INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Telephone	(857) 453-6553
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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): January 13, 2015

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 January 13, 2015, InspireMD, Inc. issued a press release announcing the six month follow-up data from its CGuard ™ CARENET (**CAR** otid **E** mbolic protection Study using micro **NET**) trial and that the results will be presented at the upcoming LINC (**L** eipzig **I** nterve **N** tional **C** ourse) meeting in Leipzig, Germany on January 27, 2015.

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 January 13, 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.

INSPIREMD, INC.

Date: January 13, 2015

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

Exhibit 99.1

InspireMD to Announce Positive Six Month Results from the CGuard ™ CARENET Trial at LINC 2015

CGuard ™ All Comer Data Continues to Show Excellent Clinical Benefits of the MicroNet ™ Covered Technology

Six-Month Ultrasound Analysis is Indicative of Patent Carotid Arteries Without Restenosis Concern When Compared to Conventional Carotid Stents

BOSTON, MA – January 13, 2015 — InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced that six month follow-up data from its CGuard ™ CARENET (**CAR** otid **E** mbolic protection Study using micro **NET**) trial continued to show promising clinical benefits, including exceptional safety and efficacy, and most importantly resolution of ischemic lesions and a reduced incidence of restenosis.

More detailed data will be presented at the upcoming LINC (**L** eipzig **I** nterve **N** tional **C** ourse) meeting in Leipzig, Germany on Tuesday, January 27 at 10:58am.

The reduction in both the incidence and volume of new ischemic lesions, as well as this six-month data showing minimal restenosis concern, indicates that the therapeutic benefits of the CGuard ™ MicroNet technology may extend well beyond the acute procedural period. The CARENET trial recruited a total of 30 patients and showed very promising safety and efficacy with 0% MACCE (meaning no death, stroke or myocardial infarction) at 30 days, substantially lower than in other non-mesh covered carotid stenting trials. Additionally, the incidence of new ischemic ipsilateral lesions as assessed by Diffusion Weighted Magnetic Resonance Imaging (DW-MRI) after carotid artery stenting (CAS) was reduced by almost 50% when compared to published historical control groups of non-mesh covered carotid stents. All but one of the new ischemic lesions at 48 hour follow up were completely resolved at 30 days. The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than historical control groups. The ultrasound analysis performed at six months has shown healthy healing of the carotid artery without restenosis concern when compared to other CAS.

Alan Milinazzo, CEO of InspireMD, commented, "We continue to be impressed with the clinical data from our CGuard ™ CARENET study. After we first presented our 30-day follow-up data at TCT 2014 in September of last year, we gained additional market feedback through a limited market release of the technology. Now, the six-month follow-up data, to be presented at LINC in a few weeks, will show that the CGuard ™ has minimal restenosis concern when compared to other carotid stents. In addition, Mr. Milinazzo added, "this data, combined with the earlier DW-MRI data showing a vast reduction in the incidence, and volume, of new ipsilateral lesions continues to validate the short and long term benefits of this MicroNet covered technology when treating patients with carotid artery disease."

The CGuard ™ CARENET data will be presented during the main carotid session at LINC titled, " *Deep Dive Session: Carotid Revascularization* " chaired by Dr. Frank Veith and Dr. William Gray on Tuesday, January 27 from 9:00am – 12:30pm. Prof Piotr Musiałek, Co-Principal Investigator for the CARENET study, from Jagiellonian University Medical College at John Paul II Hospital, in Krakow, Poland will present this CARENET late breaking clinical data in his talk titled, " *The CARENET All-Comer Trial Using the CGuard ™ MicroNet ™ Covered Embolic Prevention Stent* ." In addition to presenting all-comer data from the CARENET trial he will also present the 6 month follow up data from the study that was originally presented at TCT 2014.

The Leipzig Interventional Course (LINC) is one of the world's fastest growing courses committed to advancing the scientific and clinical evaluation and treatment of patients with complex vascular disease through the interdisciplinary discussion of novel endovascular techniques and systemic scientific evaluation. More than 4,000 participants from over 70 countries are expected to attend with a faculty of over 200 leading physicians and interventionalists from around the world.

About CGuard EPS
The proprietary CGuard EPS 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 dislodge and 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 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 within the carotid artery.

CGuard EPS is CE Mark approved. CGuard EPS, however, is not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

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) 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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