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): July 8, 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 July 8, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the Company concluded enrollment in its CGuard CARENET (carotid embolic protection study using micronet) clinical trial.

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 July 8, 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 8, 2014

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated July 8, 2014

InspireMD Announces Successful Completion of CGuard ™ CARENET (CAR otid E mbolic protection study using micro NET) Trial

100% procedural success rate achieved in first multi-specialty clinical experience

BOSTON, MA – July 8, 2014 — InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced that it has concluded enrollment in its CARENET clinical trial. The multi-specialty (Interventional Cardiologists, Interventional Radiologists and Vascular Surgeons) trial is assessing the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The acute procedural performance of the CGuard device was 100% successful for all of the 30 patients enrolled in the trial.

Thirty patients were enrolled at four sites across Europe and will be followed up using traditional assessments post-procedure and at 30 days to include MACE (death, stroke, MI), and ipsilateral stroke (31 days to 1 year). In addition, DW-MRI (Diffusion Weighted Magnetic Resonance Imaging) is being done pre and post procedure and at 30 days, as well as ultrasound examination at 30 days and 1 year on every patient.

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 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.

"I am excited that enrollment in the CGuard CARENET study has just been completed. I have treated many patients with carotid artery disease over the years and the unique CGuard embolic protection system with MicroNet has changed the way I think about treating these challenging patients," stated Professor Joachim Schofer, MD, from the Hamburg University Cardiovascular Center, in Hamburg, Germany. "The experience that we have gained using the CGuard device has given us a sense of confidence in regards to new technology options when treating these patients. 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 reviewing and analyzing all of the CARENET data over the next several weeks and sharing the results soon afterward."

"The completion of the CGuard CARENET trial on schedule with 100% procedural success rate is an important milestone for InspireMD," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD, "Our investigators have done a wonderful job throughout this trial, and their feedback on the CGuard has been very positive and informative. The initial results support our belief that the MicroNet technology may deliver life-saving benefits to patients with carotid artery disease and revolutionize the way the carotid stenting procedures are performed. We are looking forward to analyzing the data from the CARENET trial and sharing the results in mid-September at the upcoming TCT conference. "

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.

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