# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 10/29/14 for the Period Ending 10/29/14

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| Address | 321 COLUMBUS AVENUE<br>BOSTON, MA 02116 |
| Telephone | (857) 453-6553 |
| CIK | 0001433607 |
| Symbol | NSPR |
| SIC Code | 3841 - Surgical and Medical Instruments and Apparatus |
| Industry | Medical Equipment & Supplies |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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): October 29, 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<br>Boston, Massachusetts<br>(Address of principal executive offices) | 02116<br>(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 October 29, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved the Company's submitted investigational device exemption amendment for certain manufacturing process changes to the MGuard Prime EPS that were proposed in response to the Company's April 30, 2014 voluntary field action.

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 October 29, 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: October 29, 2014

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

**Exhibit 99.1**

**InspireMD Investigational Device Exemption (IDE) amendment approved by the FDA**

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*Validation of manufacturing process changes for the MGuard Prime EPS*

**BOSTON, MA** – October 29, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in Embolic Protection Systems (EPS), today announced that the FDA has approved the Company's submitted IDE amendment for certain manufacturing process changes to the MGuard Prime EPS that were proposed in response to the Company's April 30, 2014 Voluntary Field Action (VFA). InspireMD said while patient enrollment in the US MASTER II trial has been discontinued, which was intended to support this IDE application, the FDA's approval of the IDE amendment is an important endorsement of the process changes.

"The FDA approval of the amendment to our MASTER II IDE further validates the safety of our manufacturing process changes to our MGuard Prime EPS," commented Alan Milinazzo, CEO of InspireMD. "Along with the European approvals of our process changes, the rigorous review of the FDA should provide an extra level of confidence to our physicians worldwide."

The Company received European regulatory approval for these process changes in June, and now believes all returned MGuard Prime EPS inventory has been successfully modified and returned to direct hospital customers and the majority of their distributors. As such, the Company resumed full commercial activities in direct markets in Western Europe as of mid-October and expects direct and distributor based selling to ramp up throughout the fourth quarter of 2014.

As previously announced, in light of current market conditions moving toward drug eluting stent (DES) adoption and the delay in enrollment due to the FDA review process, the Company revised its MGuard strategy for the U.S. This included the decision not to resume enrollment in the MASTER II trial for the primary endpoints of ST segment resolution and death and target vessel re MI. This decision will allow the Company to direct more resources to the DES program and commercial activities for the MGuard and CGuard.

The Company successfully enrolled 310 patients in the MASTER II trial prior to suspending enrollment in April due to the product manufacturing process changes that were just approved by the FDA. The initial clinical analysis of these 310 patients at 30 day follow up showed encouraging clinical results in the MGuard group versus the control group. The Company will continue to follow these 310 MASTER II patients for one year from time of enrollment, and expects to report 30 day data at a major medical meeting in the first quarter of 2015.

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

**About Stenting and MGuard™ Prime 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 Prime EPS is integrated with a precisely engineered micro net mesh that is designed 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 Prime 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™ 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, (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 and (xiv) the escalation of hostilities in Israel, which could impair our ability to manufacture our products. 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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