

InspireMD, Inc.
Form 10-Q
May 16, 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: March 31, 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 \$0.001 par value, outstanding as of May 16, 2011: 64,104,001

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

INSPIREMD, INC. (formerly Saguaro Resources, Inc.)
Condensed Consolidated Balance Sheets (Unaudited)
As of March 31, 2011

U.S. Dollars in thousands	March 31, 2011	December 31, 2010
Assets		
Current Assets		
Cash and Cash Equivalents	\$9,615	\$636
Restricted Cash	342	250
Accounts Receivable		
Trade	482	852
Other	85	75
Prepaid Expenses	29	3
Inventory		
On hand	1,332	1,704
On consignment	331	371
Total Current Assets	12,216	3,891
Property, Plant and Equipment, net of accumulated depreciation and amortization	303	282
Non-Current Assets		
Deferred debt issuance costs	12	15
Fund in respect of employee right upon retirement	189	167
Total Non-Current Assets	201	182
Total Assets	\$12,720	\$4,355
Liabilities and Equity (Capital Deficiency)		
Current Liabilities		
Current maturities of long-term loans	\$351	\$355
Accounts payable and accruals		
Trade	470	1,103
Other	1,958	1,509
Advanced payment from customers	581	559
Loans from shareholders	-	20
Deferred revenues	299	398
Convertible loans	1,100	-
Total Current Liabilities	4,759	3,944
Long-Term Liabilities		
Long term loan	-	75
Liability for employees rights upon retirement	237	206
Convertible loan	-	1,044
Total Long-Term Liabilities	237	1,325

Commitments and Contingencies (note 9)		
Total Liabilities	4,996	5,269
Equity (Capital Deficiency)		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 63,120,667 shares issued and outstanding at March 31, 2011 and 49,863,801 shares issued and outstanding at December 31, 2010		
	6	5
Additional paid-in capital	31,589	21,057
Accumulated deficit	(23,871)	(21,976)
Total Equity (Capital Deficiency)	7,724	(914)
Total Liabilities and Equity (Capital Deficiency)	\$ 12,720	\$ 4,355

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

INSPIREMD, INC. (formerly Saguaro Resources, Inc.)

Condensed Consolidated Statements of Operations (Unaudited)

Three Months Ended March 31, 2011 and 2010 and Twelve Months Ended December 31, 2010

U.S. Dollars in thousands except per share data	For the Three Months Ended March 31,		Twelve Months Ended
	2011	2010	2010
Revenues	\$ 1,686	\$ 2,097	\$ 4,949
Cost of Revenues	899	1,337	2,696
Gross Profit	787	760	2,253
Operating Expenses			
Research and development	343	401	1,338
Selling and marketing	428	333	1,236
General and administrative	1,186	670	2,898
Total Operating Expenses	1,957	1,404	5,472
Loss From Operations	(1,170)	(644)	(3,219)
Financial Expenses, net	715	70	154
Loss Before Tax Expenses	(1,885)	(714)	(3,373)
Tax Expenses	10	15	47
Net Loss	\$(1,895)	\$(729)	\$(3,420)
Net Loss per Share - Basic and Diluted	\$(0.037)	\$(0.015)	\$(0.07)
Weighted-Average Number of Ordinary Shares Used in Computing Net Loss per Share - Basic and Diluted	50,798,900	48,595,241	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)

Three Months Ended March 31, 2011 and 2010 and Twelve Months Ended December 31, 2010

U.S. Dollars in thousands

Ordinary shares

	Number of shares	Par value	Additional paid-in capital	Accumulated deficit	Total equity (capital deficiency)
Balance At January 1, 2011	49,863,801	\$ 5	\$ 21,057	\$ (21,976)	\$ (914)
Changes During Three Months Ended March 31, 2011:					
Net loss	-	-	-	(1,895)	(1,895)
Employee and non-employee share-based compensation expenses	-	-	2,188	-	2,188
Issuance of ordinary shares, net of \$50 issuance costs	802,866	*	940	-	940
Issuance of share capital and warrants, net of \$2,277 issuance costs.	12,008,936	1	6,736	-	6,737
Conversion of convertible loan	445,064	*	668	-	668
Balance At March 31, 2011	63,120,667	\$ 6	\$ 31,589	\$ (23,871)	\$ 7,724
Balance At January 1, 2010	48,338,380	\$ 5	\$ 17,212	\$ (18,556)	\$ (1,339)
Changes During Three Months Ended March 31, 2010:					
Net loss	-	-	-	(729)	(729)
Employee and non-employee share-based compensation expenses	-	-	377	-	377
Issuance of ordinary shares, net of \$6 issuance costs	454,096	*	552	-	552
Balance At March 31, 2010	48,792,476	\$ 5	\$ 18,141	\$ (19,285)	\$ (1,139)
Balance At January 1, 2010	48,338,380	\$ 5	\$ 17,212	\$ (18,556)	\$ (1,339)
Changes During Twelve Months Ended December 31, 2010:					
Net loss	-	-	-	(3,420)	(3,420)
Employee and non-employee share-based compensation expenses	-	-	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)

Three Months Ended March 31, 2011 and 2010 and Twelve Months Ended December 31, 2010

U.S. Dollars in thousands	3 months ended March 31		12 months ended December 31
	2011	2010	2010
Cash Flows From Operating Activities			
Net loss	\$(1,895)	\$(729)	\$(3,420)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	25	28	91
Loss from sale of property, plant and equipment	15	-	-
Change in liability for employees rights upon retirement	25	(4)	42
Financial expenses	654	34	94
Share-based compensation expenses	385	376	1,620
Gains on amounts funded in respect of employee rights upon retirement, net	(3)	(2)	(11)
Changes in operating asset and liability items:			
Decrease (increase) in Prepaid expenses	(26)	(16)	36
Decrease in Trade receivables	370	982	337
Decrease (increase) in Other receivables	(18)	(29)	9
Decrease in Inventory on consignment	40	475	722
Decrease (increase) in inventory on hand	372	226	(758)
Increase (decrease) in Trade payables	(633)	(205)	196
Decrease in Deferred revenues	(100)	(1,698)	(1,577)
Increase (decrease) in Other payable and advance payment from customers	428	545	(91)
Net cash used in operating activities	(361)	(17)	(2,710)
Cash Flows from Investing Activities			
Decrease (increase) in restricted cash	(92)	43	52
Purchase of property, plant and equipment	(28)	(35)	(81)
Proceeds from sale of property, plant and equipment	29	-	-
Amounts funded in respect of employee rights upon retirement, net	(11)	23	(17)
Net cash provided by (used in) investing activities	(102)	31	(46)
Cash Flows from Financing Activities			
Proceeds from issuance of shares and warrants, net of issuance costs	9,468	554	2,245
Convertible Loan	100	-	-
Repayment of long term loan	(94)	-	(281)
Proceeds from convertible loan at fair value through profit or loss, net of \$60 issuance costs	-	-	1,073
Repayment of loans from shareholders	(20)	-	-
Net cash provided by financing activities	9,454	554	3,037
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(12)	(4)	(21)
Increase (Decrease) in Cash and Cash Equivalents	8,979	564	260

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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	\$9,615	\$940	\$636

(*) During the period, convertible loans in the amount of \$668,000 were converted into shares of common stock of the Company.

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

INSPIREMD, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 2011

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.

InspireMD Ltd. is a limited company incorporated under the laws of the State of Israel in April 2005. On December 29, 2010, the Company entered into a Share Exchange Agreement (the “Exchange Agreement”) by and among the Company and InspireMD Ltd., a private Israeli company. 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 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 2012. However, depending on the operating results in 2011, the Company may need to obtain additional cash in 2012 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 the Company's audited financial statements for the

year ended December 31, 2010. The results of operations for the three months ended March 31, 2011 are not necessarily indicative of results that could be expected for the entire fiscal year.

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

NOTE 3 - RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS, continued

considerations. The adoption of the new guidance did not have a material impact on the Company's 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 became 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 the Company's consolidated financial statements.

NOTE 4 - FACTORING OF RECEIVABLES

During the three month period ended March 31, 2011, the Company entered into a factoring agreement with a certain banking institution on a non-recourse basis. The factoring of trade receivables under this agreement is accounted for as a sale. Under the terms of this factoring agreement, the Company transfers ownership of eligible trade receivables without recourse to the banking institution in exchange for cash. Proceeds on the transfer reflect the face value of the account less a discount. The discount is 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 has 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 were recorded to "financial expenses - net" within the Condensed Consolidated Statements of Operations.

NOTE 5 - CERTAIN TRANSACTIONS

During the first quarter of 2011 and prior to the Share Exchange, the Company 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, the Company 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, the Company 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 does not bear annual interest;
- in the event of a share exchange or similar transaction, the Lender shall 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

- Inspire MD), 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 does not close a share exchange or similar transaction by June 1, 2011, the Lender shall have the right to extend the loan and its terms for up to additional 6 months (as noted in note 1 the Share Exchange was closed on March 31, 2011); and
 - in no event shall the loan be repaid by the Company.

Subsequent to the consummation of the Share Exchange on March 31, 2011, the Lender notified the Company of its intention to convert the loan in the amount of \$100,000 into shares of the Company's common stock. The conversion is expected to occur during the second quarter of 2011.

NOTE 5 - CERTAIN TRANSACTIONS, continued

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

Pursuant to the Share Exchange described in Note 1 above, 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 shares of its 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 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. 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 notes were assumed by the Company with the maturity date being extended to May 15, 2011.

In connection with the Private Placement, the Company paid placement agent fees of approximately \$300,000 and issued a five-year warrant to purchase 373,740 shares of our common stock, at an initial exercise price of \$1.80 per share. The fair value of the warrant 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 1,500,000 shares of common stock held by them into escrow, which shares shall be released to the Company for cancellation or surrender to an entity designated by the Company should the Company record at least \$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 Shareholders in connection with the Share Exchange 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 February 20, 2011, the Company have 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 of the Company's shares and options. According to the tax pre-ruling, the shares and options exchange will not resolve immediate tax event for the Company's 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 share holders holding over of 5%.

During the first quarter of 2011, the Company entered into investor relations consulting agreements (the “Consulting Agreements”) with investor relationship companies (the “Advisors”) to provide financial advisory services and other investment banking services. Pursuant to the Consulting Agreements, in addition to a monthly fee, the Company will issue 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.

The Company recorded share-based compensation expenses of \$113,000 related to these issuances.

On March 31, 2011, the Company issued certain consultants three-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, which warrants have a fair value of \$1,500,000. The expenses related to the issuance of the warrants are recorded in equity as an issuance cost.

NOTE 6 - FAIR VALUE MEASUREMENT

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

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

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

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

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

NOTE 6 - FAIR VALUE MEASUREMENT, continued

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.

Convertible loan recorded at 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 profit or loss as of March 31, 2011. This security is measured at fair value on a recurring basis and classified in the "Significant Unobservable inputs (Level 3)" category.

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 Company's other financial long-term assets and other financial long-term liabilities approximate their fair value.

NOTE 7 - INVENTORY

Inventories consist of the following:

	March 31, 2011	As of December 31, 2010
	(\$ in thousands)	
Finished goods	\$ 458	\$ 957
Work in process	769	573
Raw materials and supplies	105	174
Total	\$ 1,332	\$ 1,704

NOTE 8 - RELATED PARTIES TRANSACTIONS

In July 2010, the Company's board of directors approved new employment 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.

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES

Commitments

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 last quarter of 2010 and began selling the MGuard Prime in the first quarter of 2011.

Litigation

The Company is a party to various claims arising in the ordinary course of its operations in the aggregate amount of \$1,030,000. The Company has not recorded an expense related to damages in connection with these matters because management, based upon the opinion of its legal counsel, is of the opinion that the ultimate resolution of these claims will not have a material effect on the financial position of the Company, its result of operations and cash flows.

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. The Company has recorded a provision of \$105,000 in the financial statements in 2011. The related expense has been recorded to "General and administrative" within the Condensed Consolidated Statements of Operations.

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES, continued

In November 2010, a former senior employee a claim 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 Company, based upon the opinion of its legal counsel, has recorded a provision of \$20,000 in the financial statements.

In November 2010, a former founder and legal advisor of the Company submitted a claim against the Company for options to purchase 496,056 shares of the Company at an exercise price of \$0.001 per share in the Magistrate's Court in Tel Aviv. The Company, based upon the opinion of its legal counsel, has recorded a share-based compensation expense of \$134,000 allocated to the year ended December 31, 2006.

In November 2010, a former legal advisor of the Company submitted a claim against the Company in the amount of \$53,000 in the Magistrate's Court in Tel Aviv, claiming a breach of terms of employment. The Company, based upon the opinion of its legal counsel has recorded a provision of \$53,000 allocated to the year ended December 31, 2006.

In February 2011, a finder submitted a claim against the Company in the amount of \$327,000 in the Magistrate's Court in Tel Aviv, claiming a future success fee and commission for assistance in finding the Company's distributor in Brazil. The Company, based upon the opinion of its legal counsel, has recorded a provision of \$327,000 in the financial statements in 2011. The related expense has been recorded to "General and administrative" within the Condensed Consolidated Statements of Operations.

NOTE 10 - TAXES ON INCOME

Amendment of the Law for the Encouragement of Capital Investments, 1959

The Law for Encouragement of Capital Investments, 1959 (the "Law") was amended as part of the Economic Policy Law for the years 2011-2012, which was passed in the Knesset (the Israeli parliament) on December 29, 2010 (the "Amendment"). The Amendment became effective January 1, 2011.

The Amendment sets alternative benefit tracks to those currently in place under the provisions of the Law, as follows: an investment grants track designed for enterprises located in national development zone A and two new tax benefits tracks (preferred enterprise and a special preferred enterprise), which provide for application of a unified tax rate to all preferred income of a company, as defined in the amendment.

The tax rates at company level, under the Law:

Years	National Development Zone A	Other Areas in Israel
"Preferred Enterprise"		
2011-2012	10%	15%
2013-2014	7%	12.5%
2105 and thereafter	6%	.12%
"Special Preferred Enterprise"		
2011 and thereafter	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 forth 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 the 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 no 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 set forth 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. Since, as at December 31, 2010, the Amendment had not yet been “enacted”, as defined in Topic 740, the measurement of the current and deferred taxes for the year ended December 31, 2010 is made without taking into consideration the Amendment. The Company believes that the adoption of the Amendment does not have an impact on its consolidated financial statements.

NOTE 11 - ENTITY WIDE DISCLOSURE

The Company operates in one reportable segment.

Revenues by Geographic Area

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

	3 months ended March 31		Year ended December 31
	2011	2010	2010
	(\$ in thousands)		
Israel	\$ 50	-	\$ 119
India	1,083	-	-
Poland	55	1,370	1,446
Other	498	727	3,384
	\$ 1,686	\$ 2,097	\$ 4,949

Revenues by Principal Customers

	3 months ended March 31		Year ended December 31
	2011	2010	2010
	(\$ in thousands)		
Customer A	64	%	-
Customer B	3	%	29

All tangible long lived assets are located in Israel.

NOTE 12 - SUBSEQUENT EVENTS:

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, the Company paid placement agent fees of approximately \$471,000 and five-year term warrants to purchase 57,000 shares of the Company common stock at an initial exercise price of \$1.80 per share.

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.

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 United States, Europe or Israel;
- 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.

When considering our forward-looking statements, keep in mind the risk factors included in our Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011.

Overview

On December 29, 2010, the Company entered into a Share Exchange Agreement (the “Exchange Agreement”) by and among the Company and InspireMD Ltd., a private Israeli company. 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 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, and the Company succeeded to the business of InspireMD Ltd. as its sole line of business.. In connection with the Share Exchange, the Company’s sole officer resigned and was replaced by designees of InspireMD Ltd. In addition, in connection with the Share Exchange, the Company’s sole director resigned and was replaced by designees of InspireMD Ltd.

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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. Operations reported for periods prior to the Share Exchange are those 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 manufactures its stents by way of a sub-contractor agreement. The Company currently depends on a single manufacturer.

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 the convertible loan.

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. 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 March 31, 2011 Compared to Three Months Ended March 31, 2010

Revenues. For the three months ended March 31, 2011, total revenue decreased 19.6% to \$1.7 million from \$2.1 million during the same period in 2010. The decrease in revenue was primarily attributable to the recognition of previously recorded deferred revenues in the first quarter of 2010 for which there was no comparable revenues in 2011. On a product delivery basis, shipments increased during the first three months of 2011 versus the same period in 2010.

Gross Margin. Our gross margin percentage for the three months ended March 31, 2011 increased to 46.7% of revenues, compared to 36.2% during the same period in 2010. The increase in our gross margin resulted primarily from higher pricing, more efficient manufacturing and economies of scale due to the increase in purchasing volumes.

Research and Development Expense. For the three months ended March 31, 2011, research and development expense decreased 14.5% to \$0.3 million from \$0.4 million during the same period in 2010. The decrease in cost resulted primarily from lower share based compensation expenses in the first quarter of 2011 offset by first time FDA clinical trial expenses. Research and development expense as a percentage of revenue increased to 20.3% in 2011 from 19.1% in 2010.

Selling and Marketing Expense. For the three months ended March 31, 2011, selling and marketing expense increased 28.5% to \$0.4 million from \$0.3 million during the same period in 2010. The increase in cost resulted primarily from additional promotional activities worldwide. Selling and marketing expense as a percentage of revenue increased to 25.4% in 2011 from 15.9% in 2010.

General and Administrative Expense. For the three months ended March 31, 2011, general and administrative expense increased 77.0% to approximately \$1.2 million from \$0.7 million during the same period in 2010. The increase in cost resulted primarily from an increase in investor related activities and provisions for pending litigation. General and administrative expense as a percentage of revenue increased to 70.3% in 2011 from 32.0% in 2010.

Financial Expenses. For the three months ended March 31, 2011, financial expense increased to approximately \$0.7 million from \$0.1 million during the same period in 2010. The increase in expense resulted primarily from approximately \$0.6 million of additional expense in the first quarter of 2011 pertaining to the revaluation of the convertible loan at fair value. Financial expense as a percentage of revenue increased to 42.4% in 2011, from 3.3% in 2010.

Tax Expenses. Tax expense remained relatively flat at \$10,000 for the three months ended March 31, 2011 as compared to 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 159.9% to \$1.9 million for the three months ended March 31, 2011 from \$0.7 million during the same period in 2010. The increase in net loss resulted primarily from the increase in financial expenses and other general and administrative expenses in the first quarter of 2011.

Liquidity and Capital Resources

General. At March 31, 2011, we had cash and cash equivalents of approximately \$9.6 million, as compared to \$0.6 million at the same period in 2010. The increase was attributable primarily to the private placement that was consummated in conjunction with the consummation of the Share Exchange on March 31, 2011. 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 overall working capital.

Cash used in our operating activities was approximately \$0.4 million for the three months ended March 31, 2011, and approximately \$17,000 at the same period in 2010. The principal reasons for the decrease in cash flow from operations in 2011 included a \$1.9 net loss offset by \$0.7 million in the non cash financial expenses related to the revaluation of the convertible loan, a \$0.4 million increase in working capital and \$0.4 million worth of non-cash share-based compensation.

Cash used in investing activities was approximately \$0.1 million for the three months ended March 31, 2011, and the cash provided by investing activities was approximately \$31,000 at the same period in 2010. The principal reason for the decrease in cash flow from investing activities was an increase in restricted cash.

Cash flow generated from financing activities was approximately \$9.5 million for the three months ended March 31, 2011, and \$0.6 million at 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 consummation of the Share Exchange on March 31, 2011 and other private equity issuances prior the Share Exchange in the aggregate amount of \$9.5 million. The principal reason for the increase in cash flow from financing activities during the same period in 2010 was the issuance of shares of our common stock in private placement transactions.

As of March 31, 2011, current assets exceeded our current liabilities by 2.6 times. Current assets increased approximately \$8.3 million during 2011 mainly due to cash from the private placement on March 31, 2011, and current liabilities increased by \$0.8 million during the same period. As a result, our working capital surplus increased by approximately \$7.5 million to approximately \$7.5 million during the first quarter of 2011.

Management of the Company is of the opinion that as a result of the consummation of the Share Exchange, which occurred on March 31, 2011, the Company has sufficient cash to continue its operations into 2012. However, depending on the operating results in 2011, the Company may need to obtain additional cash in 2012 to continue to fund operations.

Credit Facilities. As of March 31, 2011, we had a long term loan in the amount of approximately \$0.4 million bearing interest at the three month US\$ LIBOR rate plus 4% per annum. The loan is payable in eight quarterly installments during a period of three years beginning April 2010 and ending on 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 at an “IPO” is higher than \$100 million.

Convertible Loan. Prior to March 31, 2011, we had a convertible loan with an aggregate principal amount outstanding of approximately \$1,580,000 that accrued 8% interest. Following the consummation of the Share Exchange on March 31, 2011, \$580,000 plus accrued interest converted into shares of the Company. The remaining principle in the amount of \$1,000,000 is due on May 15, 2011.

Sales of Stock. During the first quarter of 2011, we issued an aggregate of 7,256,866 shares of common stock and warrants to purchase 3,227,000 shares of common stock for gross proceeds of approximately \$10.7 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 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 Company does not expect the standard to have material effect on its 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 the Company's consolidated financial statements.

ITEM 4. Controls and Procedures

Management’s Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of March 31, 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 March 31, 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.

PART II - OTHER INFORMATION

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information included or incorporated by reference in this report before deciding whether to invest in shares of our common stock. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements. You should carefully read and consider these risk factors together with all of the other information included in this report and all information incorporated by reference before you decide to purchase shares of our common stock.

Risks Related to Our Business

Our failure to successfully market, sell, manufacture or distribute our stent products would have a material adverse effect on our business and the value of our business.

We have limited experience marketing, selling, manufacturing or distributing the products we intend to sell, if and when we receive the regulatory approvals required to do so. Furthermore, we will need to substantially increase our manufacturing, marketing, sales and distribution capabilities in order to do so successfully. If unsuccessful in any of these activities, our business and the value of our securities could be materially and adversely affected.

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We expect to derive our revenue from sales of our MGuard™ stent products. 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 commercial and market uncertainties that are 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.

Market acceptance of our products, and the products of any future licensees, is uncertain.

Even if our products are developed successfully and achieve all necessary regulatory approvals, they may not enjoy commercial acceptance or success, which would adversely affect our potential market share, and our business, financial condition and results of operations. Several factors could limit the successful commercialization of our products, including:

- limited market acceptance or familiarity among patients, physicians, medical centers and third-party purchasers;
- inadequate reimbursement for our products by third party payors;
- our inability to develop a sales force or distributors capable of effectively marketing our products;
- our inability to manufacture and supply a sufficient amount of products to meet market demands; and
- the number, relative effectiveness, and cost of competing products that may enter the market.

The foregoing factors could also limit the successful commercialization by any future licensee of products incorporating our technology, which would ultimately affect our results of operations.

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 no experience scaling our manufacturing capability, and if we are unable to increase our production to meet demand, our business and results of operations would suffer.

To be successful, we must manufacture products of sufficient quality in sufficient quantities to meet demand, in compliance with regulatory requirements, and at an acceptable cost. We have no experience in large-scale manufacturing, and may not be able to develop commercially viable manufacturing capabilities or increase our capacity to meet increased demand for our interventional cardiology products. We will need to expand our production facilities for our products if we receive sizeable orders. An important element in the manufacture of our products will be our ability to scale our unit volume to meet sales projections, while maintaining high product quality. To date, the application of the mesh sleeve to the stent has been a manual process. We are dependent upon SewFine LLC for the development of a process to automate the production of our MGuard™ stent products. We and any potential licensee may also encounter manufacturing problems in relation to the following:

- production yields;
- quality control and assurance;
- availability of third-party components or products;

- shortages of qualified personnel;
- compliance with local and international regulations;
- production and distribution costs; and
- development of advanced manufacturing techniques and process controls.

To the extent we use third-party manufacturers or enter into manufacturing joint ventures with third parties, we cannot be certain that we will be able to contract with such companies on acceptable terms, if at all, or that such third parties will satisfy our quality standards or meet supply requirements on a timely basis, if at all.

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 (“PMA”) application to the United States Food and Drug Administration (“FDA”) 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 the PMA applications for the Cypher stent and the Taxus Express2 stent, which are approved by the FDA and currently marketed, involved patient populations of approximately 1,000 and 1,300, respectively, and a 12-month follow up period. The FDA may require us to submit data on a greater number of patients or for a longer follow-up period than those for the PMA 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, or CABG, 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.

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 obtain necessary regulatory approvals, if such approvals are received at all.

Because our products are new and long-term success measures have not been completely validated, regulatory agencies, including the FDA, 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 FDA 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 30 employees. As a result, we may experience a long regulatory process in connection with obtaining regulatory approvals for our products.

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, 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 FDA and other regulatory bodies. In particular, we and our suppliers will be required to comply with the FDA's Quality System Regulation ("QSR") for the manufacture of our MGuard™ stent, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval in the United States. The FDA enforces the QSR through unannounced inspections. We and our third-party manufacturers and suppliers have not yet been inspected by the FDA 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 FDA 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 FDA 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, the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the FDA 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 FDA 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 FDA. If the FDA 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 QSR, 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. For example, Boston Scientific Corporation has initiated significant recalls of its stent products due to manufacturing and other quality issues associated with the products.

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

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

We intend to market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from those obtained in the United States. 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 FDA approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE Mark or FDA 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.

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.

The products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia. The process of obtaining regulatory approvals to market a medical device, particularly in the United States, Europe and Japan, 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 continuing 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.

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 United States and internationally in connection with our current product and products under development. We face competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. When we commercialize our products, we expect to face intense competition from Cordis Corporation, a subsidiary of Johnson & Johnson; Boston Scientific Corporation; Guidant; Medtronic, Inc.; Abbott Vascular Devices; Terumo, and others. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources, than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those

developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

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. If we cannot obtain necessary materials or components, we may be unable to manufacture products of sufficient quality in sufficient quantities to meet customer needs. We may also be unable to develop new products and applications and conduct clinical trials. This would compromise our ability to obtain necessary regulatory approvals, thereby impairing our ability to expand into new markets or develop new products.

Our stents may be subject to certain pricing restrictions that could reduce our product revenue.

The successful commercialization of our stents will depend, in part, on the extent to which third-party reimbursement is available from government health administration authorities, private health care insurers and other health-care funding organizations. Some element of price control over medical devices exists in most major markets and third party reimbursement is highly variable and complex. 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. There can be no assurance that health administration or third party coverage will allow any potential licensee or us to achieve pricing that provides an appropriate return on such licensees' or our investment. If any potential licensee fails to achieve such pricing, it may de-emphasize or cease to commercialize our products, which could have a material adverse effect on our business and results of operations.

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.

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.

We intend to design the protocol of our planned pivotal U.S. clinical trial for our MGuard Prime™ stent based in part on prior clinical trials that used different stents. The results of these prior clinical trials may not be indicative of the clinical results we would obtain for our U.S. pivotal clinical trial.

We intend to commercialize our technology in the United States in the form of our MGuard Prime™ stent, which is a cobalt-chromium stent covered with a polymer mesh. We have only limited clinical data on our MGuard™ Coronary with bio-stable mesh stent, which we derived from the MGuard™ Coronary with bio-stable mesh study. We intend to design the protocol for our planned United States pivotal clinical trial based on the results of prior clinical trials. This trial is being designed in large part based on the results of our MGuard™ Coronary with bio-stable mesh study.

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, 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 additional 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.

In addition, while we have validated our manufacturing process for consistency, we have experienced drug release kinetic variability within and between manufacturing lots, and we may experience similar issues in the future. Manufacturing lot variability may result in unfavorable clinical trial results.

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.

Our manufacturing facilities and the manufacturing facilities of our suppliers must comply with applicable regulatory requirements. If we fail to achieve regulatory approval for these manufacturing facilities, our business and results of operations would be harmed.

Completion of our clinical trials and commercialization of our product candidates requires access to, or the development of, manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our products. The FDA and other regulatory bodies must approve facilities that manufacture our products for commercial purposes, as well as the manufacturing processes and specifications for the product. Suppliers of components of, and products used to manufacture our products, must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject our and our suppliers to potential regulatory inspections and stoppages. Our suppliers may not satisfy these requirements. If we or our suppliers do not achieve the required regulatory approval for our manufacturing operations, our commercialization efforts could be delayed, which would harm our business and results of operations.

Quality issues in our manufacturing processes could delay clinical development and commercialization efforts.

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.

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

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

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and future revenues, if any, would be adversely affected.

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

The Patient Protection and Affordable Care Act and Health Care and Educational Reconciliation Act (the “Health Care Acts”) were enacted into law in March 2010. Certain provisions of the Health Care 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 United States, this new tax may materially and adversely affect our business and results of operations. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Many of our competitors are much larger than us, with significant resources and incentives to initiate litigation against us.

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

laws of some foreign jurisdictions do not protect intellectual property rights to the same degree as in the United States, and many companies have encountered significant difficulties in protecting 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.

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 depend on single-source suppliers for some of the components in our MGuard™ stent. The loss of such suppliers could delay our clinical trials or prevent or delay commercialization of our MGuard™ stent.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. We depend on QualiMed, which manufactures the body of the stent, as well as MeKo Laserstrahl-Materialbearbeitung, BMT and SewFine for various important elements of our products. We may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA 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 manufacture and delivery of our MGuard™ stent would be interrupted 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 FDA 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.

If we are unable to manage our expected growth, we may not be able to commercialize our products, including our MGuard™ stent.

We intend to continue to rapidly expand operations and grow our research and development, product development and administrative operations and invest substantially in our manufacturing facilities. This expansion has and is expected to continue to place a significant strain on our management and operational and financial resources. In particular, the commencement of our planned pivotal clinical trial in the United States will consume a significant portion of management's time and our financial resources. To manage expected growth and to commercialize our MGuard™ stent, we will be required to improve existing, and implement new, operational and financial systems, procedures and controls and expand, train and manage our growing employee base. 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.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In the United States in recent years, new legislation has been proposed at the federal and state levels that would effect major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted. The potential for adoption of these proposals

affects or will affect our ability to raise capital, obtain additional collaborators and market our products. We expect to experience pricing pressures in connection with the future sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals. Our results of operations could be adversely affected by future healthcare reforms.

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.

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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 1968 (the "ISL"). Section 15 to the ISL requires the filing of a prospectus with the Israel Security Authority (the "ISA") 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. We filed an application for "No action" with the ISA in connection with the foregoing. To date, the ISA has not provided any response to such application. A failure to receive "No action" relief could expose us to fines and other remedies that could be detrimental to us.

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 raised approximately \$9,681,000 million in the Private Placement in connection with the Share Exchange, and we 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.

Risks Related to Our Organization and Our Common Stock

As a result of the Share Exchange, we became a company that is subject to the reporting requirements of federal securities laws, which can be expensive and may divert resources from other projects, thus impairing our ability to grow.

As a result of the Share Exchange, we became a public reporting company and, accordingly, subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the Securities and Exchange Commission (the “SEC”) and furnishing audited reports to stockholders will cause our expenses to be higher than they would have been if we remained privately held and did not consummate the Share Exchange.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our common stock.

It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures. 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. In addition, if we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, then we may not be able to obtain the independent accountant certifications required by such act, which may preclude us from keeping our filings with the SEC current and may adversely affect any market for, and the liquidity of, our common stock.

Public company compliance may make it more difficult for us to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs and to make certain activities more time consuming and costly. As a public company, we also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

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”. Securities analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will, in the future, want to conduct any secondary offerings on our behalf.

Our stock price may be volatile.

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

changes in our industry;
competitive pricing pressures;
our ability to obtain working capital financing;
additions or departures of key personnel;
limited “public float” in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
sales of our common stock;
our ability to execute our business plan;
operating results that fall below expectations;
loss of any strategic relationship;
regulatory 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 materially and adversely affect the market price of our common stock.

Our securities are restricted securities with limited transferability.

Our securities should be considered a long-term, illiquid investment. Our common stock has not been registered under the Securities Act, and cannot be sold without registration under the Securities Act or any exemption from registration. In addition, our common stock is not registered under any state securities laws that would permit its transfer. Because of these restrictions, a stockholder will likely find it difficult to liquidate an investment in 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 which 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.

Our shares of common stock are very thinly traded, and the price may not reflect our value and there can be no assurance that there will be an active market for our shares of common stock in the future.

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. Investors may not be able to liquidate their investment or liquidate it at a price that reflects the value of the business. If a more active market should develop, the price may be highly volatile. Because there may be a low price for our shares of common stock, many brokerage firms may not be willing to effect transactions in the securities. Even if an investor finds a broker willing to effect a transaction in the shares of our common stock, the combination of brokerage commissions, transfer fees, taxes, if any, and any other selling costs may exceed the selling price. Further, many lending institutions will not permit the use of such shares of common stock as collateral for a loans.

We may apply the proceeds of the Private Placement to uses that ultimately do not improve our operating results or increase the price of our common stock.

We intend to use \$1,000,000 of the net proceeds from the Private Placement to complete the Dr. Gregg Stone-Dr. Alexandre Abizaïd trials, \$7,600,000 for the FDA trials with Harvard Clinical Research Institute and the remainder for general corporate purposes. However, our management has broad discretion in how we actually use these

proceeds. These proceeds could be applied in ways that do not ultimately improve our operating results or otherwise increase the value of our common stock.

We may need additional financing which may not be available on acceptable terms, which may in turn dilute your investment in us.

Our future capital requirements will depend on many factors including but not limited to: continued market acceptance of our services; competitive pressure on the price of our products; the extent to which we invest in new locations, develop new relationships with producers of polymers and chemicals as well as consumers of polymers and chemicals; and the response of competitors to our products. We believe that the existing cash balances, including the net proceeds from the Private Placement, and funds generated from operations will provide us with sufficient funds to finance our operations for the foreseeable future. To the extent that our current funds, together with existing resources, are insufficient to fund our activities over the long-term, we may need to raise additional funds through equity or debt financing or from other sources. The sale of additional equity or convertible debt may result in additional dilution to our stockholders and such securities may have rights, preferences or privileges senior to those of the common stock. To the extent that we rely upon debt financing, we will incur the obligation to repay the funds borrowed with interest and may become subject to covenants and restrictions that restrict operating flexibility. No assurance can be given that additional equity or debt financing will be available or that, if available, it can be obtained on terms favorable to us or our stockholders. Failure to obtain necessary financing could have a material adverse effect on our business, financial condition and results of operations.

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.

Item 6. Exhibits

(a) Exhibits

Exhibit No. Description

2.1*	Share Exchange Agreement, dated as of December 29, 2010, by and among InspireMD Ltd., Saguaro Resources, Inc., and the Shareholders of InspireMD Ltd. that are signatory thereto
2.2***	Amendment to Share Exchange Agreement, dated February 24, 2011
2.3***	Second Amendment to Share Exchange Agreement, dated March 25, 2011
3.1**	Amended and Restated Certificate of Incorporation
3.2**	Amended and Restated Bylaws
10.1**	2011 Umbrella Option Plan
10.2***	Form of Stock Option Award Agreement

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- 10.3*** Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations, dated as of March 31, 2011
- 10.4*** Stock Purchase Agreement, by and between InspireMD, Inc. and Lynn Briggs, dated as of March 31, 2011
- 10.5*** Securities Purchase Agreement, dated as of March 31, 2011, by and among InspireMD, Inc. and certain purchasers set forth therein
- 10.6*** Form of \$1.80 Warrant
- 10.7*** Form of \$1.23 Warrant
- 10.8*** \$1,250,000 Convertible Debenture, dated July 20, 2010, by and between InspireMD Ltd. and Genesis Asset Opportunity Fund, L.P.
- 10.9*** Unprotected Leasing Agreement, dated February 22, 2007, by and between Block 7093 Parcel 162 Company Ltd. Private Company 510583156 and InspireMD Ltd.

- 10.10*** Securities Purchase Agreement, dated as of July 22, 2010, by and among InspireMD Ltd. and certain purchasers set forth therein
- 10.11*** Manufacturing Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of September 11, 2007
- 10.12*** Development Agreement, by and between InspireMD Ltd. and QualiMed Innovative Medizinprodukte GmbH, dated as of January 15, 2007
- 10.13*** License Agreement, by and between Svelte Medical Systems, Inc. and InspireMD Ltd., dated as of March 19, 2010
- 10.14*** Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of April 1, 2005
- 10.15*** Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of October 1, 2008
- 10.16*** Second Amendment to the Employment Agreement, by and between InspireMD Ltd. and Ofir Paz, dated as of March 28, 2011
- 10.17*** Personal Employment Agreement, by and between InspireMD Ltd. and Asher Holzer, dated as of April 1, 2005
- 10.18*** Amendment to the Employment Agreement, by and between InspireMD Ltd. and Asher Holzer, dated as of March 28, 2011
- 10.19*** Personal Employment Agreement, by and between InspireMD Ltd. and Eli Bar, dated as of June 26, 2005
- 10.20*** Employment Agreement, by and between InspireMD Ltd. and Bary Oren, dated as of August 25, 2009
- 10.21*** Employment Agreement, by and between InspireMD Ltd. and Craig Shore, dated as of November 28, 2010
- 10.22*** Form of Indemnification Agreement between InspireMD, Inc. and each of the directors and executive officers thereof
- 10.23*** Agreement with Bank Mizrahi Tefahot LTD. for a loan to InspireMD Ltd. in the original principal amount of \$750,000
- 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.

* Incorporated by reference to Saguaro Resources, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 5, 2011

** Incorporated by reference to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011

*** Incorporated by reference to InspireMD, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011

SIGNATURES

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

INSPIREMD, INC.

Date: May 16, 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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