per stent and 6,566 stents recognized in revenue for the same period in 2010. Our cost of goods sold per stent decreased from an average of \$362 per stent recognized in revenue for the nine months ended September 30, 2010 to an average of \$283 per stent for the same period in 2011. The higher price per stent for the nine months ended September 30, 2010 was affected by the price of stents sold in 2008 and 2009 to one of our European distributors in Euros when the Euro was much stronger than the U.S. dollar, at an average price of \$997 when translated to U.S. dollars.



**Research and Development Expense.** For the nine months ended September 30, 2011, research and development expense increased 69.2% to approximately \$1.6 million from approximately \$1.0 million during the same period in 2010. The increase in cost resulted primarily from higher clinical trial expenses of approximately \$0.8 million, attributable mainly to the U.S. Food and Drug Administration clinical trial (approximately \$0.6 million) and the MGuard for Acute ST Elevation Reperfusion Trial (MASTER Trial) (approximately \$0.2 million), offset by approximately \$0.2 million reduction in miscellaneous expenses. Research and development expense as a percentage of revenue increased to 34.8% for the nine months ended September 30, 2011 from 22.9% in the same period of 2010.

**Selling and Marketing Expense.** For the nine months ended September 30, 2011, selling and marketing expense increased 47.1% to approximately \$1.3 million, from approximately \$0.9 million during the same period in 2010. The increase in selling and marketing expense resulted primarily from approximately \$0.2 million of additional salaries and approximately \$0.3 of share based compensation of predominately newly hired sales personnel as we expand our sales activities worldwide, and approximately \$0.1 million of commissions pertaining mainly to our first time shipment of approximately \$1.2 million to our distributor in India. This increase was partially offset by a decrease of approximately \$0.1 million in advertising, and a decrease of approximately \$0.1 million in miscellaneous expenses. Selling and marketing expense as a percentage of revenue increased to 28.6% in 2011 from 21.7% in 2010.

**General and Administrative Expense.** For the nine months ended September 30, 2011, general and administrative expense increased 141.9% to approximately \$4.9 million from \$2.0 million during the same period in 2010. The increase in cost resulted primarily from an increase in share based compensation of \$1.1 million which predominately pertains to directors' compensation, an increase of approximately \$0.4 million in salary expenses (due to an increase in employee infrastructure to accommodate and comply with Securities and Exchange Commission standards and reporting), an increase in investor related activities of approximately \$0.4 million (due to us having been a publicly reporting company during the nine months ended September 30, 2011, but not during the same period in 2010), an increase of approximately \$0.5 million in litigation expenses (primarily due to a provision for our potential loss regarding a threatened lawsuit from a finder claiming a future success fee and commissions for assistance in finding our distributor in Brazil), and approximately \$0.3 million in legal fees (also related primarily to compliance with Securities and Exchange Commission standards), and approximately \$0.2 million increase in miscellaneous expenses. General and administrative expense as a percentage of revenue increased to 103.5% in 2011 from 47.7% in 2010.

**Financial Expenses.** For the nine months ended September 30, 2011, financial expense increased 496.7% to approximately \$0.9 million from \$0.2 million during the same period in 2010. The increase in expense resulted primarily from a one-time financial expense recording of approximately \$0.6 million in the first quarter of 2011 pertaining to the revaluation of an outstanding convertible loan at fair value prior to redemption and approximately \$0.2 million for the favorable impact of exchange rate differences for the nine months ended September 30, 2010 that did not occur during the nine months ended September 30, 2011. This increase was partially offset by a decrease of approximately \$0.1 million in miscellaneous expenses. Financial expense as a percentage of revenue increased from 3.5% in 2010, to 19.0% in 2011.

**Tax Expenses.** Tax expense remained relatively flat at \$45,000 for the nine months ended September 30, 2011, as compared to \$39,000 during the same period in 2010. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

**Net Loss.** Our net loss increased by approximately \$4.2 million, or 187.3%, to \$6.4 million for the nine months ended September 30, 2011 from \$2.2 million during the same period in 2010. The increase in net loss resulted primarily from an increase in operating expenses of approximately \$4.0 million (see above for explanations) and an increase of approximately \$0.7 million in financial expenses (see above for explanation). This increase was partially offset by an increase in gross profit of approximately \$0.5 million.





## Liquidity and Capital Resources

### Nine months Ended September 30, 2011 Compared to Nine months Ended September 30, 2010

General. At September 30, 2011, we had cash and cash equivalents of approximately \$7.5 million, as compared to \$0.6 million at December 31, 2010. The increase is attributable primarily to the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances prior to and after the share exchange transactions. We have historically met our cash needs through a combination of issuance of new shares, borrowing activities and sales. Our cash requirements are generally for product development, clinical trials, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately \$3.9 million for the nine months ended September 30, 2011, and approximately \$2.2 million for the same period in 2010. The principal reasons for the usage of cash in our operating activities for the nine months ended September 30, 2011 include a net loss of approximately \$6.4 million, and a decrease in working capital of approximately \$1.2 million, offset by approximately \$2.8 million in non-cash share based compensation, and approximately \$0.9 million in non-cash financial expenses related to the revaluation of a convertible loan.

Cash flow generated from investing activities was approximately \$0.1 million during the nine months ended September 30, 2011, compared to approximately \$0.1 million of cash used by investing activities during the same period in 2010. The principal reason for the increase in cash flow from investing activities was a decrease in restricted cash of approximately \$0.2 million.

Cash flow generated from financing activities was approximately \$10.8 million for the nine months ended September 30, 2011, and \$2.7 million for the same period in 2010. The principal reason for the increase in cash flow from financing activities during 2011 was the private placement conducted in conjunction with the share exchange transactions on March 31, 2011 and other private equity issuances and exercise of options prior to and after the share exchange transactions in the aggregate amount of approximately \$12.1 million, offset by the repayment of the non-converted portion of a convertible loan in the amount of approximately \$1.0 million and the partial repayment of a long-term loan in the amount of approximately \$0.3 million.

As of September 30, 2011, our current assets exceeded current liabilities by a multiple of 3.2. Current assets increased approximately \$7.6 million during 2011, mainly due to cash raised from the private placements in 2011, while current liabilities decreased approximately \$0.3 million during the same period. As a result, our working capital surplus increased by approximately \$8.0 million to approximately \$7.9 million during the nine months ended September 30, 2011.

Credit Facilities. As of September 30, 2011, we had a long term loan in the amount of approximately \$0.2 million bearing interest at the three month U.S. Dollar LIBOR rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years that began in April 2010 and ends in January 2012. According to the loan agreement, in case of an "exit transaction," we will be required to pay to the bank an additional \$0.25 million if the sum received in a "liquidity event" or the value of the company in an "IPO" is higher than \$100 million.

Convertible Loans. Prior to September 30, 2011, we had a convertible loan with an aggregate principal amount outstanding of approximately \$1.58 million that bore 8% interest. Following the share exchange transactions on March 31, 2011, \$580,000 plus accrued interest converted into shares of our common stock. The remaining principle in the amount of \$1.0 million was repaid on May 15, 2011.

Sales of Stock. For the nine months ended September 30, 2011, we issued an aggregate of 9,415,145 shares of common stock and warrants to purchase 6,709,073 shares of common stock for gross proceeds of approximately \$12.0 million.

## Off Balance Sheet Arrangements

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

## Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (“FASB”) issued amendments to the accounting and disclosure for revenue recognition. These amendments, effective for fiscal years beginning on or after June 15, 2010 (early adoption is permitted), modify the criteria for recognizing revenue in multiple element arrangements and require companies to develop a best estimate of the selling price to separate deliverables and allocate arrangement consideration using the relative selling price method. Additionally, the amendments eliminate the residual method for allocating arrangement considerations. We do not expect the standard to have material effect on our consolidated financial statements.

In January 2010, the FASB updated the “Fair Value Measurements Disclosures”. More specifically, this update will require (a) an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers; and (b) information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This update clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value, and require disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. This will become effective as of the first interim or annual reporting period beginning after December 15, 2009, except for the gross presentation of the Level 3 roll forward information, which is required for annual reporting periods beginning after December 15, 2010 and for interim reporting periods within those years. The adoption of the new guidance did not have a material impact on our consolidated financial statements.

In May 2011, the FASB issued amended guidance and disclosure requirements for fair value measurements. These amendments are not expected to have a material impact to our consolidated financial results. These changes will be effective January 1, 2012 on a prospective basis. Early application is not permitted.

## Item 4. Controls and Procedures

### Management’s Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of September 30, 2011, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of September 30, 2011.

### Changes in Internal Control over Financial Reporting

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

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## PART II - OTHER INFORMATION

### 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 financial and other information included in this Form 10-Q, and our amended registration statement on Form S-1/A filed with the Securities and Exchange Commission on October 12, 2011, as may be amended. 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, and actual outcomes may vary materially from those included in this Form 10-Q.

#### Risks Related to Our Business

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 could 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. 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 patents may not provide us with commercially meaningful protection for our products or 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 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, patent applications in the U.S. are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the U.S. The laws of some foreign

jurisdictions do not protect intellectual property rights to the same degree as in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in 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 or enforceability of our patents. If a court decides that such patents are not valid, not enforceable or of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patents 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 provide us with freedom to operate unimpeded by the patent rights of others.

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 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. As a result, there can be no assurance that we will ever generate substantial revenues or sustain profitability.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our MGuard™ stent at our facilities in Tel Aviv, Israel, and we have contracted with QualiMed Innovative Medizinprodukte GmbH, a German manufacturer, to assist in production. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our MGuard™ stent until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our MGuard™ stent for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

We currently have limited resources, facilities and experience to commercially manufacture our product candidates. In order to produce our MGuard™ stent in the quantities that we anticipate will be required to meet anticipated market demand, we will need to increase, or “scale up,” the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity, and developing commercial-scale manufacturing facilities will require the investment of substantial funds and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required scale-up in a timely manner or at all. If unable to do so, we may not be able to produce our MGuard™ stent in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, if at all. If we develop and obtain regulatory approval for our MGuard™ stent and are unable to manufacture a sufficient supply of our MGuard™ stent, our revenues, business and financial prospects would be adversely affected. In addition, if the scaled-up production process is not efficient or produces stents that do not meet quality and other standards, our future gross margins may decline. Also, our current and planned personnel, systems,

procedures and controls may not be adequate to support our anticipated growth. If we are unable to manage our growth effectively, our business could be harmed.



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

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

Clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Clinical trials necessary to support a pre-market approval application to the U.S. Food and Drug Administration for our MGuard™ stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Clinical trials supporting a pre-market approval applications for the Cypher stent developed by Johnson & Johnson and the Taxus Express2 stent developed by Boston Scientific Corporation, which were approved by the U.S. Food and Drug Administration and are currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. In some trials, a greater number of patients and a longer follow up period may be required. The U.S. Food and Drug Administration may require us to submit data on a greater number of patients or for a longer follow-up period than those for pre-market approval applications for the Cypher stent and the Taxus Express2 stent. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

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

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

We believe that physicians will not widely adopt the MGuard™ stent unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our MGuard™ stent provides a safe and effective alternative to other existing treatments for coronary artery disease, including coronary artery bypass grafting balloon angioplasty, bare-metal stents and other drug-eluting stents, provided by Johnson & Johnson, Boston

Scientific Corporation, Medtronic Inc., Abbott Laboratories and others.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that the MGuard™ stents are an attractive alternative to other procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other drug-eluting stents or bare-metal stents that have received regulatory approval and that are available on the market, our ability to successfully market the MGuard™ stent will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our MGuard™ stent will vary. Clinical trials conducted with the MGuard™ 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™ 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™ stent is a safe and effective alternative, it is not a drug-eluting stent, which may further hinder its support and adoption by physicians.

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

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the U.S. Food and Drug Administration, may take a significant amount of time in evaluating product approval applications. For example, there are currently several methods of measuring restenosis and we do not know which of these metrics, or combination of these metrics, will be considered appropriate by the U.S. Food and Drug Administration for evaluating the clinical efficacy of stents. Treatments may exhibit a favorable measure using one of these metrics and an unfavorable measure using another metric. Any change in the accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only 3 employees. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

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



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

Any product for which we obtain marketing approval in the U.S., along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the U.S. Food and Drug Administration and other regulatory bodies. In particular, we and our suppliers will be required to comply with the U.S. Food and Drug Administration's Quality System Regulation for the manufacture of our MGuard™ stent, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval in the U.S. The U.S. Food and Drug Administration enforces the Quality System Regulation through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the U.S. Food and Drug Administration and will have to successfully complete such inspections before we receive U.S. regulatory approval for our products. Failure by us or one of our suppliers to comply with statutes and regulations administered by the U.S. Food and Drug Administration and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following enforcement actions:

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

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

Even if regulatory approval of a product is granted in the U.S., the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the U.S. Food and Drug Administration determines that our promotional materials, training or other activities constitutes 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 U.S. and Europe. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE Mark or U.S. Food and Drug Administration approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE Mark or U.S. Food and Drug Administration approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE Mark 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 service companies in the U.S. and internationally in connection with our current product and products under development. We face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. When we commercialize our products, we expect to face intense competition from 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 right to our intellectual property.

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 and related claims may have already been filed against us of which we are not aware. A number of these 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, or a patent infringement claim against us, increases.

These companies have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, Johnson & Johnson and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products.

If we fail to maintain or establish satisfactory agreements with suppliers, we may not be able to obtain materials that are necessary to develop our products.

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

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

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

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

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in clinical trials. We may also be exposed to product liability claims based on the sale of any such products following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our

business. We also have liability insurance for our 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, including our chief executive officer, Ofir Paz, and president, Asher Holzer, each of whom 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, and 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; and
- general economic and political conditions in these foreign markets.

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

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

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

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

In the U.S., 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 Health Care and Educational Reconciliation Act in the U.S. 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 does levy a 2.3% excise tax on all U.S. medical device sales beginning in 2013. If we commence sales of our MGuard™ stent in the U.S., this new tax may materially and adversely affect our business and results of operations. The legislation also focuses

on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the U.S., or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

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 our management will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

We may have violated Israeli securities law.

We may have violated section 15 of the Israeli Security Law of 1968. Section 15 to the Israeli Security Law of 1968 requires the filing of a prospectus with the Israel Security 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 Security 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 Security Law of 1968 are as follows: imprisonment of 5 years; a fine of up to approximately \$317,000 to be paid by management of the violating company; and a fine of up to approximately \$1,590,000 to be paid by the violating company, any of which penalties could result in a material adverse effect on our operations.

We 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 current stockholders' ownership interests.

We will need to raise additional capital in the future, which may not be available on reasonable terms or at all. We recently raised approximately \$10,500,000 and expect that such proceeds, together with our income, will be insufficient to fully realize all of our business objectives. For instance, we will need to raise additional funds to accomplish the following:

- 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 current stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

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

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we are unable to obtain such additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares. Further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

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

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

All of our assets are located outside the U.S. and we do not currently maintain a permanent place of business within the U.S. In addition, most of our directors and all of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the U.S. any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. 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.

#### Risks Related to Our Organization and Our Common Stock

We are subject to financial reporting and other requirements for which our accounting, internal audit and other management systems and resources may not be adequately prepared.

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. Section 404 will require 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 will place significant demands on our management, administrative, operational, internal audit and accounting resources. We are presently upgrading our systems; implementing financial and management controls, reporting systems and procedures; implementing an internal audit function; and we have hired additional accounting, internal audit and finance staff. If we are unable to accomplish these objectives in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. 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.

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

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

Our stock price may be volatile after this offering, which could result in substantial losses for investors.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
  - additions or departures of key personnel;
- sales of our common stock, particularly under any registration statement for the purposes of selling any other securities, including management shares;
- limited availability of freely-tradable “unrestricted” shares of our common stock to satisfy purchase orders and demand;
  - our ability to execute our business plan;
  - operating results that fall below expectations;
  - loss of any strategic relationship;
  - industry developments;
  - economic and other external factors; and
- period-to-period fluctuations in our financial results.

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

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

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

In addition, the penny stock rules require that prior to a transaction the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. The penny stock rules are burdensome and may reduce purchases of any offerings and reduce the trading activity for shares of our common stock. As long as our shares of common stock are subject to the penny stock rules, the holders of such shares of common stock may find it more difficult to sell their securities.

There is, at present, only a limited market for our common stock and we cannot ensure investors that an active market for our common stock will ever develop or be sustained.

Our shares of common stock are thinly traded. Due to the illiquidity, the market price may not accurately reflect our relative value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. Because our common stock is so thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price and investors may not be able to liquidate their investment in us at all or at a price that reflects the value of the business. In addition, our common stock currently trades on the OTC Bulletin Board, which generally lacks the liquidity, research coverage and institutional investor following of a national securities exchange like the NYSE Amex, the New York Stock Exchange or the Nasdaq Stock Market. While we intend to list our common stock on a national securities exchange once we satisfy the initial listing standards for such an exchange, we currently do not, and may not ever, satisfy such initial listing standards.

Our board of directors can authorize the issuance of preferred stock, which could diminish the rights of holders of our common stock, and make a change of control of us more difficult even if it might benefit our stockholders.

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

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

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Upon the effectiveness of the registration statement of which this prospectus forms a part, 414,942 shares of our common stock will become freely tradable. In addition, an additional approximately 58,278,977 shares of our common stock will

become saleable under Rule 144 following April 6, 2012. As these shares and as additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price of our common stock.

In addition, if our stockholders sell substantial amounts of our common stock in the public market, upon the expiration of any statutory holding period under Rule 144, upon the expiration of lock-up periods applicable to outstanding shares, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an “overhang” and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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

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

#### Risks Related to Our Intended Reverse Stock Split

There can be no assurance that we will be able to meet all of the requirements for listing our common stock on the Nasdaq Capital Market or to meet the continued listing standards of the Nasdaq Capital Market after a reverse stock split.

The Nasdaq Capital Market has numerous initial listing requirements applicable to the listing of our common stock and its continued listing thereafter. While we believe we currently meet these standards, other than the minimum bid price requirement of more than \$4.00 per share, we cannot assure you that our common stock will be accepted for listing on the Nasdaq Capital Market following the reverse stock split or that we will maintain compliance with all of the requirements for our common stock to remain listed. Moreover, there can be no assurance that the market price of our common stock after the reverse stock split will adjust to reflect the decrease in common stock outstanding or that the market price following a reverse stock split will either exceed or remain in excess of the current market price.

If the reverse stock split is implemented, the resulting per-share price may not attract institutional investors, investment funds or brokers and may not satisfy the investing guidelines of these investors or brokers, and consequently, the trading liquidity of common stock may not improve.

While we believe that a higher share price may help generate investor and broker interest in our common stock, the reverse stock split may not result in a share price that will attract institutional investors or investment funds or satisfy the investing guidelines of institutional investors, investment funds or brokers. A decline in the market price of our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of the reverse stock split. If the reverse stock split is implemented and the market price of our common stock declines, the percentage decline may be greater than would occur in the absence of the reverse stock split. The market price of our common stock is also based on our performance and other factors, which are unrelated to the number of shares of common stock outstanding.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On April 18, 2011, we consummated a private placement with an investor pursuant to which we sold 666,667 shares of our common stock and a five-year warrant to purchase up to 333,333 shares of common stock at an exercise price of \$1.80 per share for aggregate cash proceeds of \$1,000,000. The securities sold in this offering were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance

on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(2) and Regulation D (Rule 506) under the Securities Act of 1933, as amended. This investor was an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended) at the time of the private placement.

On April 18, 2011, we consummated a private placement with two accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended), pursuant to which we sold 283,334 shares of our common stock and a five-year warrant to purchase 141,667 shares of our common stock at an exercise price of \$1.80 per share, for aggregate cash proceeds of \$425,000. The securities sold in this offering were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(2) and Regulation D (Rule 506) under the Securities Act of 1933, as amended.

On April 18, 2011, upon the consummation of the above described April 18, 2011 private placements, we issued a five-year warrant to purchase up to 57,000 shares of common stock at an exercise price of \$1.80 per share to Palladium Capital Advisors, LLC, our placement agent in the April 18, 2011 private placements. The warrant was not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and was offered and sold in reliance on the exemption from registration afforded by Section 4(2) and Regulation D (Rule 506) under the Securities Act of 1933, as amended, and corresponding provisions of state securities laws, which exempt transactions by an issuer not involving a public offering. Palladium Capital Advisors, LLC was an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended) at the time of the private placement

On April 21, 2011, we consummated a private placement with Mr. Reinder Hogeboom pursuant to which we sold 33,333 shares of our common stock and a five-year warrant to purchase 16,667 shares of our common stock at an exercise price of \$1.80 per share, for aggregate cash proceeds of \$50,000. The securities sold in this offering were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Regulation S under the Securities Act of 1933, as amended. Reinder Hogeboom was not a “U.S. person” (as that term is defined in Rule 902 of Regulation S) at the time of the private placement.

On January 4, 2011, we entered into a convertible loan agreement with our distributor in Israel, in the amount of \$100,000. On June 1, 2011, we issued 81,161 shares of common stock to the lender upon conversion of the note. These securities were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Regulation S under the Securities Act of 1933, as amended. The lender was not a “U.S. person” (as that term is defined in Rule 902 of Regulation S) at the time of the issuance.

## Item 6. Exhibits

### (a) Exhibits

#### Exhibit No. Description

10.1 \$1.50 Nonqualified Stock Option Agreement, dated as of July 11, 2011, by and between InspireMD, Inc. and Sol J. Barer, Ph.D. (Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on July 15, 2011)

10.2 \$2.50 Nonqualified Stock Option Agreement, dated as of July 11, 2011, by and between InspireMD, Inc. and Sol J. Barer, Ph.D. (Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on July 15, 2011)

10.3



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\$1.95 Nonqualified Stock Option Agreement, dated as of August 5, 2011, by and between InspireMD, Inc. and Paul Stuka (Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2011)

- 10.4 \$1.95 Nonqualified Stock Option Agreement, dated as of August 5, 2011, by and between InspireMD, Inc. and Eyal Weinstein (Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2011)

- 10.5 Clinical Trial Services Agreement, dated as of October 4, 2011, by and between InspireMD Ltd. and Harvard Clinical Research Institute, Inc. (Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2011)
- 10.6 Consultancy Agreement by and between InspireMD Ltd. and Sara Paz Management and Marketing Ltd., dated as of September 1, 2011 (Incorporated by reference to Exhibit 10.41 to Amendment No. 4 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 12, 2011)
- 10.7 Amended and Restated InspireMD, Inc. 2011 UMBRELLA Option Plan (Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 4, 2011)
- 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.

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: November 14, 2011

By: /s/ Ofir Paz  
Name: Ofir Paz  
Title: Chief Executive Officer

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

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