INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE
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Telephone	(857) 453-6553
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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): February 5, 2014

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other urisdiction 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 8.01 Other Events.

On February 5, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the Company implanted its new CGuard carotid embolic protection system in recent procedures, including a patient treated during the 17 th Annual Symposium on Interventional Cardiology & Angiology held in Hamburg, Germany on February 1, 2014.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated February 5, 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 5, 2014

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated February 5, 2014

InspireMD Reports Successful Implantation of the New CGuard ™ Carotid Embolic System with MicroNet ™ Technology

Acclaimed Embolic Protection System Expands to Treat Carotid Artery Disease

BOSTON, MA – February 5, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection systems, today announced that its new CGuard ™ carotid embolic protection system has been successfully implanted in recent procedures, including a patient treated during the 17 th Annual Symposium on Interventional Cardiology & Angiology held in Hamburg, Germany on February 1, 2014.

The proprietary CGuard carotid embolic protection system uses the same MicroNet ™ technology featured on its MGuard ™ and MGuard Prime ™ coronary systems. The MicroNet technology is a single fiber knitted mesh wrapped on an open cell stent design in order to trap the debris that can travel downstream after a patient is treated with traditional stenting methods. This protects patients from plaque debris and blood clots breaking off and traveling distally in the arteries which can lead to life threatening strokes. The size, or aperture, of the MicroNet 'pore' is only 150-180 microns in order to maximize protection against plaque and thrombus.

"For the past several years, improvements in technology for treating carotid artery disease have been extremely limited," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "Due to large cell openings, traditional carotid artery stents have certain limitations and challenges when used for this indication. Our multi-year experience with our MicroNet technology in the coronary space has been critical in the development of our new CGuard carotid embolic protection technology. We will continue to develop and refine this system, in order to better understand the life-saving implications it can have for those suffering from cardiac and carotid issues. Our goal is to offer patients clear benefits with this technology and we are pleased with our initial experiences with CGuard."

The CGuard is CE-Marked and is currently being evaluated clinically in Europe. The initial clinical placements are expected to provide physician feedback and information for the Company to better understand the complexities and challenges of this disease state within the patient population and help define further clinical activities for CGuard.

"As a clinician who has successfully implanted the CGuard carotid embolic protection in multiple patients, I have experienced first-hand the life-saving applications it can have," stated Professor Joachim Schofer, MD, from the Hamburg University Cardiovascular Center, in Hamburg, Germany. "The small pore size of the MicroNet technology allows excellent blood flow while trapping potentially harmful plaque debris and thrombus. The CGuard technology provides an elegantly simple solution for embolic protection for my carotid patients."

For more information about InspireMD and its offerings, visit www.inspire-md.com.

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.

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) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) 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 (xii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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