

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): August 11, 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 Boston, Massac (Address of principal ex Registrant's	chusetts ecutive offices) telephone number, including area code: (857) 45	
	(Former	name or former address, if changed since last rep	oort)
ny	Check the appropriate box below if the Forn of the following provisions:	8-K filing is intended to simultaneously satisfy	the filing obligation of the registrant under
]	Written communications pursuant to Rule 425	under the Securities Act (17 CFR 230.425)	
]	Soliciting material pursuant to Rule 14a-12 un	der the Exchange Act (17 CFR 240.14a-12)	
	Pre-commencement communications pursuant	to Rule 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
	Pre-commencement communications pursuant	to Rule 13e-4 (c) under the Exchange Act (17 C	FR 240.13e-4(c))

Item 8.01 Other Events.

On August 11, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that Professor Joachim Schofer, M.D., will present the results of the Company's CGuard CARENET (carotid embolic protection using micronet) trial at the Transcatheter Cardiovascular Therapeutics conference in Washington, D.C., on September 16, 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 August 11, 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: August 11, 2014 By:/s/ Craig Shore

Name: Craig Shore Title: Chief Financial Officer



InspireMD to Announce Results of CGuard TM CARENET Trial at the TCT Innovation Session on Late Breaking Early Human Clinical Studies

Results will be announced on Tuesday, September 16 in Washington, D.C.

BOSTON, MA – **August 11, 2014** — <u>InspireMD, Inc.</u> (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced that Professor Joachim Schofer, MD, at the Hamburg University Cardiovascular Center, will present the results of the CARENET (<u>CAR</u> otid <u>E</u> mbolic protection using micro <u>NET</u>) trial at the <u>Transcatheter Cardiovascular Therapeutics</u> (TCT) conference, in Washington, D.C. on Tuesday September 16, 2014.

The detailed findings from the CARENET trial, which completed enrollment last month, will be presented at the TCT 2014 Innovation Session: Late Breaking Early Human Clinical Studies at 4:20 pm ET under the title "Evaluation of a PET Mesh Covered Stent in Patients with Carotid Artery Disease: Results of the First in Man CARENET Trial."

CARENET is a multi-specialty trial – including Interventional Cardiologists, Interventional Radiologists and Vascular Surgeons – assessing the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The trial evaluates data from traditional assessments carried out post-procedure and at 30 days to include MACE (death, stroke, myocardial infarction), and ipsilateral stroke (31 days to one year). In addition, DW-MRI (Diffusion Weighted Magnetic Resonance Imaging) will be evaluated pre- and post-procedure and at 30 days, as well as ultrasound examination at 30 days and one year on every patient.

"The Innovation Session with late breaking trials updates at TCT showcases cutting-edge clinical studies from around the world," said Alan Milinazzo, CEO of InspireMD. "We are proud that the CARENET trial has been included in this exclusive session at TCT alongside other exciting new technologies. We look forward to sharing the results from the trial with medical professionals and those at the forefront of advances in interventional cardiovascular medicine globally."

The proprietary CGuard carotid embolic protection system uses the same MicroNetTM technology featured on the MGuardTM and MGuard PrimeTM 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.

About TCT

Transcatheter Cardiovascular Therapeutics (TCT) is the world's largest educational meeting specializing in interventional cardiovascular medicine. For over 25 years, TCT has been the center of cutting-edge educational content. TCT showcases the latest advances in current therapies and clinical research.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuardTM with MicroNet TM 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 TM) 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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