INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE
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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): July 23, 2014

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(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 July 23, 2014, InspireMD, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 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

Exhibit Number	Description
99.1	Earnings release dated July 23, 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: July 24, 2014

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

InspireMD Reports Financial Results for the Second Quarter Ended June 30, 2014

BOSTON, MA – July 23, 2014 – InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced its financial and operating results for the second quarter, which ended June 30, 2014.

Recent Operating Highlights

- Received European approval to resume manufacturing and distribution of MGuard™ Prime EPS
  - Manufacturing and sales were temporarily suspended due to Voluntary Field Action (VFA) implemented on April 30, 2014
  - Modified manufacturing process now in place to enhance system performance
- Completed the expansion of its international sales organization and is positioned to ramp up MGuard Prime EPS sales and limited market release (LMR) launch of CGuard in the second half of 2014
- Completed CARENET (CARotid Embolic protection study using microNET) trial for the CGuard ™ EPS
  - 100% procedural success rate
  - Results expected to be announced in mid September 2014 at the TCT Conference
- Appointed Dr. James Barry as Chief Operating Officer
  - More than 18 years' experience in senior roles at Boston Scientific
  - Extensive background in developing drug eluting stents

"The financial performance for the quarter is within our expectations, as sales activities for the MGuard Prime EPS were temporarily halted following our voluntary field action (VFA). We successfully managed the VFA regulatory process in Europe and have now shifted our focus to ramping our commercial activities," said Alan Milinazzo, CEO of InspireMD. "This quarter also marked the successful completion of enrollment in the CARENET trial, which we view as a significant milestone in our plans to develop the CGuard EPS for patients with carotid artery disease. Enrollment had a 100% procedural success rate and we are looking forward to sharing the results of the trial at the TCT conference in September."

"Additionally, we are pleased to welcome Dr. Jim Barry as our new Chief Operating Officer. We are now entering a critical phase in the development of our DES strategies and Jim's expertise will be invaluable to us," Concluded Milinazzo.

Operational Overview

European regulatory approval for a new manufacturing process improving stent retention and performance in the MGuard Prime EPS was granted following the Company's VFA that was implemented on April 30, 2014. The Company is in the process of modifying and redeploying all the MGuard Prime EPS stents that were returned by clinical and commercial sites. The Company expects sales of the MGuard Prime EPS to ramp over the next several months. Due to the VFA, the Company did not fill any new customer sales orders during the past two months. The MGuard Prime EPS is currently InspireMD's primary commercial product and, as a result, the Company recorded sales of $0.2 million for the second quarter ended June 30, 2014.

The planned expansion of the Company's international sales organization has been completed with the additional hiring of several direct salespeople in Tier 1 countries in Europe and Latin America. The team currently includes 20 people positioned to advance sales of the Company's coronary and carotid devices.

The Company successfully completed enrollment in the CARENET (CARotid Embolic protection using microNET) study. CARENET is a multi-specialty trial to evaluate the safety and efficacy of the CGuard EPS for use in carotid artery disease. The acute procedural performance of the CGuard device was 100% successful for all of the 30 patients enrolled in the trial. Follow up will be done using traditional assessments post procedure and at 30 days to include MACE (death, stroke, MI) and ipsilateral stroke. The Company is in the process of evaluating the results and anticipates sharing these data in September at the upcoming TCT Conference in Washington DC.

The Company continues to conduct studies to ascertain the safety and efficacy of combining its proprietary MicroNet™ technology with existing drug eluting stent technologies. Pre-clinical tests are being done with several already CE Marked or FDA approved drug eluting coronary stents and the Company continues to negotiate with manufacturers and evaluate opportunities in this space. InspireMD remains committed to this phase of the development of the next generation embolic protection system.

Enrollment in the MASTER II trial remains temporarily suspended, pending review by the FDA of the manufacturing improvements to the MGuard Prime EPS. However, the Company continues to move forward with site activation and audit activities so that the Company will be able to accelerate enrollment once the study is resumed, which is expected to be in the third or fourth quarter of 2014. The MASTER II trial will evaluate the safety and effectiveness of the MGuard™ Prime EPS in patients suffering from ST Elevation Myocardial Infarction (STEMI). The results are also 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.

Quarter Ended June 30, 2014 Financial Results

On April 30, 2014 sales were temporarily suspended due to the VFA. As such, revenue for the quarter ended June 30, 2014 was $0.2 million compared to $1.5 million during the same period in 2013.

Gross profit (loss) for the quarter ended June 30, 2014 totaled $(0.4) million, a decrease of 158.5% compared to $0.7 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 quarter ended June 30, 2014 were $6.8 million, an increase of 40.2% compared to $4.9 million for the same period in 2013. This increase was primarily due to higher research and development expenses attributable to the MASTER II trial, the CARENET trial, efforts to improve stent retention and expenditures in sales and marketing as the Company increased its efforts to support the new sales strategies in key European and Latin American countries.

The loss from operations for the quarter ended June 30, 2014 was $7.2 million, an increase of 71.6% compared to a loss of $4.2 million for the same period in 2013.

Financial expenses for the quarter ended June 30, 2014 decreased 97.0% to $0.3 million from $10.8 million during the same period in 2013. The decrease in financial expenses resulted primarily from $9.9 million of non-cash effects in the quarter ended June 30, 2013 related to the adjustment of the conversion ratio of our convertible debentures prior to their retirement in April 2013. No such expense occurred during the same period in 2014.

The net loss for the quarter ended June 30, 2014 totaled $7.6 million, or $0.22 per basic and diluted share, compared to a net loss of $14.9 million, or $0.48 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the quarter ended June 30, 2014 was $6.5 million, or $0.19 per basic and diluted share, an increase of 107.8%, compared to a non-GAAP net loss of $3.1 million, or $0.10 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the quarter ended June 30, 2014 primarily excludes $1.1 million of share-based compensation. The non-GAAP net loss for quarter ended June 30, 2013 primarily excludes $10.7 million in non-cash financial expenses and $1.1 million in share-based compensation expenses.

Six Months Ended June 30, 2014 Financial Results

Revenue for the six months ended June 30, 2014 decreased $1.3 million to $1.7 million compared to $3.0 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 VFA.

Gross profit for the six months ended June 30, 2014 totaled $0.5 million, a decrease of 69.1% compared to $1.5 million for the same period in 2013. This decrease in gross profit was attributable to a decrease in revenues as well as the impact of expenses related to the VFA.

Total operating expenses for the six months ended June 30, 2014 were $13.2 million, an increase of 48.2% compared to $8.9 million for the same period in 2013. This was primarily due to increased research and development expenses attributable to the MASTER II trial, the CARENET trial, efforts to improve stent retention and expenditures in sales and marketing as the Company increased its efforts to support the new sales strategies in key European and Latin American countries.

The loss from operations for the six months ended June 30, 2014 was $12.8 million, an increase of 72.0% compared to a loss of $7.4 million for the same period in 2013.

Financial expenses for the six months ended June 30, 2014, decreased 94.1% to $0.7 million from $12.4 million during the same period in 2013. The decrease in financial expenses resulted primarily from $9.9 million of non-cash effects in the six months ended June 30, 2013 related to the adjustment of the conversion ratio of our convertible debentures prior to their retirement in April 2013, as well as $1.5 million of non-cash expense in the six months ended June 30, 2013 related to our issuance of common stock without new consideration to certain investors resulting from anti-dilution rights. No such expense occurred during the six months ended June 30, 2014.

The net loss for the six months ended June 30, 2014 totaled $13.5 million, or $0.40 per basic and diluted share, compared to a net loss of $19.8 million, or $0.80 per basic and diluted share, in the same period in 2013.

Non-GAAP net loss for the six months ended June 30, 2014 was $11.4 million, or $0.34 per basic and diluted share, an increase of 118.0% compared to a non-GAAP net loss of $5.2 million, or $0.21 per basic and diluted share, for the same period in 2013. The non-GAAP net loss for the six months ended June 30, 2014 primarily excludes $2.1 million of share-based compensation. The non-GAAP net loss for the six months ended June 30, 2013 primarily excludes $12.2 million in non-cash financial expenses and $2.4 million in share-based compensation expenses.

Cash and Cash Equivalents

As of June 30, 2014, cash and cash equivalents were $9.0 million, compared to $17.5 million as of December 31, 2013.

Investor Conference Call

The Company will host a conference call at 4:30 p.m. ET on Wednesday, July 23 rd 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: 13586684. 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 . 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 for a limited time. A dial-in replay of the call will also be available to those interested until August 6 th . To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code: 13586684.

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, 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.

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.

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

	Three months ended June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenues	$ 193	$ 1,500	$ 1,675	$ 3,014
Cost of revenues	584	832	1,209	1,506
Gross Profit (Loss)	(391)	668	466	1,508
Operating Expenses:				
Research and development	2,448	1,047	5,025	1,954
Selling and marketing	1,948	1,204	3,224	2,008
General and administrative	2,448	2,632	4,987	4,972
Total operating expenses	6,844	4,883	13,236	8,934
Loss from operations	(7,235)	(4,215)	(12,770)	(7,426)
Financial expenses	325	10,755	738	12,447
Loss before tax expenses	(7,560)	(14,970)	(13,508)	(19,873)
Tax expenses (Income)	2	(23)	22	(41)
Net Loss	$ (7,562)	$ (14,947)	$ (13,530)	$ (19,832)
Net loss per share – basic and diluted	$ (0.22)	$ (0.48)	$ (0.40)	$ (0.80)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,115,814	31,033,657	34,083,936	24,650,333

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

	Three months ended June 30,		Six months ended June 30,	
	2014	**2013**	**2014**	**2013**
GAAP Net Loss	$ (7,562)	$ (14,947)	$ (13,530)	$ (19,832)
Non-GAAP Adjustments:				
Non-cash financial expenses (income) [3]	(41)	10,698	(47)	12,156
Share-based compensation expenses	1,080	1,109	2,099	2,408
Royalties buyout expenses and amortization	25	13	40	21
Total Non-GAAP Adjustments	1,064	11,820	2,092	14,585
Non-GAAP Net Loss	$ (6,498)	$ (3,127)	$ (11,438)	$ (5,247)
Non-GAAP net loss per share – basic and diluted	$ (0.19)	$ (0.10)	$ (0.34)	$ (0.21)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,115,814	31,033,657	34,083,936	24,650,333

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

ASSETS	June 30, 2014	December 31, 2013
Current Assets:		
Cash and cash equivalents	$ 8,988	$ 17,535
Restricted cash		93
Accounts receivable:		
Trade	493	1,855
Other	420	387
Prepaid expenses	215	141
Inventory	1,514	1,593
Total current assets	11,630	21,604
Property, plant and equipment, net	663	652
Non-current assets:		
Deferred issuance costs	276	310
Funds in respect of employee rights upon retirement	493	434
Long term prepaid expenses	84	114
Royalties buyout	812	852
Total non-current assets	1,665	1,710
Total assets	$ 13,958	$ 23,966

LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)	June 30, 2014	December 31, 2013
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,529	$ 1,623
Other	4,344	3,141
Advanced payment from customers	214	179
Current maturity of loan	3,037	1,181
Total current liabilities	9,124	6,124
Long-term liabilities:		
Liability for employees rights upon retirement	745	610
Long term loan	6,886	8,593
Total long-term liabilities	7,631	9,203
Total liabilities	16,755	15,327
Equity:		
Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 34,159,043 and 33,983,346 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	3	3
Additional paid-in capital	93,046	90,952
Accumulated deficit	(95,846)	(82,316)
Total equity (capital deficiency)	(2,797)	8,639
Total liabilities and equity (less capital deficiency)	$ 13,958	$ 23,966

(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, and all 2013 financial information 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 June 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.