INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE BOSTON, MA 02116
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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): October 1, 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 October 1, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that it had recorded the first commercial sales of the Company's CGuard carotid embolic protection systems. 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 October 1, 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: October 1, 2014

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

Exhibit 99.1

InspireMD Announces Initial Commercial Sales of the CGuard ™ EPS

Commercial activities ahead of schedule following release of strong clinical data in the multi-specialty CARENET trial

BOSTON, MA – October 1, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection systems (EPS), today announced that it has recorded the first commercial sales of the CGuard™ carotid EPS. The Company accelerated the limited market release (LMR) of the CGuard based on strong interest created by the recent positive data reported in the CARENET clinical trial.

"We are excited to begin the commercial phase of our carotid business strategy and have had strong interest in the CGuard since our CARENET data was presented at the TCT conference on September 16 th . The initial commercial phase of our launch will be through our direct sales team in Europe and will focus on high volume, key opinion leaders in the carotid space. Our plan is to generate usage and a broader awareness of the CGuard in key European markets throughout the next two quarters and then convert to a full market release (FMR) in Q2 of 2015." stated Alan Milinazzo, CEO of InspireMD.

InspireMD initiated limited commercial sales of the CGuard EPS through its direct sales organization in select European countries following the announcement of positive results from the CARENET (**CAR** otid **E** mbolic protection study using micro **NET**) Trial. CARENET was a multi-specialty trial that assessed the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The CARENET trial recruited 30 patients and achieved its primary endpoint with 0 percent MACE (meaning no death, stroke or myocardial infarction) at 30 days. Additionally, as compared to published historical control groups of non-mesh covered carotid stents, the incidence of new ischemic lesions as assessed by Diffusion Weighted Magnetic Resonance Imaging (DW-MRI) after carotid artery stenting was reduced by almost 50 percent. The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than these historical control groups. The reduction in both the number of new ischemic lesions and the volume of those lesions indicates therapeutic benefits of the MicroNet technology in this patient cohort after 30 days, as compared to the historical control groups.

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 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.

InspireMD held an informative conference call discussion that focused on the clinical benefits that the MicroNet™ covered CGuard carotid EPS may offer patients undergoing carotid artery stenting compared to existing treatments on the market. A digital replay of the event is available until October 24, 2014 on the Investor Relations section of the Company's website at http://www.inspire-md.com/site_en/for-investors/ .

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

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) 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.

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

Media Contact:
Samantha Wolf
KCSA Strategic Communications
212-896-1220
swolf@kcsa.com