INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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 19, 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 8.01 Other Events.

On March 19, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the Company has enrolled the first patient into its Cartoid Embolic protection study using microNET, which is a multi-center European clinical trial for the Company's new CGuard carotid embolic protection system.

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 March 19, 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: March 21, 2014

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated March 19, 2014

InspireMD Announces First Patient Enrolled Into New CGuard ™ CARENET (CAR otid E mbolic protection study using micro NET) Clinical Trial

Proven Embolic Protection System Expands to Treat Carotid Artery Disease

BOSTON, MA – March 19, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection systems, today announced that it has successfully enrolled the first patient into the CARENET (**CAR** otid **E** mbolic protection study using micro **NET**) multi-center European clinical trial for the new CGuard ™ carotid embolic protection system.

The CARENET clinical study is a multi-specialty trial that is designed to provide data and evidence of the CGuard carotid embolic protection system to better understand the complexities and challenges of patients that experience carotid artery disease. The objective of the CARENET study is to evaluate the safety and efficacy of the CGuard system in the treatment of carotid lesions in consecutive patients suitable for carotid artery stenting (CAS).

The proprietary CGuard carotid embolic protection system uses the same MicroNet™ technology featured on the MGuard™ and MGuard Prime™ coronary embolic protection systems. The MicroNet technology is a single fiber knitted mesh wrapped on an open cell stent platform designed to trap debris that can travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect 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 the potentially dangerous plaque and thrombus which is liberated during the procedure.

"Initiating the CARENET trial ahead of schedule is important for the Company and is indicative of the tremendous clinical interest about the potential benefits of the MicroNet technology in this complex setting," stated Alan Milinazzo, Chief Executive Officer of InspireMD. "The excitement from physicians around the CGuard design and its potential clinical benefit is viewed as a potential breakthrough for carotid stenting therapy. The CARENET study is the first step towards that clinical validation."

"I have treated many patients with carotid artery disease over the years, and I am excited to participate in the CARENET clinical trial using the unique CGuard embolic protection system," 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 that has not been available in the past. I look forward to using this device with other sites throughout Europe in the CARENET trial to help treat my patients with carotid disease."

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 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.

Investor Contacts:
Todd Fromer / Garth Russell
KCSA Strategic Communications
Phone: 212-896-1215 / 212-896-1250
Email: tfromer@kcsa.com / grussell@kcsa.com

Media Contacts:
Samantha Wolf / Taylor McGrann
KCSA Strategic Communications
212-896-1220 / 212-896-1253
swolf@kcsa.com / tmcgrann@kcsa.com