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): July 29, 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 July 29, 2013, InspireMD, Inc. (the "Company") issued a press release announcing that the Company enrolled its first patient in the Master II IDE clinical trial to evaluate the safety and effectiveness of the Company's MGuard™ Prime Embolic Protection Stent in patients suffering from ST Elevation Myocardial Infarction. The results of the trial are intended to support the Company's Investigational Device Exemption application with the U.S. Food and Drug Administration to market the MGuard Prime MicroNet™ covered coronary stent system in the U.S.

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 July 29, 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: July 30, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated July 29, 2013

InspireMD Announces First Patient Enrolled in U.S.
Registration Trial for MGuard™ Prime EPS

BOSTON and TEL AVIV July 29, 2013 — InspireMD, Inc. (NYSE MKT: NSPR) ("Inspire" or the "Company"), a leader in embolic protection stents, said the first patient has been enrolled in the Master II IDE clinical trial to evaluate the safety and effectiveness of the MGuard™ Prime Embolic Protection Stent (EPS) in patients suffering from ST Elevation Myocardial Infarction (STEMI).

The multi-center, randomized trial is expected to include up to 70 sites in the U.S. and Europe and as many as 1,114 patients. The results are intended to support the Company's Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA) to market the MGuard™ Prime MicroNet™ covered coronary stent system in the U.S.

The trial has two co-primary endpoints: superiority in complete ST resolution and non-inferiority in death and target vessel myocardial infarction. In addition, a 356 patient sub-study will be conducted to assess the effect of the MGuard Prime™ EPS on infarct size, as measured by Magnetic Resonance Imaging (MRI).

The trial's principal investigators are Gregg Stone, M.D. of New York Presbyterian Hospital and Columbia University Medical Center in New York City, and Jose P. S. Henriques, M.D. of the Academic Medical Center in Amsterdam.

The first procedure was performed at ZNA Middelheim by Stefan Verheye, M.D. "Distal embolization and no-reflow are severe concerns when treating our STEMI patients. From our experience over the last two years, the MGuard Prime EPS has improved patient outcome and led to brilliant results, thanks to its unique protective mesh" said Dr. Verheye. "I am excited about participating in the MASTER II Trial and enthusiastic about its potential impact on patient care worldwide."

"Enrolling our first patient in MASTER II is a very important milestone for the company. We are committed to advancing patient care through robust clinical research", said Alan Milinazzo, InspireMD's CEO and President. "MASTER II provides another important opportunity for us to demonstrate the safety of MGuard EPS and to validate its effectiveness compared to current standard of care treatment for STEMI patients."

The FDA trial, known as MASTER II (MGuard™ for Acute ST Elevation Reperfusion), is the second in a series of randomized clinical studies intended to validate the safety and effectiveness of the MGuard™ EPS platform and achieve registration with appropriate regulatory authorities worldwide.

InspireMD's MGuard™ EPS technology previously yielded positive results in the MASTER Trial findings, showing a statistically and clinically significant acute advantage with regard to ST segment resolution. As a result, the MGuard™ EPS may hold the potential to lower the incidence of adverse events and improve the survival of patients suffering from acute myocardial infarction.

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 that prevents 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 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:
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