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): September 28, 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 September 28, 2015, InspireMD, Inc. (the "Company") issued a press release announcing the full market launch of the CGuard ™ Embolic Prevention System by its strategic distribution partner, Penumbra, Inc. at the CIRSE (**C** ardiovascular and **I** nterventional **R** adiological **S** ociety of **E** urope) Annual Congress in Lisbon, Portugal. A copy of the 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 September 28, 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: September 28, 2015

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

Exhibit 99.1

InspireMD Announces Full Market Launch of CGuard ™ Distributed by Penumbra at CIRSE Annual Congress

BOSTON, MA – September 28, 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 the full market launch of the CGuard ™ Embolic Prevention System for the treatment of carotid artery disease by its strategic distribution partner, Penumbra, Inc. (NYSE: PEN) , at the CIRSE Annual Congress in Lisbon, Portugal. Penumbra, a global interventional therapies company that designs, develops, manufactures and markets innovative medical devices to the neurovascular and peripheral vascular communities, leverages its direct European commercialization team to launch CGuard ™ Distributed by Penumbra. The 2015 Congress marks the 30 th year of CIRSE, **C** ardiovascular and **I** nterventional **R** adiological **S** ociety of **E** urope, which aims to be a leader in interventional radiology (IR) education, drawing over 6,500 attendees from the medical community across 90 countries.

At CIRSE 2015, Penumbra hosted a well-attended physician symposium titled, "CGuard ™ – MicroNet Covered Embolic Prevention Stent System: A Game-Changer in CAS" led by Prof. Piotr Musialek on Sunday, September 27 th . Dr. Musialek is principle investigator in the all comer PARADIGM study that continues to document both the short term and long term benefits of using the MicroNet covered CGuard technology in patients with carotid artery disease. In-booth demonstrations, teaching materials, and clinical case studies were also featured for conference attendees.

Alan Milinazzo, CEO of InspireMD, commented, "We are excited that our partner, Penumbra, has begun its full commercial launch of CGuard at CIRSE, a respected venue for learning about new technologies in the IR, vascular, and neurovascular community. Early feedback from physician attendees has been positive, with follow on meetings scheduled, in addition to discussions on additional possible uses of the MicroNet ™ technology in the neurovascular space." Milinazzo continued, "The Penumbra commercial team is strong and growing, with a well-established footprint across all specialists that manage carotid artery disease. We are confident of successful commercial progress in the coming months and look forward to supporting Penumbra as we introduce this breakthrough technology to our customers."

In addition, Jim Pray, President, International of Penumbra, stated, "The Penumbra team believes that the CGuard technology will give our customers a new, proven alternative to traditional treatment options for patients with carotid artery disease. We have been trained on the CGuard technology and are officially launching it here at the CIRSE meeting this week. We look forward to working with our customers to provide them with this exciting new carotid embolic prevention system."

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 his clinical presentation of 71 CGuard procedures in unselected all-comer patients in the PARADIGM evaluation as: 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 Penumbra, Inc.

Penumbra, Inc. (www.penumbrainc.com) is a global interventional therapies company that designs, develops, manufactures and markets innovative medical devices. The company has a broad portfolio of products that address challenging medical conditions and significant clinical need across two major markets, neuro and peripheral vascular. Penumbra has approximately 1,000 employees and sells its products to hospitals primarily through its direct sales organization in the U.S., most of Europe, Canada and Australia, and through distributors in select international markets.

About InspireMD, Inc.

InspireMD (www.inspiremd.com) 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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