INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 03/13/12 for the Period Ending 03/06/12

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CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

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): March 6, 2012

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	000-54335	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 March 6, 2012, InspireMD, Inc. (the "Company") issued a press release announcing financial results for the fiscal year ended December 31, 2011. A copy of such press release is furnished as Exhibit 99.1.

The information in this Current Report and the accompanying exhibits are being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), and are not incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference to this Current Report in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Earnings release dated March 6, 2012.

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: March 13, 2012

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Earnings release dated March 6, 2012.

FOR IMMEDIATE RELEASE

InspireMD Announces its 2011 Year End Financial Results

Annual Shipments of MGuard ™ Increase 78% vs. 2010

Tel Aviv, Israel – March 6, 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 year ended December 31, 2011.

Ofir Paz, Co-Founder and CEO of InspireMD, said: "I am encouraged by the progress we made at InspireMD in 2011, as we experienced increased demand for our MGuard ™ stent system from early adopters outside the United States and a related increase in product shipments. We also expanded the international presence of MGuard ™ through distributors in new territories and invested in our sales infrastructure to help drive future growth . "

Dr. Asher Holzer, Co-Founder and President of InspireMD, added "In 2011 we substantially increased our R&D investments in connection with launching a comprehensive clinical trial program for MGuard ™ , including a randomized MASTER trial in patients with acute ST-segment elevation myocardial infarction (the most severe form of a heart attack, referred to as "STEMI"). Patients are being enrolled on schedule in this MASTER trial and we expect to report results in the second half of 2012. We also began preparatory work for our MGuard ™ FDA registration trial."

2011 Achievements

- Initiated MASTER Trial comparing MGuard ™ with the standard of care in STEMI patients. As of March 2, 2012, 202 patients (out of 432 planned) were enrolled.
- Expanded the international presence of MGuard ™ through distributors in South Africa, India and Russia. MGuard ™ is currently approved and sold via distributors in more than 30 countries.
- Doubled MGuard ™ production levels to meet the ongoing increase in demand in shipments.
- Commenced trading as a public company in the United States on the Over-the-Counter Bulletin Board (OTC BB).
- Concluded a series of financings in which the Company raised an aggregate of approximately $12.1 million of cash.
- Elected Sol J. Barer, Ph.D. as Chairman of the Board of Directors, and elected Paul Stuka and Eyal Weinstein as independent directors.

Financial Highlights

- On a product delivery basis, shipments increased 78% during 2011 compared to the same period in 2010. Revenues for the year increased 21% to $6.0 million from $4.9 million due to revenue recognition policies related to entries into new regions and compliance with U.S. GAAP standards.

- Gross profit was $3.0 million, or 49 . 9% gross profit margin , compared to $2.3 million or 45.5% gross margin in 2010.
- Total operating expenses were $16.7 million for 2011 compared to $5.5 million in 201 0. This increase was mainly driven by share - based compensation of $7.8 million, increased R&D expenditures relating to the MASTER trial and planned FDA trials of $1.2 million, other sales and marketing expenses of $0.4 million and corporate business expenses related to becoming a public company of $1.8 million.
- The Company reported a loss from operations of $13.7 million in 2011 compared to a loss from operations of $3.2 million 2010.
- The net loss for the year was $14.7 million, or $0.24 per weighted average share, compared to a net loss of $3.4 million in 2010.
- The Company ended 2011 with cash and cash equivalents of approximately $5.1 million, as compared to $636,000 at the end of 2010. The cash balance was supplemented by $10.6 million in net proceeds from equity offerings throughout the year and $1.5 million from the exercise of options .

Recent (Post Period) Developments

- Reported positive clinical results from the MICAMI (Microvascular Coronary Flow Comparison in Acute Myocardial Infarction Angioplasty) 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.
- Elected Dr. James Barry, a former senior executive at Boston Scientific , to the Board of Directors as an independent director.

CONSOLIDATED STATEMENTS OF OPERATIONS [(1)]
(U.S. dollars in thousands, except per share data)

	December 31	
	2011	2010
Revenues	$ 6,004	$ 4,949
Cost of revenues	3,011	2,696
Gross profit	2,993	2,253
Operating expenses:		
Research and development	2,474	1,338
Selling and marketing	1,973	1,236
General and administrative (including $8,542 and $869 of share based compensation for the years ended December 31, 2011 and 2010 respectively)	12,275	2,898
Total operating expenses	16,722	5,472
Loss from Operations	(13,729)	(3,219)
Financial expenses (income), net	934	154
Loss before tax expenses	(14,663)	(3,373)
Tax expenses	2	47
Net Loss	$ (14,665)	$ (3,420)
Net loss per share - basic and diluted	$ (0.24)	$ (0.07)
Weighted average number of common shares used in computing net loss per share - basic and diluted	61,439,700	49,234,528

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

	December 31	
	2011	2010
Assets		
Current assets:		
Cash and cash equivalents	$ 5,094	$ 636
Restricted cash	91	250
Accounts receivable:		
Trade	2,284	852
Other	118	75
Prepaid expenses	72	3
Inventory:		
On hand	2,061	1,704
On consignment	110	371
Total current assets	9,830	3,891
Property, plant and equipment, net	420	282
Non-current assets:		
Deferred debt issuance costs	-	15
Fund in respect of employee rights upon retirement	215	167
Total non-current assets	215	182
Total assets	$ 10,465	$ 4,355
Liabilities and Equity (capital deficiency)		
Current Liabilities:		
Current maturities of long-term loans	$ 94	$ 355
Accounts payable and accruals :		
Trade	814	1,103
Other	2,217	1,509
Advanced payment from customers	316	559
Loans from shareholders	-	20
Deferred revenues	-	398
Total current liabilities	3,441	3,944
Long term liabilities:		
Long term loan	-	75
Liability for employees rights upon retirement	270	206
Convertible loan	-	1,044
Total long-term liabilities	270	1,325
Total liabilities	3,711	5,269
Equity (capital deficiency):		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 68,178,946 and 49,863,801 shares issued and outstanding at December 31, 2011 and 2010, respectively	7	5
Additional paid-in capital	43,388	21,057
Accumulated deficit	(36,641)	(21,976)
Total equity (capital deficiency)	6,754	(914)
Total liabilities and equity (less capital deficiency)	$ 10,465	$ 4,355

(1) All 2011 financial information is derived from the Company's 2011 unaudited financial statements and all 2010 financial information is derived from the Company's 2010 audited financials statements that were included in the Company's registration statement on Form S-1, as filed with the Securities and Exchange Commission on December 22, 2011.

About MGuard™ Coronary Stent

MGuard™ combines 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 seeks to provide 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 bare metal stent or drug eluting stent products in STEMI patients undergoing primary angioplasty. Results are expected in the second half 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 focusing 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 December 22, 2011. 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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