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): March 15, 2013

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.)

4 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(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 March 15, 2013, InspireMD, Inc. (the "Company") issued a press release announcing that the Company received CE mark approval this morning for its Carotid Embolic Protection Stent. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated March 15, 2013

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: March 15, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 15, 2013

InspireMD Receives CE Mark Approval
for Carotid Embolic Protection Stent

InspireMD's Carotid Embolic Protection Stent, based on InspireMD's proprietary MicroNet ™ mesh technology, is designed to provide procedural and post-procedural distal embolic protection in Carotid Artery Stenting (CAS) procedures and thereby reduce risk of stroke events.

Tel-Aviv, Israel, March 15, 2013 -- InspireMD, Inc. (OTC BB: NSPR) ("Inspire" or the "Company"), the developer of the MGuard™ Embolic Protection Stent (EPS), announced today that the Company received CE mark approval this morning for its self-expanding Nitinol carotid EPS. This carotid embolic protection stent is based on the proprietary MicroNet ™ mesh protection platform technology used to treat heart attack patients with InspireMD's commercially available coronary EPS stents, MGuard ™ and MGuard Prime ™ .

When treating carotid arterial disease, close to half of Carotid Artery Stenting (CAS) procedures cause distal embolic events that may lead to stroke within 30 days. The InspireMD Carotid Embolic Protection Stent (EPS) is wrapped with a MicroNet ™ mesh to prevent embolic events during and post CAS procedure. The MicroNet ™ is designed to hold plaque and thrombus in place against the wall of the blocked artery, preventing debris from falling into the bloodstream and causing a potentially fatal downstream blockage or stroke.

In coronary procedures, InspireMD's EPS technology has already shown improvements through the MASTER trial findings that revealed a statistically and clinically significant acute advantage of MGuard EPS with regard to ST segment resolution. As a result, MGuard EPS may hold the potential to lower the incidence of adverse events and prolong survival of heart attack victims. The new InspireMD Carotid EPS stent will be available in a matrix of sizes ranging from small diameters of 5x20mm to large diameters up to 10x60mm for large carotid arteries.

Commenting on today's approvals, InspireMD's President and CEO, Alan Milinazzo, commented, "The CE mark approval for our MGuard carotid system is a major milestone for the Company and is further validation of the Micronet technology. We look forward to accelerating our clinical development program with our carotid system. The CE mark should enhance our partnership strategy in the near term."

About InspireMD's EPS Technology

In stroke and acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The InspireMD EPS stent system technology is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the blockage from breaking off. The embolic protection is comprised of an ultra-thin polymer micron net that is integrated with the stent. The mesh is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is CE Mark approved. InspireMD's Coronary EPS is now CE Mark approved. MGuard™ is not approved for sale in the U.S. by the U.S. Food and Drug Administration.

About InspireMD, Inc.

InspireMD is a medical device company focusing on the development and commercialization of its proprietary stent system technology, MGuard™. InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the OTC 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, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) 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 (xii) 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 Transition Report on From 10-K/T 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.

For additional information:

InspireMD Desk
Redington Inc.,
+1-212-926-1733
+1-203-222-7399
inspiremd@redingtoninc.com