INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 02/04/13 for the Period Ending 02/04/13

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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): February 4, 2013

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

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

4 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:

☐ 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 February 4, 2013, InspireMD, Inc. issued a press release announcing its financial results for the fiscal quarter ended December 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

Exhibit Number	Description
99.1	Earnings release dated February 4, 2013.

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: February 4, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Earnings release dated February 4, 2013.

InspireMD Reports Results For Period Ended Dec. 31, 2012

Quarter Highlighted by Positive MASTER Trial
Results at 24 th Annual TCT Meeting

TEL AVIV, Israel, FEB. 4, 2013 — InspireMD, Inc. ("InspireMD" or the "Company") (OTC: NSPRD) announced financial results for the period ended Dec. 31, 2012, the second quarter of its 2013 fiscal year.

Revenue for the period was up 165% over the Sept. 30, 2012 quarter, reflecting early results of marketing initiatives that were launched following the announcement of positive results of the MASTER trial of the Company's MGuard™ Embolic Protection Stent (EPS™) at the 24 th Annual Transcathter Cardiovascular Therapeutics (TCT) scientific meeting in Miami on October 24, 2012.

Alan Milinazzo, newly appointed President and CEO of InspireMD said, "The interventional cardiology community was clearly enthusiastic about the MASTER trial's results. The study's positive results set the stage for enhanced sales and marketing activities which began during the first week of December at the important ICI meeting in Tel Aviv."

The MASTER trial's positive results, presented at the TCT by Study Chairman Gregg W. Stone, MD, reported that the novel MGuard EPS provided a statistically and clinically significant advantage in acute treatment of heart attack patients, indicating lower incidences of post stenting adverse events compared to the control group, and the potential to prolong survival.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the Food and Drug Administration (FDA) at this time. The Company has filed an Investigational Device Exemption with the U.S. FDA to initiate a Premarket Approval trial.

Key Financial Highlights 2Q Ended Dec. 31, 2012 Include:

—Revenue for the quarter ended Dec. 31, 2012 totaled $1.4 million, which was slightly above the $1.3 million recorded in the same period in 2011, but 165% higher than the $500,000 in revenue recorded in the quarter ended Sept. 30, 2012. As previously noted, the prior quarter was negatively affected by stocking and selling disruptions caused by a realignment of the Company's distributors in advance of the presentation of the MASTER trial at the TCT.

—Gross profit for the Dec. 31, 2012 period was $803,000, compared to $621,000 for the Dec. 31, 2011 period, up nearly 30% owing to higher revenue and lower production costs.

—Total operating expenses for the Dec. 31, 2012 period were $5.2 million, compared to $8.9 million in the Dec. 31, 2011 period, a decrease of $3.7 million. The decrease was attributable to a $5.6 million decrease in G&A expenses (mainly due to timing of the recording of share-based compensation related to board members) in the Dec. 31, 2012 period. This decrease was offset by a $0.9 million one-time royalties buyout expense, an increase in sales and marketing activities of $0.6 million (primarily related to the TCT meeting and subsequent launch of MGuard EPS), and an increase of $0.4 million in R&D expenses (mainly to support clinical trials).

—The loss from operations for the Dec. 31, 2012 period was ($4.4 million), compared to ($8.2 million) for the Dec. 31, 2011 period.

—Net income of $3.6 million related to the revaluation of contingently redeemable warrants, less financial and tax expenses of $1.1 million, brought final net income for the Dec. 31, 2012 period to ($1.9 million), or ($0.11) per basic and diluted share, compared to a final net income of ($8.2 million), or ($0.49) per basic and diluted share for the Dec. 31, 2011 period. The weighted average number of shares of common stock used in computing net loss per share (basic and diluted) was 17.7 million for the quarter just ended, and 16.7 million for the prior year's quarter.

—At Dec. 31, 2012, cash and cash equivalents stood at approximately $5.4 million, compared to $10.3 million at June 30, 2012.

Key Activities 2Q FY 2013 Included:

—Results of the MASTER trial of MGuard EPS were presented on Oct. 24, 2012 at TCT. The 432-patient randomized trial met its primary endpoint (proportion of patients with ST segment resolution of ≥ 70%, measured at 60 to 90 minutes post procedure), showing the MGuard EPS was significantly superior to the control arm of bare metal and drug eluting stents in the treatment of heart attack patients.

—The MASTER trial's results were published in the November 6, 2012 print edition of the peer-reviewed *Journal of American College of Cardiology (JACC)*, Vol. 60, No. 19. The authors concluded that "among patients with acute STEMI (**ST** Segment **E** levation **M** yocardial **I** nfarction) undergoing emergent PCI enrolled in the present multicenter, randomized, controlled trial, the MGuard Embolic Protection Stent (EPS) compared to standard metallic stents resulted in superior rates of epicardial coronary flow and complete STR, with trends present toward reduced microvascular obstruction, infarct size and mortality."

—The Company implemented initial changes to its sales and marketing activities to leverage both the MASTER trial outcomes as well as the availability of the MGuard Prime cobalt chromium stent platform. Five sales and marketing executives were hired to accelerate market penetration.

—On Dec. 20, 2012, the Company announced a one-for-four reverse stock split of its common stock as part of the process to qualify its shares for quoting on a national U.S. stock exchange. The reverse split decreased the number of issued and outstanding shares of common stock from approximately 72.1 million to approximately 18.0 million. The Company's authorized common stock was not affected by the reverse stock split.

Subsequent Event

—On Jan. 3, 2013, Alan Milinazzo was named President, CEO, and a member of the board. He replaced Ofir Paz, who previously announced his intention to step down as CEO in Sept. 2012 once a successor was named. Mr. Paz continues to serve as a director.

Mr. Milinazzo, who previously served in executive positions at Medtronic and Boston Scientific Corporation, brings more than 15 years of important commercial, operations, and international experience in interventional cardiology to bear on InspireMD's commercial strategy and operations as it launches the MGuard EPS platform.

He was instrumental in the launch of ENDEAVOR , Medtronic's first drug eluting stent platform, which has since generated more than $1 billion in revenue. He previously spent 12 years in executive positions at Boston Scientific, another major stent producer, serving as Vice President of Marketing at its $200 million SCIMED European unit, responsible for product launches, clinical programs and regulatory strategies.

Mr. Milinazzo most recently served as President and CEO of Nasdaq-quoted Orthofix International N.V., positions he was promoted to in 2006 after being hired a year earlier as Chief Operating Officer. During his tenure at Orthofix, Mr. Milinazzo transformed it into a category leader in novel spine and orthopedic stem cell therapy, while growing revenue from $300 million to $580 million and nearly doubling profits.

In commenting on Mr. Milinazzo's appointments, Sol J. Barer, PhD, Chairman of InspireMD said: "Alan brings an exceptional set of experiences to us as a proven executive in the medical device field, particularly as relates to interventional cardiology and stents specifically. He brings a long list of strategically and commercially important accomplishments as a public company executive, he has the right blend of domestic and international experience for a company with our opportunities and intentions, and a well-documented entrepreneurial drive that's critical to success in managing the evolving needs and challenges of an emerging company such as ours."

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

	Three months ended December 31,		Six months ended December 31,	
	2012	**2011**	**2012**	**2011**
Revenues	$ 1,350	$ 1,292	$ 1,859	$ 3,278
Cost of Revenues	547	671	777	1,472
Gross Profit	803	621	1,082	1,806
Operating Expenses:				
Royalties buyout expenses	918		918	
Other research and development expenses	1,256	834	2,202	1,381
Selling and marketing	1,206	626	1,608	928
General and administrative	1,789	7,398	4,001	9,884
Total operating expenses	5,169	8,858	8,729	12,193
Loss from Operations	(4,366)	(8,237)	(7,647)	(10,387)
Expenses (income) related to revaluation of contingently redeemable warrants, net	(3,569)		(296)	
Expenses related to interest on convertible loan and other financial expenses	1,081	39	2,026	147
Loss before tax expenses	(1,878)	(8,276)	(9,377)	(10,534)
Tax Expenses	42	(43)	49	(18)
Net Loss	$ (1,920)	$ (8,233)	$ (9,426)	$ (10,516)
Net loss per share – basic and diluted	$ (0.11)	$ (0.49)	$ (0.54)	$ (0.64)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	17,727,815	16,674,356	17,401,025	16,374,636

CONSOLIDATED BALANCE SHEETS [(2)]
(U.S. dollars in thousands)

	December 31, 2012	June 30, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,433	$ 10,284
Restricted cash	93	37
Accounts receivable:		
Trade	1,273	1,824
Other	212	264
Prepaid expenses	94	93
Inventory:		
On hand	1,977	1,744
On consignment	20	63
Total current assets	9,102	14,309
Property, plant and equipment, net of accumulated depreciation and amortization	479	462
Other non-current assets:		
Funds in respect of employees rights upon retirement	776	961
Deferred debt issuance costs	335	282
Royalties buyout	905	
Total other non-current assets	2,016	1,243
Total assets	$ 11,597	$ 16,014

	December 31, 2012	June 30, 2012
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 501	$ 441
Other	2,426	2,925
Advanced payment from customers	184	174
Deferred revenues	10	10
Convertible loan	6,461	
Total current liabilities	9,582	3,550
Long-term liabilities:		
Liability for employees rights upon retirement	451	354
Convertible loan		5,018
Contingently redeemable warrants	1,410	1,706
Total long-term liabilities	1,861	7,078
Total liabilities	11,443	10,628
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 18,026,680 and 17,040,040 shares issued and outstanding at December 31, 2012 and June 30, 2012.	2	2
Additional paid-in capital	53,349	49,101
Accumulated deficit	(53,147)	(43,722)
Total equity	204	5,386
Total liabilities and equity	$ 11,597	$ 16,014

(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 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.
(2) All December 31, 2012 financial information is derived from the Company's 2012 unaudited financial statements and all June 30, 2012 financial information is derived from the Company's 2012 audited financial statements, as disclosed in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission.

About Stenting and MGuard™ EPS™

Standard stents were not engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The MGuard EPS is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients, the MGuard EPS requires no change in current physician practice - an important factor in promoting acceptance and general use in time-critical emergency settings.

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 quoted on the OTC under the ticker symbol NSPRD.

About MGuard Embolic Protection Coronary Stent

MGuard™ EPS™ 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 is integrated with the stent. The MGuard EPS is designed to provide outstanding and lifelong embolic protection, without affecting deliverability.

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 (SEC), including the Company's Transition Report on From 10-K/T and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://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.

For additional information:

InspireMD Desk
Redington, Inc.
212 926-1733
203 222-7399
inspiremd@redingtoninc.com