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): May 16, 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 May 16, 2013, InspireMD, Inc. (the "Company") issued a press release announcing that it received reimbursement approval for its MGuard™ Coronary Embolic Protection Stent from UNIMED, Brazil's largest private health care insurer.

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 May 16, 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: May 16, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated May 16, 2013

InspireMD Announces Reimbursement Coverage for MGuard™ Coronary Embolic Protection Stent (EPS) from Brazil's Largest Private Insurer

- More than 18 Million Brazilians have Reimbursable Access to MGuard EPS -

BOSTON and TEL AVIV, MAY 16 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection stents, today announced that it received reimbursement approval for the MGuard™ Coronary Embolic Protection Stent (EPS) from UNIMED, Brazil's largest private health care insurer.

Alan Milinazzo, InspireMD's President and CEO said, "Reimbursement in Brazil is a significant achievement that should enable us to expand our presence globally and further penetrate this important market of over 195 million citizens. We are pleased that UNIMED is recognizing MGuard's clinical value in preventing unstable plaque and clots from breaking away and causing further trauma in acute heart attack patients. "

According to the Brazilian Society of Interventional Cardiology (SBHCI), of the approximately 30,000 Brazilians treated for acute heart attacks each year, roughly one-third experience ST-segment elevation on ECG (STEMI) and require Primary PCI.

"This is the first step in a process that is expected to eventually enable doctors to treat patients with acute coronary syndromes, particularly those with acute myocardial infarction who may be at a high risk of distal embolization, with this innovative EPS system that has shown improved procedural outcomes" said Prof. Dr. Alexandre A. Abizaid, Director of Interventional Cardiology at Institute Dante Pazzanese in São Paulo, Brazil.

UNIMED is the largest cooperative medical system both in Brazil and globally, providing private health insurance to more than 18 million Brazilians. With 38% of the Brazilian health plan market, UNIMED has more than 109,000 physicians and 3,097 hospitals in its network, according to Brazil's National Health Insurance Agency (ANS).

About Stenting and MGuard™ EPS

Standard stents were not engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In 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 MGuard EPS is integrated with a precisely engineered micro net mesh to prevent the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients with regard to ST segment resolution, the MGuard EPS requires no change in current physician practice - an important factor in promoting acceptance and general use in time-critical emergency settings.

About InspireMD, Inc.
InspireMD seeks to utilize its proprietary MGuard technology to make its products the industry standard for embolic protection stents 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 technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the U.S. Food and Drug Administration (FDA) 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, 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 Form 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