

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): December 2, 2015

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction
of incorporation)

001-35731
(Commission File Number)

26-2123838
(IRS Employer
Identification No.)

321 Columbus Avenue
Boston, Massachusetts

(Address of principal executive offices)

02116

(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))
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Item 8.01 Other Events.

On December 2, 2015, InspireMD, Inc. issued a press release announcing receipt of a DEKRA medical device certification for the manufacture and commercialization of its CGuard™ delivery catheter. 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 December 2, 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: December 2, 2015

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Receives EU Regulatory Approval for Additional Supplier of CGuard™ Delivery Catheters

BOSTON, MA – December 2, 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 receipt of a DEKRA medical device certification for the manufacture and commercialization of its CGuard™ delivery catheter, which now incorporates some design enhancements and a lower cost manufacturing structure to support the scale-up of operations. The certification also allows the Company to add-on facilities for seamless manufacturing work flow. DEKRA is a notified body for global certification of products, combining CE Marking with ISO 13485 Quality Management Systems in the testing of medical devices for sale in the European Union (EU). The delivery catheter is commercialized in conjunction with the Company’s CGuard Embolic Prevention System (EPS).

Alan Milinazzo, CEO of InspireMD commented, “We are pleased to receive DEKRA certification for our enhanced CGuard™ delivery catheter, used when delivering the CGuard™ EPS into the carotid anatomy, supporting a more profitable and fluid scaling of our manufacturing operations. Our CGuard™ system continues to be well received during our initial product launch in key markets around Europe and our recent positive 12 month CARENET data should bolster our commercial efforts going forward.”

Twelve month CGuard™ CARENET (CARotid Embolic protection Study using micro NET) trial results demonstrated zero strokes or stroke-related deaths. 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™. In addition, the all-comer single center PARADIGM trial continue to show favorable angiographic and clinical outcomes in using the CGuard™ system in treating patients with carotid artery disease. PARADIGM is an investigator-initiated prospective evaluation of All-comer percutaneous Carotid Revascularization in symptomatic and increased-risk asymptomatic carotid artery stenosis using Mesh-covered embolic prevention stent system.

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.

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
