INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE
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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): November 20 , 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 November 20, 2015, InspireMD, Inc. issued a press release announcing that positive twelve month follow-up data from its CGuard ™ CARENET (**CAR** otid **E** mbolic protection Study using micro **NET**) trial were presented at the 42 nd Annual Symposium on Vascular and Endovascular Issues (VEITH) in New York on November 20, 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 November 20, 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: November 20, 2015

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

Exhibit 99.1

InspireMD Announces Positive Twelve Month Follow-Up CARENET Trial Data at VEITH Symposium 2015

BOSTON, MA – November 20, 2015 - InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS), neurovascular devices and thrombus management technologies, announced today positive 12 month follow up data from its CGuard ™ **CARENET** (**CAR** otid **E** mbolic protection Study using micro **NET**) trial at the 42 nd Annual Symposium on Vascular and Endovascular Issues (VEITH) in New York. Prof. Piotr Musiałek, Co-Principal Investigator for the CARENET study, from Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland, presented the 12 month follow up data, an industry first on a mesh covered carotid stent technology.

At the New Techniques, Technologies and Concepts session, Prof. Musialek presented the new data on the InspireMD CGuard ™ Mesh Covered Carotid Stent Program. His lecture, entitled "MicroNet Covered Embolic Prevention Carotid Stent System: From CARENET And PARADIGM Studies To Routine Clinical Practice," focused on the CARENET 12 month results, which demonstrated zero strokes or stroke-related deaths at 12 months. Further, duplex ultrasound analysis confirmed no changes in the in-stent velocities between 6 and 12 months. This indicates no sign of vessel narrowing and is consistent with the durability of carotid artery treatment seen using CGuard ™. According to Prof. Musialek, previously demonstrated reduction in both the incidence and the volume of new ischemic lesions, together with the 12 month data that show minimal restenosis concern, suggests that the therapeutic benefits of the CGuard ™ technology may extend well beyond the acute procedural period.

Prof. Piotr Musialek commented, "It is very exciting to present the 12 month follow up data from the CGuard ™ CARENET study, which continues to validate the use of the MicroNet ™ covered CGuard ™ , with zero strokes at 12 months. In addition, the 12 month data showed no change in peak systolic velocity between 6 months and 12 months, suggesting no restenosis concerns. These findings, combined with the results from our recent all-comer single center PARADIGM trial, continue to show the increased therapeutic benefits of the CGuard ™ technology in treating patients with carotid artery disease. This technology is a game-changer in today's practice of carotid revascularization and my colleagues and I look forward to continued use of this unique technology in routine clinical practice."

Alan Milinazzo, CEO of InspireMD commented, "Twelve month CARENET results further validate that the CGuard ™ represents a superior next generation stenting technology, supporting broader application in carotid artery disease treatment, with physicians steadily impressed with its superior clinical data. We plan to leverage compelling CARENET and PARADIGM clinical evidence to expand upon our ongoing, active CGuard ™ commercial activities."

PARADIGM , led by principal investigator Prof. Musialek, is an investigator-initiated **P** rospective evaluation of **A** ll-comer pe **R** cutaneous c **A** roti **D** revascularization **I** n symptomatic and increased-risk asymptomatic carotid artery stenosis, using CGuard™ **M** esh-covered embolic prevention stent system, indicated that the CGuard™ system is appropriate for use in an all-comer carotid revascularization population and is associated with an extremely favorable angiographic and clinical outcome.

VEITH Symposium 2015 provides vascular surgeons, interventional radiologists, interventional cardiologists and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease. The event features presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques.

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 ™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

About CGuard™ EPS

The proprietary CGuard™ Embolic Prevention System (EPS) uses the same MicroNet™ technology featured on the MGuard™ and MGuard Prime™ coronary Embolic Protection Systems. The CGuard™ EPS is designed to prevent peri-procedural and late embolization by trapping potential emboli against the arterial wall while maintaining excellent perfusion to the external carotid artery and branch vessels.

MicroNet™ is a bio-stable mesh woven from a single strand of 20 micron Polyethylene Terephthalate.

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

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 Annual Report on Form 10-K 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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