INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE
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Telephone	(857) 453-6553
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SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
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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): November 2, 2012

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 November 2, 2012, InspireMD, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 2, 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: November 2, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Earnings release dated November 2, 2012.

InspireMD Reports Results For Period Ending Sept. 30, 2012

TEL AVIV, Israel, NOV. 2 — InspireMD, Inc. ("InspireMD" or the "Company") (OTC: NSPR) announced financial results for the period ended September 30, 2012, the first quarter of its 2013 fiscal year.

As previously indicated, revenue declined from the same period in 2011 due mainly to stocking and selling disruptions caused by a realignment of the Company's distributors in advance of the presentation of the MASTER trial of its MGuard™ Embolic Protective Stent (EPS) at the 24 th Annual Transcathter Therapeutics (TCT) scientific meeting in Miami on October 24.

The positive results, presented at the TCT's Late Breaking Clinical Trials Session by Study Chairman Gregg W. Stone, MD, showed that the novel MGuard EPS provided a statistically and clinically significant acute advantage and, as a result, may hold the potential to lower the incidence of adverse sequela and prolong survival of heart attack victims.

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 plans to initiate a FDA approval study on or before March 31, 2013.

Key financial highlights 1Q ended September 30, 2012 include:

—Revenue for the period ended September 30, 2012 totaled $509,000, compared to $1,986,000 in the same period in 2011, a decrease of $1,477,000, or 74.4 percent, due largely to anticipated disruptions in stocking and sales activities in the periods leading up to the TCT.

—Gross profit for the Sept. 30 2012 period was $279,000, compared to $1,185,000 for the Sept. 30, 2011 period, a decline of 76.5 percent.

—Total operating expenses for the Sept. 30, 2012 period were $3,560,000, compared to $3,335,000 in the Sept. 30, 2011 period. A $274,000 decrease in G&A in the Sept. 30, 2012 period was offset by a $399,000 increase in R&D (mainly to support the MASTER trial), and a slight increase in sales and marketing expense.

—The loss from operations for the Sept. 30, 2012 period was ($3,281,000), compared to ($2,150,000) for the Sept. 30, 2011 period.

—$4,225,000 in financial and tax expenses for the Sept. 30, 2012 period brought the final net loss to ($7,506,000), or ($0.11) per basic and diluted share. Financial and tax expenses for the Sept. 30, 2011 period were $133,000, bringing final net loss for the period to ($2,283,000), or ($0.04) per basic and diluted share.

—At September 30, 2012, cash and cash equivalents stood at approximately $8.3 million, compared to $10.3 million at June 30, 2012.

Subsequent Achievements/Activities
—The MASTER trial of MGuard EPS, presented on Oct. 24 at TCT, 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.

—During the past month, the Company instituted changes which it believes will strengthen relationships with its best distribution partners, and it is in the process of appointing new distributors in certain territories.

—Direct sales channels are being established in key European countries where end user average selling prices and the lack of strong distributors are limiting factors.

—Five experienced sales and marketing executives joined the Company last month to help bolster sales of MGuard EPS following the MASTER trial through third party distribution and direct sales channels.

About Stenting and MGuard EPS
Standard stents weren't 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 NSPR.

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 designedto provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is CE Mark approved. MGuard™ is not approved for sale in the U.S. by the U.S. Food and Drug Administration at this time.

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

	Three months ended September 30 ,	
	2012	**2011**
Revenues	$ 509	$ 1,986
Cost of Revenues	230	801
Gross Profit	279	1,185
Operating Expenses:		
Research and development	946	547
Selling and marketing	402	302
General and administrative	2,212	2,486
Total operating expenses	3,560	3,335
Loss from Operations	-3,281	-2,150
Financial (income),expenses net	4,218	108
Loss before tax expenses	-7,499	-2,258
Tax Expenses	7	25
Net Loss	$ (7,506)	$ (2,283)
Net loss per share – basic and diluted	$ (0.11)	$ (0.04)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	68,296,940	64,300,685

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

ASSETS	**June 30, 2012**	**June 30, 2012**
Current Assets:		
Cash and cash equivalents	$ 8,297	$ 10,284
Restricted cash	37	37
Accounts receivable:		
Trade	1,078	1,824
Other	408	264
Prepaid expenses	56	93
Inventory:		
On hand	2,076	1,744
On consignment	22	63
Total current assets	11,974	14,309
Property, plant and equipment, net of accumulated depreciation and amortization	463	462
Other non-current assets:		
Funds in respect of employees rights upon retirement	304	282
Deferred debt issuance costs	874	961
Total other non-current assets	1,178	1,243
Total assets	$ 13,615	$ 16,014

LIABILITIES AND EQUITY

	September 30, 2012	June 30, 2012
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 556	$ 441
Other	2,628	2,925
Advanced payment from customers	169	174
Deferred revenues	10	10
Total current liabilities	3,363	3,550
Long-term liabilities:		
Liability for employees rights upon retirement	394	354
Convertible loans	5,635	5,018
Contingently redeemable warrants	4,979	1,706
Total long-term liabilities	11,008	7,078
Total liabilities	14,371	10,628
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 68,596,903 and 68,160,161 shares issued and outstanding at September 30, 2012 and June 30, 2012.	7	7
Additional paid-in capital	50,464	49,101
Accumulated deficit	-51,227	-43,722
Total equity (capital deficiency)	-756	5,386
Total liabilities and equity (capital deficiency)	$ 13,615	$ 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 September 30, 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.