

INSPIREMD, INC.

FORM 8-K (Current report filing)

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Address	321 COLUMBUS AVENUE BOSTON, MA 02116
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): April 27, 2015

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35731</u> (Commission File Number)	<u>26-2123838</u> (IRS Employer Identification No.)
<u>321 Columbus Avenue Boston, Massachusetts</u> (Address of principal executive offices)		<u>02116</u> (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 April 27, 2015, InspireMD, Inc. (the “Company”) issued a press release announcing that it received approval to commercialize the Company’s MGuard™ Prime with MicroNet technology in Brazil. 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 April 27, 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: April 27, 2015

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces MGuard™ Prime Approval in Brazil

BOSTON, MA – April 27, 2015 – InspireMD, Inc. (NYSE MKT: NSPR) (“InspireMD” or the “Company”), a leader in stent embolic protection systems (“EPS”), today announced it received approval to commercialize MGuard™ Prime with MicroNet technology in Brazil. The approval was granted by the Agência Nacional de Vigilância Sanitária (ANVISA). The BRICCS (Brazil, Russia, India, China, South Africa and South Korea) coronary stents sector is estimated to reach \$1billion by 2016, growing at an average compound annual rate of 9.6% in 2012 to 2018, according to Research and Markets.

Alan Milinazzo, CEO of InspireMD, commented, “Brazil is the largest Latin American coronary stent market with a rapidly aging population, growing economy, and improving healthcare system, fueling coronary stenting procedure volumes.” Mr. Milinazzo also added, “Approval of the MGuard Prime is significant as we look to return to revenue growth as Brazil has traditionally been a very strong market for us with support from a number of leading interventional cardiologists around the country.”

Dr. Alex Abizaid, Chief of Coronary Interventions at Institute Dante Pazzanese de Cardiologia in São Paulo, Brazil, commented, “I am gratified that MGuard™ Prime is now approved and available to treat STEMI patients in Brazil. Clinical trials and registry studies have provided a substantial body of evidence supporting the use of MGuard in primary PCI with the objective of improving patient outcomes. With MGuard Prime, the treatment of acute MI has reached a new level involving a simple device that can be used in daily practice in the cardiac cath laboratory.”

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™) 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.

Investor Contacts:

InspireMD, Inc.

Craig Shore

Chief Financial Officer

Phone:  1-888-776-6804 FREE

Email: craigs@inspiremd.com

PCG Advisory

Vivian Cervantes

Investor Relations

Phone: (212) 554-5482
