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): May 17, 2016

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, MA	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 305-2410

(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 May 17, 2016, InspireMD, Inc. (the "Company") issued a press release announcing that CGuard EPS reported positive results in PARADIGM-101, an investigator led clinical evaluation of the system or routine use in 101 consecutive, increased risk patients undergoing carotid artery stenting. The results of the study were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, France. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated May 17, 2016

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: May 17, 2016

By: /s/ Craig Shore

Name: Craig Shore
Title: Chief Financial Officer

Exhibit 99.1

InspireMD's CGuard ™ Highlighted at the Late-Breaking Clinical Trial Session at the EuroPCR 2016 Conference

BOSTON, MA – May 17, 2016 – InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS), neurovascular devices and thrombus management technologies, today announced that CGuard ™ EPS reported positive results in PARADIGM-101, an investigator led clinical evaluation of the system for routine use in 101 consecutive, increased risk patients undergoing carotid artery stenting. Principle investigator Prof. Piotr Musialek presented the results of the study at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, France.

PARADIGM-101 is Prof. Musialek's clinical evaluation of the safety and periprocedural and 30 day clinical efficacy of routine use of the CGuard ™ system in unselected carotid stenosis patients, building upon the earlier PARADIGM study. The trial also assessed the CGuard ™ system's ability to minimize vessel narrowing after carotid stenting.

In the presentation, *Prospective evaluation of all-comer percutaneous carotid revascularisation In symptomatic and increased-risk asymptomatic carotid artery stenosis using the MicroNet-covered embolic prevention stent system in 101 consecutive patients: PARADIGM-101,* Prof. Musialek's key findings included:

- CGuard ™ delivery success was 99.1%. The clinical evaluation also found no device foreshortening or elongation;
- Angiographic diameter stenosis or vessel narrowing was reduced from 83±9% to only 6.7±5% ($p<0.001$);
- Periprocedural complications were 0%;
- One event was adjudicated by the Clinical Events Committee as a minor stroke (0.9%), with no change in NIH Stroke Scale or modified Ranking scale;
- At 30 days, no new events (0%) were noted by independent neurologist evaluation.

Prof. Musialek commented, "PARADIGM-101 supports the use of CGuard ™ in a high risk, all comer population of patients with carotid artery stenosis, building upon the safety of the MicroNet ™ covered CGuard ™ as a novel, therapeutic stent platform. This latest data indicates that routine use of CGuard ™ may prevent cerebral events – such as strokes - by holding plaque against the vessel wall, preventing emboli from being released into the blood stream." Prof. Musialek concluded, "On the basis of PARADIGM findings, CGuard may open a safe door for endovascular management to more than 90% of all-comer patients with carotid stenosis who require interventional treatment."

EuroPCR is a leading course in interventional cardiovascular medicine, with over 12,000 attendees.

For more information about InspireMD and its offerings, visit www.inspiremd.com.

About PARADIGM

PARADIGM 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 C **G** uard™ **M** esh-covered embolic prevention stent system. At EuroPCR 2015, Dr. Musialek summarized the results of his PARADIGM evaluation of 71 CGuard ™ procedures in unselected all-comer patients: 1) stent system success and procedure success rate of 100%; 2) periprocedural complications of 0%, and remained at 0% at 30 days; and 3) no MACNE occurred periprocedurally or at 30 days, by operator-independent neurologist and non-invasive cardiologist evaluation.

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 (PET).

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.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ 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}), neurovascular, 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 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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