

# INSPIREMD, INC.

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

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Industry	Medical Equipment, Supplies & Distribution
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Fiscal Year	12/31



**Item 2.02 Results of Operations and Financial Condition.**

On November 12, 2014, InspireMD, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2014. 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 November 12, 2014





## InspireMD Reports Financial Results for the Third Quarter ended September 30, 2014

*Master II 30 day data to be presented December 15th at the ICI Meeting 2014, Tel-Aviv*

*Announced first pre-clinical implant with partner DES platform*

**BOSTON, MA** – November 12, 2014 – 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 third quarter, ended September 30, 2014.

Alan Milinazzo, CEO of InspireMD, commented, “The third quarter was a commercial turning point for the company. With the European regulatory approvals in hand we have put the Voluntary Field Action (VFA) behind us and started shipping MGuard Prime back into multiple key international markets. Further, the strong CARENET data reported in September provides an excellent platform for our initial CGuard selling activities.”

Mr. Milinazzo concluded, “Subsequent to the end of the third quarter, we successfully completed a capital raise for \$8.1 million in gross proceeds. This cash infusion is expected to be sufficient to support key commercial milestones, including advancing development of the Company’s proprietary DES platform. Our progress in this critical development program is highlighted today with our announcement of the first pre-clinical product implants being successfully completed.”

### Recent Operating Highlights:

#### COMMERCIAL

- Began shipping MGuard Prime product back into hospital accounts; distributor partners began restocking MGuard Prime product with hospital customers post European approval of the manufacturing process changes.
- During the final days of the third quarter and following the quarter’s close, sales of InspireMD’s MGuard Prime EPS resumed in direct markets. Third quarter total revenues increased 41% over the second quarter.
- Initiated a Limited Market Release (LMR) of CGuard, and first sales announced October 1<sup>st</sup>.
  - o Full Market Release (FMR) anticipated in late Q1 2015

#### REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- Received FDA approval for Investigational Device Exemption (IDE) amendment for manufacturing process changes to the MGuard Prime EPS. While MGuard Prime EPS is not approved for sale in the U.S., this approval is an important validation of the process changes and is expected to support sales activities in international markets.
  - Reported positive CARENET first-in-man 30 day results at TCT
    - o Results demonstrated 0% MACE at 30 days and a significant improvement in reducing new ischemic lesions as measured by diffusion weighted magnetic resonance imaging (DW-MRI), as compared to historical controls.
  - Commenced animal studies with initial DES strategic partner in the fourth quarter of 2014
    - o Successful pre-clinical results would lead to submission for CE registration of a DES MicroNet™ platform in the second half of 2015
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- 30 day Master II trial data of 310 patients to be presented on December 15<sup>th</sup> at the Innovations in Cardiovascular Interventions (ICI) Meeting 2014

## FINANCIAL

- Strengthened cash position with completion of financing with gross proceeds of \$8.1 million
- Initiated cost containment efforts, including discontinuation of Master II trial enrollment
  - Strategy intended to direct more resources to the DES program and commercial activities for the MGuard Prime and CGuard.
- Obtained shelf-life extension from two years to three years, which positively impacts inventory management and working capital outlook

### Quarter Ended September 30, 2014 Financial Results

Revenue for the quarter ended September 30, 2014 decreased \$1.3 million to \$0.3 million compared to \$1.6 million during the same period in 2013. The 2014 period included an expected decline in sales volume associated with the temporary stoppage of sales activities for the MGuard™ Prime EPS following our voluntary field action.

The Company reported a gross loss for the quarter ended September 30, 2014 of \$0.1 million, a decrease of 109.5% compared to a gross profit of \$0.8 million for the same period in 2013. The loss was largely attributable to the impact of the VFA on product revenues.

Total operating expenses for the quarter ended September 30, 2014 were \$6.4 million, an increase of 36.7% compared to \$4.7 million for the same period in 2013. This increase was primarily due to higher research and development expenses attributable to expenditures in sales and marketing, as the Company increased its sales efforts in key European countries and clinical trial and development expenses associated with our CGuard™ EPS product.

The loss from operations for the quarter ended September 30, 2014 was \$6.5 million, an increase of 66.8% compared to a loss of \$3.9 million for the same period in 2013.

Financial expenses for the quarter ended September 30, 2014 increased 449.1% to \$0.3 million from \$0.1 million during the same period in 2013. The increase in financial expenses resulted primarily from an increase in amortization and interest expenses relating to our loan.

The net loss for the quarter ended September 30, 2014 totaled \$6.8 million, or \$0.20 per basic and diluted share, compared to a net loss of \$4.0 million, or \$0.12 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the quarter ended September 30, 2014 was \$5.7 million, or \$0.16 per basic and diluted share, an increase of 89.7% compared to a non-GAAP net loss of \$3.0 million, or \$0.09 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the quarter ended September 30, 2014 primarily excludes \$1.1 million of share-based compensation. The non-GAAP net loss for quarter ended September 30, 2013 primarily excludes \$0.9 million in share-based compensation expenses and \$0.1 million in non-cash financial expenses.

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## **Nine Months Ended September 30, 2014 Financial Results**

Revenue for the nine months ended September 30, 2014 decreased \$2.6 million to \$1.9 million compared to \$4.6 million during the same period in 2013. The 2014 period included a decline in sales volume associated with the temporary stoppage of sales activities for the MGuard™ Prime EPS following our VFA.

Gross profit for the nine months ended September 30, 2014 totaled \$0.4 million, a decrease of 83.1%, compared to \$2.3 million for the same period in 2013. This decrease in gross profit was attributable to the impact of the VFA, which included a decrease in revenues as well as \$0.4 million in expenses related to the modification of the MGuard Prime EPS.

Total operating expenses for the nine months ended September 30, 2014 were \$19.6 million, an increase of 44.2%, compared to \$13.6 million for the same period in 2013. This increase was primarily due to higher research and development expenses attributable to the MASTER II trial, clinical trial and development expenses associated with our CGuard™ EPS product and expenditures in sales and marketing, as the Company increased its sales efforts in key European countries.

The loss from operations for the nine months ended September 30, 2014 was \$19.3 million, an increase of 70.2%, compared to a loss of \$11.3 million for the same period in 2013.

Financial expenses for the nine months ended September 30, 2014 decreased 91.6% to \$1.1 million from \$12.5 million during the same period in 2013. The decrease in financial expenses resulted primarily from \$9.9 million of non-cash effects in the nine months ended September 30, 2013 related to the conversion and repayment of our convertible debentures in April 2013, as well as \$1.5 million of non-cash associated with the issuance of certain shares of common stock without consideration in satisfaction of anti-dilution rights during this period. No such expense occurred during the nine months ended September 30, 2014.

The net loss for the nine months ended September 30, 2014 totaled \$20.3 million, or \$0.59 per basic and diluted share, compared to a net loss of \$23.8 million, or \$0.86 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the nine months ended September 30, 2014 was \$17.1 million, or \$0.50 per basic and diluted share, an increase of 107.7% compared to a non-GAAP net loss of \$8.3 million, or \$0.30, for the same period in 2013. The non-GAAP net loss for the nine months ended September 30, 2014 primarily excludes \$3.2 million of share-based compensation. The non-GAAP net loss for the nine months ended September 30, 2013 primarily excludes \$12.2 million in non-cash financial expenses and \$3.3 million in share-based compensation expenses.

## **Cash and Cash Equivalents**

As of September 30, 2014, cash and cash equivalents were \$5.0 million, compared to \$17.5 million as of December 31, 2013.

The Company reported that subsequent to the quarter's close, it successfully completed a gross \$8.1 million financing. InspireMD said it believes that these enhanced cash resources should be sufficient to achieve key commercial milestones, including advancing development of the Company's proprietary DES platform as well as sales ramps of its two commercial products, MGuard™ and CGuard™ EPS.

## **Investor Conference Call**

The Company will host a conference call at 4:30 p.m. ET on Wednesday, November 12<sup>th</sup> to review its 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: 13595115. 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.

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An archive of the webcast will be available approximately two hours 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 November 26, 2014. To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code: 13595115.

### **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.

None of InspireMD's products are approved for sale in the U.S. by the U.S. Food and Drug Administration at this time.

### **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, the Company believes 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.

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.

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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, (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 and (xiv) the escalation of hostilities in Israel, which could impair our ability to manufacture our products. 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 (1)**  
(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
<b>Revenues</b>	\$ 273	\$ 1,552	\$ 1,948	\$ 4,566
Cost of revenues	349	750	1,558	2,256
<b>Gross Profit (Loss)</b>	(76)	802	390	2,310
Operating Expenses:				
Research and development	2,460	1,544	7,485	3,498
Selling and marketing	1,806	830	5,030	2,838
General and administrative	2,139	2,313	7,126	7,285
Total operating expenses	6,405	4,687	19,641	13,621
Loss from operations	(6,481)	(3,885)	(19,251)	(11,311)
Financial expenses	313	57	1,051	12,504
Loss before tax expenses	(6,794)	(3,942)	(20,302)	(23,815)
Tax expenses (Income)	(19)	3	3	(38)
<b>Net Loss</b>	<u>\$ (6,775)</u>	<u>\$ (3,945)</u>	<u>\$ (20,305)</u>	<u>\$ (23,777)</u>
Net loss per share – basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.12)</u>	<u>\$ (0.59)</u>	<u>\$ (0.86)</u>
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	<u>34,581,521</u>	<u>33,959,773</u>	<u>34,251,620</u>	<u>27,787,580</u>



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

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>GAAP Net Loss</b>	\$ (6,775)	\$ (3,945)	\$ (20,305)	\$ (23,777)
<b>Non-GAAP Adjustments:</b>				
Non-cash financial expenses (income) <sup>(3)</sup>		77	(47)	12,232
Share-based compensation expenses	1,052	851	3,151	3,259
Royalties buyout expenses and amortization	20	11	60	32
<b>Total Non-GAAP Adjustments</b>	<b>1,072</b>	<b>939</b>	<b>3,164</b>	<b>15,523</b>
<b>Non-GAAP Net Loss</b>	<b>\$ (5,703)</b>	<b>\$ (3,006)</b>	<b>\$ (17,141)</b>	<b>\$ (8,254)</b>
Non-GAAP net loss per share – basic and diluted	\$ (0.16)	\$ (0.09)	\$ (0.50)	\$ (0.30)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,581,521	33,959,773	34,251,620	27,787,580



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

<b>ASSETS</b>	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Current Assets:		
Cash and cash equivalents	\$ 4,978	\$ 17,535
Restricted cash		93
Accounts receivable:		
Trade	397	1,855
Other	544	387
Prepaid expenses	138	141
Inventory	<u>1,682</u>	<u>1,593</u>
<b>Total current assets</b>	<u>7,739</u>	<u>21,604</u>
Property, plant and equipment, net	636	652
Non-current assets:		
Deferred issuance costs	170	310
Funds in respect of employee rights upon retirement	474	434
Long term prepaid expenses	80	114
Royalties buyout	<u>792</u>	<u>852</u>
<b>Total non-current assets</b>	<u>1,516</u>	<u>1,710</u>
<b>Total assets</b>	<u><u>\$ 9,891</u></u>	<u><u>\$ 23,966</u></u>

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**LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)**

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
<b>Current liabilities:</b>		
Accounts payable and accruals:		
Trade	\$ 1,548	\$ 1,623
Other	4,113	3,141
Advanced payment from customers	180	179
Current maturity of loan	<u>3,710</u>	<u>1,181</u>
<b>Total current liabilities</b>	<u>9,551</u>	<u>6,124</u>
Liability for employees rights upon retirement	719	610
Long term loan	<u>6,002</u>	<u>8,593</u>
<b>Total long-term liabilities</b>	<u>6,721</u>	<u>9,203</u>
<b>Total liabilities</b>	<u>16,272</u>	<u>15,327</u>
<b>Equity:</b>		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 35,107,046 and 33,983,346 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
	4	3
Additional paid-in capital	96,236	90,952
Accumulated deficit	<u>(102,621)</u>	<u>(82,316)</u>
<b>Total equity (capital deficiency)</b>	<u>(6,381)</u>	<u>8,639</u>
<b>Total liabilities and equity (less capital deficiency)</b>	<u>\$ 9,891</u>	<u>\$ 23,966</u>

(1) All 2014 financial information is derived from the Company's 2014 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, all 2013 financial information pertaining to the three months ended September 30, 2013 is derived from the Company's 2013 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, and all 2013 financial information pertaining to the nine months ended September 30, 2013 is derived from the Company's unaudited internal financial statements.



(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 induced conversion of the convertible loan, 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 September 30, 2014 financial information is derived from the Company's 2014 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission and all December 31, 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, filed with the Securities and Exchange Commission, as amended by Amendment No. 1 filed with the Securities and Exchange Commission.

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