

INSPIREMD, INC.

FORM 8-K (Current report filing)

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Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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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): March 12, 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 March 12, 2015, InspireMD, Inc. (the “Company”) issued a press release announcing its financial and operating results for the fourth quarter and year ended December 31, 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

Exhibit Number	Description
99.1	Earnings release dated March 12, 2015

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: March 13, 2015

InspireMD, Inc.

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



**InspireMD Reports Financial Results for the Fourth Quarter and Year Ended
December 31, 2014**

BOSTON, MA – March 12, 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 fourth quarter and year ended December 31, 2014.

Alan Milinazzo, CEO of InspireMD, commented, “The fourth quarter was a commercial turning point for the Company. With highly positive CARENET data in hand, we began our initial CGuard™ selling activities in a limited market release. Early results are very promising as we ramp our launch activities for CGuard RX which recently received CE approval. Further, we restarted selling MGuard™ Prime into most markets, which enables a return to revenue growth for 2015.”

Mr. Milinazzo concluded, “This week, we completed a difficult but necessary capital raise for \$13.7 million in gross proceeds. This cash infusion is expected to be sufficient to support key milestones, including the launch of CGuard RX, and critical pipeline development in our neurovascular and peripheral MicroNet™ programs.” “We believe we have put the challenges of 2014 behind us and have the strategic plan, the sense of urgency, and the resources to deliver a strong 2015.”

Recent Operating Highlights:

COMMERCIAL

- Initiated a Limited Market Release (LMR) of CGuard.
- Resumed shipping of MGuard Prime into hospital accounts. Certain distribution partners also resumed MGuard Prime restocking with hospital customers following European approval of the manufacturing process changes.

REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- Announced CE Mark approval for CGuard RX rapid exchange delivery system, a MicroNet™ covered carotid stent technology.
- Reported Six-Month Ultrasound Analysis from the CARENET study, which confirmed widely patent internal and external carotid arteries.
- Successfully completed pre-clinical PK study with initial DES candidate with promising results.
- Reported positive trends in mortality in the 30 day results on the 310 patients enrolled in MASTER II, as well as pooled data from MASTER II, and the 433 patient MASTER I trial completed and published in 2012.

FINANCIAL

- Strengthened cash position with the completion of financing on November 7th, 2014, with gross proceeds of \$8.1 million and March 9th, 2015 with gross proceeds of \$13.7 million.
- Implemented cost containment activities, including measures to significantly reduce the burn rate throughout 2015.



Quarter Ended December 31, 2014 Financial Results

Revenue for the quarter ended December 31, 2014 decreased \$0.7 million to \$0.9 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 limited resumption of sales activity following the temporary stoppage of sales activities for the MGuard Prime EPS following our voluntary field action (VFA).

The Company's gross profit for the quarter ended December 31, 2014 was \$0.4 million, a decrease of 54.2% compared to a gross profit of \$0.9 million for the same period in 2013. The decrease was largely attributable to the impact of the VFA on product revenues.

Total operating expenses for the quarter ended December 31, 2014 were \$4.8 million, a decrease of 16.6% compared to \$5.8 million for the same period in 2013. This decrease was primarily due to a reduction of clinical and development expenses related to our bare metal stent product, a reduction in sales and marketing expenses related to fewer trade shows and a decrease in general and administrative expenses primarily due to the fact that bonuses in the quarter ended December 31, 2014 were lower than the same period in 2013.

The loss from operations for the quarter ended December 31, 2014 was \$4.4 million, a decrease of 10.0% compared to a loss of \$4.9 million for the same period in 2013.

Financial expenses for the quarter ended December 31, 2014 decreased 24.4% to \$0.3 million from \$0.4 million during the same period in 2013. This decrease was primarily due to a non-cash expense of \$0.1 million associated with certain anti-dilution rights that we incurred in the three months ended December 31, 2013. No such expense was incurred during the same period in 2014.

The net loss for the quarter ended December 31, 2014 totaled \$4.8 million, or \$0.12 per basic and diluted share, compared to a net loss of \$5.4 million, or \$0.16 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the quarter ended December 31, 2014 was \$3.8 million, or \$0.09 per basic and diluted share, a decrease of 17.3% compared to a non-GAAP net loss of \$4.5 million, or \$0.13 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the quarter ended December 31, 2014 primarily excludes \$1.0 million of share-based compensation. The non-GAAP net loss for the quarter ended December 31, 2013 primarily excludes \$0.7 million in share-based compensation expenses and \$0.1 million in non-cash financial expenses.

Twelve Months Ended December 31, 2014 Financial Results

Revenue for the twelve months ended December 31, 2014 decreased \$3.3 million to \$2.8 million compared to \$6.1 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 twelve months ended December 31, 2014 totaled \$0.8 million, a decrease of 75.3%, compared to \$3.2 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 twelve months ended December 31, 2014 were \$24.5 million, an increase of 26.0%, compared to \$19.4 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 markets.



The loss from operations for the twelve months ended December 31, 2014 was \$23.7 million, an increase of 45.8%, compared to a loss of \$16.3 million for the same period in 2013.

Financial expenses for the twelve months ended December 31, 2014 decreased 89.3% to \$1.4 million from \$13.0 million during the same period in 2013. The decrease in financial expenses resulted primarily from \$9.9 million of non-cash effects in the twelve months ended December 31, 2013 related to the conversion and repayment of our convertible debentures in April 2013, as well as \$1.7 million of non-cash expenses 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 twelve months ended December 31, 2014.

The net loss for the twelve months ended December 31, 2014 totaled \$25.1 million, or \$0.71 per basic and diluted share, compared to a net loss of \$29.2 million, or \$0.86 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the twelve months ended December 31, 2014 was \$20.9 million, or \$0.59 per basic and diluted share, an increase of 63.3% compared to a non-GAAP net loss of \$12.8 million, or \$0.38 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the twelve months ended December 31, 2014 primarily excludes \$4.1 million of share-based compensation. The non-GAAP net loss for the twelve months ended December 31, 2013 primarily excludes \$12.4 million in non-cash financial expenses and \$4.0 million in share-based compensation expenses.

Cash and Cash Equivalents

As of December 31, 2014, cash and cash equivalents were \$6.3 million, compared to \$17.5 million as of December 31, 2013.

Subsequent to the quarter's close, the Company successfully completed a gross \$13.7 million financing. The Company believes its cash resources should be sufficient to support key milestones, including the launch of CGuard, progress on strategic partnership discussions, pipeline development in neurovascular and peripheral, and clinical work on an IDE submission for CGuard.

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 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.



CONSOLIDATED STATEMENTS OF OPERATIONS (1)

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

	Three months ended December 31,		Twelve months ended December 31,	
	2014	2013	2014	2013
Revenues	\$ 870	\$ 1,553	\$ 2,818	\$ 6,119
Cost of revenues	476	692	2,034	2,948
Gross Profit (Loss)	394	861	784	3,171
Operating Expenses:				
Research and development	1,259	1,771	8,744	5,269
Selling and marketing	1,583	1,817	6,613	4,655
General and administrative	1,999	2,215	9,125	9,500
Total operating expenses	4,841	5,803	24,482	19,424
Loss from operations	(4,447)	(4,942)	(23,698)	(16,253)
Financial expenses	334	442	1,385	12,946
Loss before tax expenses	(4,781)	(5,384)	(25,083)	(29,199)
Tax expenses (Income)	9	7	12	(31)
Net Loss	\$ (4,790)	\$ (5,391)	\$ (25,095)	\$ (29,168)
Net loss per share – basic and diluted	\$ (0.12)	\$ (0.16)	\$ (0.71)	\$ (0.86)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	40,152,953	33,968,030	35,393,644	33,983,346



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

	Three months ended December 31,		Twelve months ended December 31,	
	2014	2013	2014	2013
GAAP Net Loss	\$ (4,790)	\$ (5,391)	\$ (25,095)	\$ (29,168)
Non-GAAP Adjustments:				
Non-cash financial expenses (income) ⁽³⁾		123	(47)	12,355
Share-based compensation expenses	987	698	4,138	3,957
Royalties buyout expenses and amortization	40	21	100	53
Total Non-GAAP Adjustments	<u>1,027</u>	<u>842</u>	<u>4,191</u>	<u>16,365</u>
Non-GAAP Net Loss	<u>\$ (3,763)</u>	<u>\$ (4,549)</u>	<u>\$ (20,904)</u>	<u>\$ (12,803)</u>
Non-GAAP net loss per share – basic and diluted	\$ (0.09)	\$ (0.13)	\$ (0.59)	\$ (0.38)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	40,152,953	33,968,030	35,393,644	33,983,346



CONSOLIDATED BALANCE SHEETS (4)

(U.S. dollars in thousands)

ASSETS	December 31, 2014	December 31, 2013
Current Assets:		
Cash and cash equivalents	\$ 6,300	\$ 17,535
Restricted cash		93
Accounts receivable:		
Trade	635	1,855
Other	359	387
Prepaid expenses	150	141
Inventory	1,924	1,593
Total current assets	9,368	21,604
Non-current assets:		
Property, plant and equipment, net	622	652
Deferred issuance costs	153	310
Funds in respect of employee rights upon retirement	498	434
Long term prepaid expenses	66	114
Royalties buyout	752	852
Total non-current assets	1,469	1,710
Total assets	\$ 11,459	\$ 23,966



LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)	December 31, 2014	December 31, 2013
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 909	\$ 1,623
Other	3,576	3,141
Advanced payment from customers	179	179
Current maturity of loan	<u>3,809</u>	<u>1,181</u>
Total current liabilities	<u>8,473</u>	<u>6,124</u>
Long-term liabilities:		
Liability for employees rights upon retirement	687	610
Long term loan	<u>5,086</u>	<u>8,593</u>
Total long-term liabilities	<u>5,773</u>	<u>9,203</u>
Total liabilities	<u>14,246</u>	<u>15,327</u>
Equity:		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 41,368,889 and 33,983,346 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively		
	4	3
Additional paid-in capital	104,620	90,952
Accumulated deficit	<u>(107,411)</u>	<u>(82,316)</u>
Total equity (capital deficiency)	<u>(2,787)</u>	<u>8,639</u>
Total liabilities and equity (less capital deficiency)	<u>\$ 11,459</u>	<u>\$ 23,966</u>



(1) All financial information for the twelve months ended December 31, 2014 is derived from the Company's 2014 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2014 as well as all 2013 financial information is derived from the Company's unaudited, internal financial statement.

(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 December 31, 2014 financial information is derived from the Company's 2014 audited financial statements and all December 31, 2013 financial information is derived from the Company's 2013 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.
