INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE BOSTON, MA 02116
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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 30, 2014

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 Boston, Massachusetts	02116
(Address of principal executive offices)	(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 30, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the Company has initiated a Voluntary Field Action for MGuard Prime EPS. 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 30, 2014

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 30, 2014

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated April 30, 2014

InspireMD Announces Voluntary Field Action for MGuard ™ Prime EPS

BOSTON, MA – April 30, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection systems (EPS), today announced that it has initiated a Voluntary Field Action (VFA) following recent reports of MGuard Prime EPS stent dislodgements. These reports have primarily occurred during the preparation of the MGuard Prime EPS, upon removal of the protective sleeve or during withdrawal of the MGuard Prime EPS into the guide catheter. To date, there have been no reports of any patients being harmed in these recent reports reviewed by the Company.

The VFA for InspireMD's MGuard Prime cobalt chrome EPS does not apply to or impact the Company's MGuard stainless steel EPS or CGuard nitinol products.

The Company believes that it has identified the root cause of these dislodgements and, upon approval from the European regulatory agency, intends to modify all existing units of the MGuard Prime EPS in order to improve stent retention and performance. Today, InspireMD began notifying its clinical and commercial partners worldwide of its VFA for the MGuard Prime EPS and intends to modify all units in the field once regulatory approval is received.

The VFA will have a short term impact on both the commercial and clinical activities relating to the MGuard Prime EPS. The Company anticipates regulatory review to be completed by the end of the current, second quarter and would then commence shipping MGuard Prime EPS back into the marketplace.

As a result of the VFA, the Company has temporarily suspended enrollment in its MASTER II FDA trial pending a review by the FDA of the manufacturing improvements to the MGuard Prime EPS. This agency review is likely to delay enrollment in the trial for approximately 3 to 6 months. The Company intends to focus on site activation during this review period in order to accelerate enrollment once the study resumes.

"We believed it was prudent to initiate this voluntary field action in order to proactively address the issue of stent retention and to uphold our strong commitment to quality," stated Alan Milinazzo, Chief Executive Officer of InspireMD. "There will be a short-term impact on our revenue, as we have chosen to discontinue shipments of MGuard Prime while we work through the regulatory portion of this voluntary action. We also anticipate a delay of up to six months before resuming enrollment activities for the Master II FDA trial. The costs associated with upgrading the inventory of MGuard Prime units is minimal and should have little impact on our short term cash position. We view this action as a corporate responsibility and while it is a near-term setback, improving the quality of our product performance should result in long term clinical and commercial benefits."

For more information about InspireMD and its offerings, visit www.inspire-md.com .

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 Transition Report on Form 10-KT 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.

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