

# INSPIREMD, INC.

## FORM 8-K (Current report filing)

Filed 05/11/15 for the Period Ending 05/11/15

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): May 11, 2015

**InspireMD, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-35731  
(Commission File Number)

26-2123838  
(IRS Employer  
Identification No.)

321 Columbus Avenue  
Boston, MA  
(Address of principal executive offices)

02116  
(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(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 11, 2015, InspireMD, Inc. (the “Company”) issued a press release announcing its financial and operating results for the fiscal quarter ended March 31, 2015. 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 11, 2015

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**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.

Date: May 11, 2015

**InspireMD, Inc.**

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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## InspireMD Reports Financial Results for the First Quarter Ended March 31, 2015

**BOSTON, MA** – May 11, 2015 – [InspireMD, Inc.](#) (NYSE MKT: NSPR) (“InspireMD” or the “Company”), a leader in stent embolic protection systems (“EPS”), today announced its financial and operating results for the first quarter ended March 31, 2015.

Alan Milinazzo, CEO of InspireMD, commented, “The first quarter marked the beginning of our full shift in activities towards our new strategy. We began positive early commercialization of the CGuard Rapid Exchange system, while completing our salesforce reorganization to a distributor model. Importantly, we aligned the organization for capital efficiency, regained financial flexibility, made progress with our pipeline, and implemented a plan to regain NYSE MKT listing compliance.”

Mr. Milinazzo concluded, “2015 will be a transition year for InspireMD, but we believe that we have the strategic plan, the sense of urgency, and the resources to deliver on our stated operational and strategic objectives. We are encouraged by the early market reception for our carotid platform, as well as the progress we have made with our neurovascular pipeline development.”

### Recent Operating Highlights:

#### COMMERCIAL

- Early commercial launch of CGuard Rapid Exchange.
- Completed salesforce reorganization from direct to distributor model.

#### REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- Announced regulatory approval to market MGuard Prime in Brazil.
- Received regulatory approval to commercialize MGuard Prime in Columbia.

#### FINANCIAL

- Strengthened cash position with the completion of financing on March 9<sup>th</sup>, 2015 with gross proceeds of \$13.7 million.
- Continued implementation of cost containment activities, including measures to reduce the burn rate throughout 2015.

### Quarter Ended March 31, 2015 Financial Results

Revenue for the quarter ended March 31, 2015 decreased \$1.0 million to \$0.5 million compared to \$1.5 million during the same period in 2014. The 2015 period included an expected decline in sales volume associated with the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients and the impact of the transition to a new commercial strategy built on using third party distributors for our products.

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The Company's gross loss for the quarter ended March 31, 2015 was \$37,000, a decrease of 104.3% compared to a gross profit of \$0.9 million for the same period in 2014. The decrease was largely attributable to the decrease in product revenues and write-offs of inventory due to the trend of increased usage of DES stents in STEMI patients, longer shelf life requirements for third party distributors and the transition to the RX delivery system for CGuard from the over the wire platform.

Total operating expenses for the quarter ended March 31, 2015 were \$4.9 million, a decrease of 24.1% compared to \$6.4 million for the same period in 2014. This decrease was primarily due to a reduction of expenses related to MGuard's MASTER II trial, a decrease in compensation related expenses and other savings associated with our cost reduction plan offset by onetime restructuring and impairment expenses.

The loss from operations for the quarter ended March 31, 2015 was \$4.9 million, a decrease of 11.7% compared to a loss of \$5.5 million for the same period in 2014.

Financial expenses for the quarter ended March 31, 2015 decreased 25.9% to \$0.3 million from \$0.4 million during the same period in 2014. This decrease was primarily due to a decrease in interest expenses.

The net loss for the quarter ended March 31, 2015 totaled \$5.2 million, or \$0.10 per basic and diluted share, compared to a net loss of \$6.0 million, or \$0.18 per basic and diluted share, in the same period in 2014.

Non-GAAP net loss for the quarter ended March 31, 2015 was \$3.8 million, or \$0.08 per basic and diluted share, a decrease of 22.4% compared to a non-GAAP net loss of \$4.9 million, or \$0.15 per basic and diluted share, for the same period in 2014. The non-GAAP net loss for the quarter ended March 31, 2015 primarily excludes \$1.0 million of share-based compensation and \$0.3 million of expense related to the impairment of the value of our royalties buyout option associated with MGuard. The non-GAAP net loss for the quarter ended March 31, 2014 primarily excludes \$1.0 million of share-based compensation.

#### **Cash and Cash Equivalents**

As of March 31, 2015, cash and cash equivalents were \$13.2 million, compared to \$6.3 million as of December 31, 2014.

#### **About InspireMD, Inc.**

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

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## 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, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) 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 (xiii) 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 Annual Report on Form 10-K 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.*

### **Investor Contacts:**

#### **InspireMD, Inc.**

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Chief Financial Officer

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### **PCG Advisory**

Vivian Cervantes  
Investor Relations  
Phone: (212) 554-5482





**CONSOLIDATED STATEMENTS OF OPERATIONS <sup>(1)</sup>**  
**(U.S. dollars in thousands, except per share data)**

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Revenues</b>	\$ 477	\$ 1,482
Cost of revenues	514	625
<b>Gross Profit</b>	<u>(37)</u>	<u>857</u>
Operating Expenses:		
Research and development	1,352	2,577
Selling and marketing	1,017	1,276
General and administrative	1,970	2,539
Restructuring and impairment expenses	514	-
<b>Total Operating Expenses</b>	<u>4,853</u>	<u>6,392</u>
Loss from operations	(4,890)	(5,535)
Financial expenses	306	413
Loss before tax expenses	(5,196)	(5,948)
Tax expenses	16	20
<b>Net Loss</b>	<u>\$ (5,212)</u>	<u>\$ (5,968)</u>
Net loss per share – basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.18)</u>
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	<u>49,915,187</u>	<u>34,051,703</u>



**RECONCILIATION OF NON-GAAP NET LOSS <sup>(2)</sup>**  
(U.S. dollars in thousands, except per share data)

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>GAAP Net Loss</b>	\$ (5,212)	\$ (5,968)
Non-GAAP Adjustments:		
Share-based compensation expenses	1,029	1,019
Impairment of royalties buyout	316	-
Royalties buyout expenses and amortization	36	15
Non-cash financial income <sup>(3)</sup>	-	(6)
<b>Total Non-GAAP Adjustments</b>	<b>1,381</b>	<b>1,028</b>
<b>Non-GAAP Net Loss</b>	<b>\$ (3,831)</b>	<b>\$ (4,940)</b>
Non-GAAP net loss per share – basic and diluted	\$ (0.08)	\$ (0.15)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	49,915,187	34,051,703



**CONSOLIDATED BALANCE SHEETS <sup>(4)</sup>**  
**(U.S. dollars in thousands)**

<b>ASSETS</b>	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Current Assets:		
Cash and cash equivalents	\$ 13,186	\$ 6,300
Accounts receivable:		
Trade	719	635
Other	278	359
Prepaid expenses	109	150
Inventory	1,750	1,924
<b>Total current assets</b>	<b>16,042</b>	<b>9,368</b>
Non-current assets:		
Property, plant and equipment, net	584	622
Deferred issuance costs	136	153
Funds in respect of employee rights upon retirement	504	498
Long term prepaid expenses	58	66
Royalties buyout	400	752
<b>Total non-current assets</b>	<b>1,682</b>	<b>2,091</b>
<b>Total assets</b>	<b>\$ 17,724</b>	<b>\$ 11,459</b>



LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)	<u>March 31, 2015</u>	<u>December 31, 2014</u>
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 665	\$ 909
Other	2,766	3,576
Advanced payment from customers	162	179
Current maturity of loan	<u>3,909</u>	<u>3,809</u>
<b>Total current liabilities</b>	<u>7,502</u>	<u>8,473</u>
Long-term liabilities:		
Liability for employees rights upon retirement	699	687
Long-term loan	<u>4,138</u>	<u>5,086</u>
<b>Total long-term liabilities</b>	<u>4,837</u>	<u>5,773</u>
<b>Total liabilities</b>	<u>12,339</u>	<u>14,246</u>
Equity:		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 75,940,566 and 41,368,889 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	118,001	104,620
Accumulated deficit	<u>(112,623)</u>	<u>(107,411)</u>
<b>Total equity (capital deficiency)</b>	<u>5,385</u>	<u>(2,787)</u>
<b>Total liabilities and equity (less capital deficiency)</b>	<u>\$ 17,724</u>	<u>\$ 11,459</u>



(1) All 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, all 2014 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) Our non-GAAP net loss is presented as management uses this supplemental non-GAAP financial measure to evaluate performance period over period, analyze the underlying trends in our business, and establish operational goals and forecasts that are used in allocating resources. We believe by presenting this additional measurement, we are providing investors with greater transparency to the information used by our management for our financial and operational decision-making, as well as allowing investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

(3) Non-cash financial income relates to the issuance of shares as a result of the anti-dilution rights of our March 2011 investors and the revaluation of warrants.

(4) All March 31, 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2014 financial information is derived from the Company's 2014 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2014 filed with the Securities and Exchange Commission.

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