# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 10/05/15 for the Period Ending 10/05/15

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|---|---|
| Address | 321 COLUMBUS AVENUE<br>BOSTON, MA 02116 |
| Telephone | (857) 453-6553 |
| CIK | 0001433607 |
| Symbol | NSPR |
| SIC Code | 3841 - Surgical and Medical Instruments and Apparatus |
| Industry | Medical Equipment & Supplies |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

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# FORM 8-K

## CURRENT REPORT
**Pursuant to Section 13 or 15(d) of the**
**Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): October 5, 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<br>Boston, Massachusetts | 02116 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (857) 453-6553

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(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))

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**Item 8.01 Other Events.**

On October 5, 2015, InspireMD, Inc. (the "Company") issued a press release announcing that it has received regulatory approval to commercialize the CGuard [TM] Embolic Prevention System in Colombia. 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 October 5, 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: October 5, 2015

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

**Exhibit 99.1**

# InspireMD Announces CGuard ™ Approval in Colombia

**BOSTON, MA** – October 5, 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 that it has received regulatory approval to commercialize the CGuard ™ Embolic Prevention System for the treatment of carotid artery disease in Colombia. The approval was granted by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA). The global carotid stent market is expected to grow at a compound average annual rate of 13% in 2014-2019, according to Research and Markets. By region, the Latin American market is expected to expand at a strong rate, driven by endovascular procedure volume growth and the adoption of premium priced products, according to Millennium Research Group.

Alan Milinazzo, CEO of InspireMD commented, "CGuard ™ approval in Colombia is an important milestone for the Company and another critical validation for our technology. We are methodically, and successfully, bringing this important technology to key markets around the world."

As previously noted, six month results from the Company's CGuard ™ clinical trial, CARENET (CARotid Embolic protection using MicroNET) showed a 100% procedural success rate with a 3.6% MACCE (major adverse cardiac and cerebrovascular event) rate vs. comparative data of 8.09%. Six month ultrasound analysis also indicated healthy healing without restenosis concern with patent external and internal carotid arteries. In addition, the investigator-led all comer PARADIGM study continues to document both the short term and long term benefits of using the MicroNet ™ covered CGuard ™ technology in patients with carotid artery disease.

Mr. Milinazzo concluded, "We are well focused on driving our business forward, with other recent announcements that include the full commercial launch of CGuard ™ in Europe with our strategic distribution partner, Penumbra, Inc. (NYSE: PEN), expanding intellectual property coverage, continuing broad collaboration discussions that leverage our MicroNet ™ technology while advancing our development program for our neurovascular platform, and our highly disciplined cash management program."

**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.

**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.

**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.*

**Investor Contacts:**

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