

INSPIREMD, INC.

FORM 8-K (Current report filing)

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 8, 2012

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or other jurisdiction of
incorporation)

000-54335

(Commission File Number)

26-2123838

(IRS Employer
Identification No.)

4 Menorat Hamaor St.
Tel Aviv, Israel

(Address of principal executive offices)

67448

(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2012, InspireMD, Inc. issued a press release announcing its financial results for the fiscal quarter ended March 31, 2012. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, that is furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
*99.1	Earnings release dated May 8, 2012.

* This exhibit is furnished pursuant to Item 2.02 and shall not be deemed to be “filed.”

SIGNATURES

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

INSPIREMD, INC.

Date: May 8, 2012

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Earnings release dated May 8, 2012.



FOR IMMEDIATE RELEASE

InspireMD Announces First Quarter 2012 Financial Results

Tel Aviv, Israel – May 8, 2012 – InspireMD, Inc. (OTC BB: NSPR) (the “Company” or “InspireMD”), a medical device company focusing on the development and commercialization of its proprietary stent platform technology for use in patients with Acute Myocardial Infarctions, today announced financial results for the quarter ended March 31st 2012.

Ofir Paz , Co-Founder and CEO of InspireMD, said: “The quarter was marked by continued positive momentum across financial, operational and clinical areas. Demand for MGuard™ increased in the majority of our international markets. We strengthened our senior management, and additional positive data on MGuard™ was reported. We also recently raised gross proceeds of \$11 million in a private placement, which strengthened our balance sheet for the global launch of MGuard™.”

Eli Bar, Vice President of R&D added: “We continue to make excellent progress in the MASTER trial , which is now more than 85% enrolled. We remain committed to completing enrollment in the second quarter and releasing preliminary top line results in the third quarter of 2012 . A successful outcome in this trial could lead to MGuard™ becoming the standard of care for patients with acute myocardial infarctions.”

Financial Highlights

- Total revenue for the three months ended March 31, 2012 was \$1.1 million, compared with approximately \$1.7 million during the same period in 2011.
 - The decrease in revenue year over year was mainly attributable to a one time order of approximately \$1.2 million by the Company’s distributor in India during the first three months of 2011 that the Company did not receive in 2012.
 - Shipments to other countries (excluding India) during the three months ended March 31, 2012 increased by approximately \$0.6 million, or 113.9%, compared to the same period in 2011. Sales of MGuard™ increased in the majority of the Company’s major markets during the three months ended March 31, 2012, including Mexico, Israel, Germany, Poland and the Netherlands compared to the same period in 2011.
 - Gross profit in the quarter was \$0.6 million, a decrease of 28.3% or approximately \$0.2 million, from \$0.8 million during the same period in 2011. The gross margin in the quarter increased to 49.6% from 46.7% during the same period in 2011.
 - Total operating expenses were \$3.7 million, compared to \$2.0 million in the same period of 2011. This increase was mainly driven by share - based compensation of \$0.8 million, increased R&D expenditures relating to the MASTER trial and planned FDA trials of \$0.8 million, and other expenses of \$0.1 million.
 - Loss from operations in the quarter was \$3.1 million , compared to a loss from operations of \$1.2 million in the comparable period in 2011.
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- The net loss for the quarter was \$3.1 million, or \$0.05 per weighted average share, compared to a net loss of \$1.9 million in the comparable period in 2011.
- The Company ended the quarter with cash and cash equivalents of approximately \$3.4 million, as compared to \$5.1 million as of December 31, 2011 .

Achievements in 1Q 2012

- Enrollment continued in the MASTER Trial which is comparing MGuard™ with the standard of care in STEMI patients. As of May 4, 2012, 370 patients (out of 432 planned) were enrolled.
- Positive clinical results were reported from the MICAMI trial of MGuard™ at the Cardiovascular Research Technologies (CRT) conference in Washington D.C. This randomized controlled trial showed a significant improvement in microvascular reperfusion for MGuard™ vs. bare metal stents .
- Dr. James Barry was appointed to the Board of Directors as an independent director. Dr. Barry is a former senior executive at Boston Scientific and has a proven track record of bringing high value medical technology products to market.
- Robert Ratini was appointed as Vice President of Sales and Marketing. Mr. Ratini will develop and lead all global marketing strategies for InspireMD’s proprietary stent system technology, MGuard™.

Recent (Post Period) Developments

- On April 5, 2012, the Company completed a private placement with two institutional investors resulting in gross proceeds (before deducting commissions and expenses) of \$11.0 million .

CONSOLIDATED STATEMENTS OF OPERATIONS ⁽¹⁾

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

	Three months ended March 31,	
	2012	2011
Revenues	\$ 1,138	\$ 1,686
Cost of Revenues	574	899
Gross Profit	<u>564</u>	<u>787</u>
Operating Expenses:		
Research and development	1,349	343
Selling and marketing	445	428
General and administrative	1,896	1,186
Total operating expenses	<u>3,690</u>	<u>1,957</u>
Loss from Operations	(3,126)	(1,170)
Financial (income) , expenses net	(11)	715
Loss before tax expenses	(3,115)	(1,885)
Tax Expenses	25	10
Net Loss	<u>\$ (3,140)</u>	<u>\$ (1,895)</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.04)</u>
Weighted average number of shares of common stock used in computing net loss per share - basic and diluted	<u>68,178,946</u>	<u>50,798,900</u>

CONSOLIDATED BALANCE SHEETS ⁽¹⁾
(U.S. dollars in thousands)

	March 31, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,351	\$ 5,094
Restricted cash	39	91
Accounts receivable:		
Trade	2,042	2,284
Other	204	118
Prepaid expenses	89	72
Inventory:		
On hand	2,017	2,061
On consignment	59	110
Total current assets	<u>7,801</u>	<u>9,830</u>
Property, plant and equipment, net of accumulated depreciation and amortization	465	420
Other non-current assets:		
Funds in respect of employees rights upon retirement	236	215
Deferred issuance costs	25	
Total other non-current assets	<u>261</u>	<u>215</u>
Total assets	<u>\$ 8,527</u>	<u>\$ 10,465</u>

	March 31, 2012	December 31, 2011
LIABILITIES AND EQUITY		
Current liabilities:		
Current maturities of long-term loans	\$ -	\$ 94
Accounts payable and accruals:		
Trade	333	814
Other	2,858	2,217
Advanced payment from customers	192	316
Deferred revenues	25	
Total current liabilities	<u>3,408</u>	<u>3,441</u>
Long-term liability		
Liability for employees rights upon retirement	317	270
Total long-term liabilities	<u>317</u>	<u>270</u>
Commitments and contingent liabilities -		
Total liabilities	<u>3,725</u>	<u>3,711</u>
Equity:		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 68,178,946 shares issued and outstanding at March 31, 2012 and December 31, 2011.	7	7
Additional paid-in capital	44,576	43,388
Accumulated deficit	(39,781)	(36,641)
Total equity	<u>4,802</u>	<u>6,754</u>
Total liabilities and equity	<u>\$ 8,527</u>	<u>\$ 10,465</u>

(1) All 2012 financial information is derived from the Company's 2012 unaudited financial statements and all 2011 financial information is derived from the Company's 2011 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission .

About MGuard™ Coronary Stent

MGuard™ presents a novel combination of a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer micron net that wraps the stent. The MGuard™ stent provides outstanding and lifelong embolic protection, without affecting deliverability. MGuard™ is CE Mark approved. Mesh-based protection is now recommended for use in the recent Guidelines of the Task force of Myocardial Revascularization of the European Society of Cardiology (ESC).

MGuard™ is currently being investigated in the multi-center international MASTER (MGuard™ for Acute ST Elevation Reperfusion) trial. This study has been designed to evaluate the MGuard™ stent compared to commercially-approved BMS or DES products in STEMI patients undergoing primary angioplasty. Preliminary top line results are expected in the third quarter of 2012. Plans for a registration study in the US are also at an advanced stage.

About InspireMD , Inc.

InspireMD is a medical device company focused on the development and commercialization of its proprietary stent system technology, MGuard™. InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is listed on the OTC BB under the ticker symbol "NSPR".

Forward-looking Statements:

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Registration Statement on Form S-1 filed with the SEC on April 25, 2012. Investors and security holders are urged to read these documents free of charge on the SEC's web site at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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