INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 04/23/13 for the Period Ending 04/19/13

Address	321 COLUMBUS AVENUE 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): April 19, 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 April 19, 2013, InspireMD, Inc. (the "Company") issued a press release announcing the appointment of Gwen K. Bame as Vice President of Corporate Development, reporting directly to Alan Milinazzo, the Company's President and CEO.

On April 23, 2013, the Company issued a press release announcing that on April 19, 2013, the Company received an approval with conditions for its Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA). An approval with conditions indicates that the FDA concurs with the overall trial design and while minor details are being finalized, allows the company to initiate enrollment in its planned MASTER II IDE trial.

A copy of the press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated April 19, 2013
99.2	Press Release dated April 23, 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: April 23, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated April 19, 2013
99.2	Press Release dated April 23, 2013

InspireMD Hires Vice President of Corporate Development

Former Covidien Executive, Gwen Bame, Will Focus on Strategic Programs Worldwide

TEL AVIV, Israel, APR. 19 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR) said Gwen K. Bame has joined the Company as Vice President of Corporate Development, reporting directly to Alan Milinazzo, President and CEO.

"This is a new position created to strengthen our executive team with a clear focus on executing strategic programs and partnerships designed to meet our ambitious global growth objectives, said Mr. Milinazzo. "Gwen has the right blend of industry and management experience and we are delighted to welcome her to InspireMD."

Ms. Bame's responsibilities will include identifying and negotiating in/out licensing agreements, analyzing strategic partnerships and structuring of joint ventures on a worldwide basis.

Ms. Bame joined Covidien in 2009 upon its acquisition of Aspect Medical Systems, where she held various sales and marketing leadership positions during her tenure. She led significant market development programs directly and via strategic partnerships which drove adoption of the BIS technology.

Prior to her time at Covidien, Ms. Bame spent 12 years with Boston Scientific in the cardiology business in sales, marketing and corporate accounts. During her career at BSC, she negotiated roughly $350 million in contracted business across multiple business units.

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 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, 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.
212 926-1733
203 222-7399
inspiremd@redingtoninc.com

InspireMD Receives Approval from US Food and Drug Administration to Begin United States Regulatory Trial

Boston, MA and Tel-Aviv, Israel, April 23, 2013 -- InspireMD, Inc. (NYSE MKT: NSPR) ("Inspire" or the "Company"), the developer of the MGuard™ Embolic Protection Stent (EPS), announced today that on April 19, 2013, the Company received an approval with conditions for its Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA). An approval with conditions indicates that the FDA concurs with the overall trial design and while minor details are being finalized, allows the company to initiate enrollment in the MASTER II IDE trial.

The multi-center, randomized study will consist of 1,114 patients suffering from ST Elevation Myocardial Infarction (STEMI), throughout 35 sites in the U.S. and an additional 35 sites in Europe, and will support the Company's application to market its MGuard™ Prime MicroNet™ covered coronary stent system in the United States.

Gregg Stone, MD, of The Cardiovascular Research Foundation, and Dr. Jose P. S. Henriques of the Academic Medical Center Amsterdam in the Netherlands, will serve as Principal Investigators for the trial, which will consist of two co-primary endpoints: superiority in complete ST resolution and non-inferiority in death and target vessel MI. In addition, a 356 patient sub-study will be conducted to assess the effect of MGuard EPS on vessel infarct size, as measured through cardiac Magnetic Resonance Imaging (MRI).

"The approval to begin the US FDA trial is a significant milestone for the company," commented Alan Milinazzo, InspireMD's CEO and President. "This trial will provide an excellent opportunity to validate the safety and effectiveness of MGuard EPS in another large multi-center, randomized trial, comparing both bare metal and drug eluting stents, the current therapy for STEMI patients."
The FDA trial will be known as The MASTER II (MGuard™ for Acute ST Elevation Reperfusion), the second in a series of clinical studies meant to both validate the effectiveness of the MGuard EPS platform, as well as achieve registration with the appropriate regulatory authorities worldwide.

InspireMD's EPS technology previously yielded positive results in the MASTER I findings, which 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 patients suffering from acute myocardial infarction,

About InspireMD's MGuard 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 MGuard EPS stent system technology is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that cause these blockages from breaking off. The mesh is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is 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 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, 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