

# INSPIREMD, INC.

## **FORM 8-K** (Current report filing)

Filed 02/27/14 for the Period Ending 02/26/14

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

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FORM 8-K

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

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Date of Report (Date of earliest event reported): February 26, 2014

**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, Massachusetts  
(Address of principal executive offices)

02116  
(Zip Code)

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

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

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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 26, 2014, InspireMD, Inc. issued a press release announcing its financial results for the fiscal quarter and six month period ended December 31, 2013. 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

<b>Exhibit Number</b>	<b>Description</b>
99.1	Earnings release dated February 26, 2014

**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 27, 2014

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

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**FOR IMMEDIATE RELEASE**

**InspireMD Reports Financial Results for the Quarter and Six Month Period  
Ended December 31, 2013**

**BOSTON, MA** – February 26, 2014 – InspireMD Inc. (NYSE MKT: NSPR) (“InspireMD” or the “Company”), a leader in embolic protection systems, today announced financial and operating results for the quarter and the six month period ended December 31, 2013.

**Recent Highlights**

- MASTER II trial on track to complete enrollment in the fourth quarter 2014; international sites now fully activated
- Successfully implanted new CGuard™ EPS (Embolic Protection System) carotid stent in first patients with positive feedback from physicians
- Secured \$10 million of venture debt in October 2013 in order to advance drug eluting stent (DES) and carotid programs
- Appointed new sales leadership in Europe to focus on increasing global sales effectiveness
  - o 39% revenue growth in Tier 1 countries for three months ended December 31, 2013
  - o Fully implemented HPMS (High Performance Management System)

“We closed 2013 on a very positive note and created momentum across all four phases of our business strategy,” stated Alan Milinazzo, Chief Executive Officer of InspireMD. “Our MASTER II trial is on track to be fully enrolled by the end of 2014. We made significant progress within our product pipeline over the past few months, including implanting the CGuard Carotid embolic protection system in patients for the first time. We are also advancing our DES program after initial positive testing of the MicroNet mesh with a number of CE marked drug eluting stents. Both of these important programs should further enable the fourth element of our strategy which involves partnering to accelerate our business. Finally, revenue growth in our Tier 1 countries continued to improve and we added key sales positions recently to further support our commercial efforts,” Milinazzo concluded.

**Operational Overview**

The Master II clinical trial is on track to complete enrollment in the fourth quarter of 2014. In total, the multi-center, randomized trial is set to include up to 70 sites in the U.S. and Europe and as many as 1,114 patients. The MASTER II trial is evaluating the safety and effectiveness of the MGuard™ Prime EPS in patients suffering from ST Elevation Myocardial Infarction (STEMI). The results are intended to support the Company’s Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) to market the MGuard™ Prime MicroNet™ covered coronary stent system in the U.S.

The Company recently announced that its new CGuard carotid embolic protection system has been successfully implanted in multiple patients. These initial clinical placements are expected to provide physician feedback and information for the Company to better understand the complexities and challenges of treating this patient population and help define further clinical activities for CGuard. The next step for the CGuard will be moving forward with the CARENET (CARotid Embolic protection using microNET) study, which will evaluate the safety and efficacy of the CGuard EPS.

InspireMD has initiated bench testing the viability of combining its proprietary MicroNet technology with several already CE Marked drug eluting coronary stents. These tests will evaluate the safety and efficacy of the stent when it is combined with the Company’s MicroNet technology. This is an important phase in the development of our next generation embolic protection system.

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From a commercial standpoint, the results of the MASTER trial 12-month follow up have been used to advance the Company's evolving sales strategy. Directing these sales efforts is a new leadership team appointed during the quarter to focus on Tier 1 regions as well as support partners distributing the MGuard in other regions. In order to more effectively support sales in Europe, InspireMD entered into an agreement with Healthlink Europe, a medical device support services and distribution company, to provide logistical and customer support for InspireMD's commercial operations and clinical activities.

### **Quarter Ended December 31 2013 Financial Results**

Revenue for the quarter ended December 31, 2013 was \$1.6 million, an increase of 15.1% compared to \$1.4 million for the same period in 2012. This reflects a 39.5% year-over-year increase within Tier 1 regions.

Gross profit for the quarter ended December 31, 2013 totaled \$0.9 million, an increase of 7.3% compared to \$0.8 million for same period in 2012. Gross margin for the three months ended December 31, 2013 was 55.5%, a decrease from 59.5% in the three months ended December 31, 2012. The quarter ended December 31, 2013 included a write off of \$0.1 million of inventory. Excluding this write off, the gross profit would have increased by 20.3% to \$1.0 million and gross margin would have been 62.2% for the period.

Total operating expenses for the quarter ended December 31, 2013 were \$5.8 million, an increase of 12.3% compared to \$5.2 million for the same period in 2012. This was primarily due to increased sales and marketing expenses as the Company focuses on building its sales infrastructure for future growth in Tier 1 countries and research and development expenses attributable to the MASTER II trial.

The loss from operations for the quarter ended December 31, 2013 was \$4.9 million, an increase of 13.2% compared to a loss of \$4.4 million for the same period in 2012.

Total financial expenses for the quarter ended December 31, 2013 were \$0.4 million, compared to financial income of \$2.5 million in the same period in 2012. During the quarter ended December 31, 2012, the Company recognized \$3.5 million of financial income pertaining to the non-cash revaluation of certain warrants and \$0.9 million of amortization expense and related issuance costs pertaining to its previously outstanding senior convertible debentures. The quarter ended December 31, 2013 included a non-cash expense of \$0.1 million associated with certain anti-dilution rights. Excluding these non-cash effects, the financial expenses for the quarter ended December 31, 2013 would have totaled \$0.3 million, as compared to \$0.2 million for the same period in 2012.

The net loss for the quarter ended December 31, 2013 totaled \$5.4 million, or \$0.16 per basic and diluted share, compared to a net loss of \$1.9 million, or \$0.11 per basic and diluted share in the same period in 2012.

Non-GAAP net loss for the quarter ended December 31, 2013 was \$4.5 million, or \$0.13 per basic and diluted share, an increase of 45.7% compared to a non-GAAP net loss of \$3.1 million, or \$0.18 for the same period in 2012. The non-GAAP net loss for the quarter ended December 31, 2013 primarily excludes \$0.7 million of share-based compensation. The non-GAAP net loss for quarter ended December 31, 2012 primarily excludes \$2.6 million in non-recurring, non-cash income associated with the Company's previously retired convertible debt and associated warrants, \$0.9 million of MGuard™ royalties buyout expenses and \$0.5 million in share-based compensation.

### **Six Months Ended December 31 2013 Financial Results**

Revenue for the six month period ended December 31, 2013 was \$3.1 million, an increase of 67.0% compared to \$1.9 million for the same period in 2012. This reflects a 120.6% year-over-year increase within Tier 1 regions.

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Gross profit for the six month period December 31, 2013 totaled \$1.7 million, an increase of 53.7% compared to \$1.1 million for same period in 2012. The increase in gross profit is attributable to an increase in revenue, partially offset by \$0.3 million in inventory write off and non-recurring effects of the consolidation of our manufacturing facilities.

Gross margin for the six month period ended December 31, 2013 was 53.6%, a decrease from 58.2% in the six month period ended December 31, 2012. Excluding the non-recurring effects of the consolidation of our manufacturing facilities and inventory write off in the six month period ended December 31, 2013, gross margin for the six month period ended December 31, 2013 would have been 63.2%.

Total operating expenses for the six month period ended December 31, 2013 were \$10.5 million, an increase of 20.2% compared to \$8.7 million for the same period in 2012. This was primarily due to increased research and development expenses attributable to the MASTER II trial and sales and marketing expenses as the Company focuses on building its sales infrastructure for future growth in Tier 1 countries.

The loss from operations for the six month period ended December 31, 2013 was \$8.8 million, an increase of 15.4% compared to a loss of \$7.6 million for the same period in 2012.

Total financial expenses for the six month period ended December 31, 2013 were \$0.5 million, a decrease of 71.2% compared to \$1.7 million in the same period in 2012. During the six month period ended December 31, 2012, the Company recognized \$0.3 million of financial income pertaining to the non-cash revaluation of certain warrants and \$1.6 million of amortization expense and related issuance costs pertaining to its previously outstanding senior convertible debentures. Excluding these non-cash effects, as well as the non-cash effects of the anti-dilution rights in the 2013 period, financial expenses would have totaled \$0.3 million and \$0.4 million for the six month periods ended December 31, 2013 and December 31, 2012, respectively.

The net loss for the six month period ended December 31, 2013 decreased 1.0% to \$9.3 million, or \$0.27 per basic and diluted share, compared to a net loss of \$9.4 million, or \$0.54 per basic and diluted share in the same period in 2012.

Non-GAAP net loss for the six month period ended December 31, 2013 was \$7.6 million, or \$0.22 per basic and diluted share, compared to a non-GAAP net loss of \$5.7 million or \$0.33 for the same period in 2012. The non-GAAP net loss for the six month period ended December 31, 2013 primarily excludes \$1.5 million of share-based compensation. The non-GAAP net loss for six month period ended December 31, 2012 primarily excludes \$1.4 million in share-based compensation, \$1.3 million in non-recurring, non-cash cost associated with the Company's previously retired convertible debt and associated warrants and \$0.9 million of MGuard™ royalties buyout expenses.

### **Cash and Cash Equivalents**

As of December 31, 2013, cash and cash equivalents were \$17.5 million, compared to \$14.8 million as of June 30 2013. The principal source of this increase was the \$10 million in venture debt secured by the Company on October 24, 2013.

### **Change to Fiscal Year**

As announced on September 17, 2013, the Company changed its fiscal reporting year end from June 30<sup>th</sup> to December 31<sup>st</sup>. The six months ending December 31<sup>st</sup> constitutes the abridged fiscal year from July 1, 2013 to December 31, 2013. Management believes that this change will allow the Company to better align its financial periods and annual budget planning with its business cycle, as well as assist the investment community in following the Company's progress moving forward.

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## **Investor Conference Call**

The Company will host a conference call at 4:30 p.m. ET on Wednesday, February 26th to review the Company's financial results and business outlook. Participants should call (877) 407-0784 (United States) or (201) 689-8560 (International) and request the InspireMD call or provide confirmation code 13576207. A live webcast of the call will also be available on the Investor Relations section of the Company's website at [www.inspire-md.com/site\\_en/for-investors](http://www.inspire-md.com/site_en/for-investors). Please allow 10 minutes prior to the call to visit this site to download and install any necessary audio software.

An archive of the webcast will be available approximately one hour after completion of the live event and will be accessible on the Investor Relations section of the Company's website at [www.inspire-md.com/site\\_en/for-investors](http://www.inspire-md.com/site_en/for-investors) for a limited time. A dial-in replay of the call will also be available to those interested until March 12, 2014. To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code 13576207.

## **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™) and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

## **Use of Non-GAAP Financial Measures**

To supplement the Company's consolidated financial statements presented on a GAAP basis, the Company discloses a non-GAAP measure as non-GAAP net loss because management uses this supplemental non-GAAP financial measure to evaluate performance period over period, to analyze the underlying trends in its business, and to establish operational goals and forecasts that are used in allocating resources. In addition, many investors use this non-GAAP measure to monitor the Company's performance. This non-GAAP measure should not be considered as an alternative to GAAP measures as an indicator of the Company's operating performance.

Non-GAAP net loss is defined by the Company as net loss excluding non-cash financial expenses, share-based compensation expenses and royalties buyout amortization. Non-cash financial expenses are items that are related to the amortization of discount on convertible debt and related issuance costs, the revaluation of warrants and expenses related to the anti-dilution rights of our March 2011 investors.

Generally, a non-GAAP financial measure is a numerical measure of a company's performance, financial position or cash flow that either excludes or includes amounts that are not normally excluded or included in the most directly comparable measure calculated and presented in accordance with GAAP. The non-GAAP measures discussed above, however, should be considered in addition to, and not as a substitute for or superior to operating loss, cash flows, or other measures of financial performance prepared in accordance with GAAP. A reconciliation of non-GAAP to GAAP financial measure is set forth in the table below.

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The Company believes that presenting a non-GAAP net loss, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for financial and operational decision-making and allows investors to see the Company's results "through the eyes" of management. The Company further believes that providing this information assists investors in understanding the Company's operating performance and the methodology used by management to evaluate and measure such performance.

**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 the Company's 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 the Company's products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for the Company's products, (viii) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) the Company's reliance on single suppliers for certain product components, (xi) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing the Company 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 Form 10-KT 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.

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**CONSOLIDATED STATEMENTS OF OPERATIONS <sup>(1)</sup>**

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

	Three months ended December 31,		Six months ended December 31,	
	2013	2012	2013	2012
<b>Revenues</b>	\$ 1,554	\$ 1,350	\$ 3,105	\$ 1,859
Cost of revenues	692	547	1,442	777
<b>Gross Profit</b>	862	803	1,663	1,082
Operating Expenses:				
Royalties buyout expenses		918		918
Other research and development expenses	1,771	1,256	3,315	2,202
Selling and marketing	1,817	1,206	2,647	1,608
General and administrative	2,215	1,789	4,528	4,001
Total operating expenses	5,803	5,169	10,490	8,729
Loss from operations	(4,941)	(4,366)	(8,827)	(7,647)
Financial expenses (income)	442	(2,488)	499	1,730
Loss before tax expenses	(5,383)	(1,878)	(9,326)	(9,377)
Tax expenses	7	42	10	49
<b>Net Loss</b>	\$ (5,390)	\$ (1,920)	\$ (9,336)	\$ (9,426)
Net loss per share – basic and diluted	\$ (0.16)	\$ (0.11)	\$ (0.27)	\$ (0.54)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	33,968,030	17,727,815	33,963,901	17,401,025



**RECONCILIATION OF NON-GAAP NET LOSS <sup>(2)</sup>**

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

	<b>Three months ended December 31,</b>		<b>Six months ended December 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
<b>GAAP Net Loss</b>	\$ (5,390)	\$ (1,920)	\$ (9,336)	\$ (9,426)
<b>Non-GAAP Adjustments:</b>				
Non-cash financial expenses (income) <sup>(3)</sup>	123	(2,645)	200	1,332
Share-based compensation expenses	698	500	1,549	1,431
Royalties buyout expenses and amortization	21	943	32	943
<b>Total Non-GAAP Adjustments</b>	<b>842</b>	<b>(1,202)</b>	<b>1,781</b>	<b>3,706</b>
<b>Non-GAAP Net Loss</b>	<b>\$ (4,548)</b>	<b>\$ (3,122)</b>	<b>\$ (7,555)</b>	<b>\$ (5,720)</b>
Non-GAAP net loss per share – basic and diluted	\$ (0.13)	\$ (0.18)	\$ (0.22)	\$ (0.33)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	33,968,030	17,727,815	33,963,901	17,401,025



**CONSOLIDATED BALANCE SHEETS (4)**  
(U.S. dollars in thousands)

**ASSETS**

	<b>December 31, 2013</b>	<b>June 30, 2013</b>
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 17,535	\$ 14,820
Restricted cash	93	93
<b>Accounts receivable:</b>		
Trade	1,855	1,739
Other	387	388
Prepaid expenses	141	272
<b>Inventory:</b>		
On hand	1,593	1,593
<b>Total current assets</b>	<b>21,604</b>	<b>18,905</b>
Property, plant and equipment, net	652	550
<b>Non-current assets:</b>		
Deferred issuance costs	310	
Funds in respect of employee rights upon retirement	434	406
Long term prepaid expenses	114	
Royalties buyout	852	884
<b>Total non-current assets</b>	<b>1,710</b>	<b>1,290</b>
<b>Total assets</b>	<b>\$ 23,966</b>	<b>\$ 20,745</b>



## LIABILITIES AND EQUITY

	December 31, 2013	June 30, 2013
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 1,623	\$ 831
Other	3,141	3,028
Advanced payment from customers	179	174
Current maturity of loan	1,181	
Deferred revenues		10
<b>Total current liabilities</b>	<b>6,124</b>	<b>4,043</b>
Long-term liabilities:		
Liability for employees rights upon retirement	610	600
Long term loan	8,593	
<b>Total long-term liabilities</b>	<b>9,203</b>	<b>600</b>
<b>Total liabilities</b>	<b>15,327</b>	<b>4,643</b>
Equity:		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 33,983,346 and 33,888,845 shares issued and outstanding at December 31, 2013 and June 30, 2013, respectively	3	3
Additional paid-in capital	90,952	89,079
Accumulated deficit	(82,316)	(72,980)
<b>Total equity</b>	<b>8,639</b>	<b>16,102</b>
<b>Total liabilities and equity</b>	<b>\$ 23,966</b>	<b>\$ 20,745</b>



(1) All financial information for the six months ended December 31, 2013 is derived from the Company's 2013 audited financial statements, as disclosed in the Company's Transition Report on Form 10-KT for the six months ended December 31, 2013, filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2013 is derived from the Company's unaudited, internal financial statements. All 2012 financial information is derived from the Company's 2012 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q for the quarterly period ended December 31, 2012, 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 expenses (income) are items related to the amortization of the discount on the convertible loan and its related issuance costs, the issuance of shares as a result of the anti-dilution rights of our March 2011 investors and the revaluation of warrants.

(4) All December 31, 2013 financial information is derived from the Company's 2013 audited financial statements and all June 30, 2013 financial information is derived from the Company's 2013 audited financial statements, as disclosed in the Company's Transition Report on Form 10-KT for the six months ended December 31, 2013, filed with the Securities and Exchange Commission.

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