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 17, 2012

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	000-54335	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 17, 2012, InspireMD, Inc. issued a press release announcing three year results from its EF (extended follow-up) MAGICAL trial. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated May 17, 2012.

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 18, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated May 17, 2012.

FOR IMMEDIATE RELEASE

InspireMD Announces Positive 3-Year Results from Extended MAGICAL trial

Low Major Adverse Events Observed 3 Years After Treatment with MGuard ™ in Acute Myocardial Infarction Patients

Tel Aviv, Israel – May 17, 2012 – InspireMD, Inc. (OTC BB: NSPR) (the "Company" or "InspireMD"), a medical device company focusing on the development and commercialization of its proprietary stent platform technology for use in patients with Acute Myocardial Infarction, announced positive three-year results from the EF (extended follow up) MAGICAL trial yesterday at a Company-sponsored symposium at the EuroPCR conference in Paris.

The Company said that the safety and efficacy of MGuard ™ observed in the MAGICAL trial were maintained at three-years.

MAGICAL was a prospective, single arm, multi-center study conducted in 2008-09 that enrolled 60 STEMI (myocardial infarction with ST segment elevation) patients. The initial results showed that, following MGuard ™ placement, 90% of patients achieved TIMI grade 3 flow, 73.3% achieved myocardial blush grade 3 and 61.4% achieved complete ST segment resolution. The major adverse cardiac and cerebrovascular event (MACCE) rate at six months following the procedure was 1.7%.

The three year follow-up data showed an overall 10.5% MACCE rate. Within this composite end point, the target lesion revascularization rate (TLR) was 1.8%, cardiac death was 7%, stroke occurred at a rate of 1.8% and a subsequent myocardial infarction rate was 0%. In addition, there was no reduction in cardiac function over this three-year period, as measured by echocardiogram. LVEF (left ventricular ejection function) at three years (n= 36) was 56% ± 10%, compared with 54% ± 12% immediately post procedure.

The extended follow up data was presented by the trial's principal investigator, Prof. Dariusz Dudek from the Jagiellonian University in Krakow, Poland . Dr. Dudek commented: "The long term follow-up results of the MAGICAL Trial are very encouraging. This data supports and extends the earlier positive follow-up data in this trial. This long term follow-up data, if further supported in a larger randomized study, would make MGuard™ a leading interventional solution for patients suffering from acute coronary syndromes and more importantly the longer term complications."

Eli Bar, Vice President and Chief Technology Officer at InspireMD, said: "The positive one year results we saw previously in the MAGICAL trial were a key factor in our decision to focus MGuard™ on patients with STEMI. This three-year follow-up data, showing a meaningful sustained benefit, further validates our decision to provide a superior solution to patients suffering from heart attacks and the longer term problems these patients face."

MGuard™ is currently being investigated in the multi-center international MASTER (MGuard™ for Acute ST Elevation Reperfusion) trial. This study has been designed to evaluate the MGuard™ stent compared to commercially-approved BMS or DES products in STEMI patients undergoing primary angioplasty. Preliminary top line results are expected in the third quarter of 2012. Plans for a registration study in the US are also at an advanced stage.

About EuroPCR

EuroPCR is the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions. It serves as one of the leading international courses in Interventional Medicine. It is taking place this year in Paris, France May 15 – 18. More than 12,000 participants from around the world are expected to attend.

About MGuard ™ Coronary Stent

MGuard™ combines a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer micron net that wraps the stent. The MGuard™ stent seeks to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard™ is CE Mark approved. Mesh-based protection is now recommended for use in the recent Guidelines of the Task force of Myocardial Revascularization of the European Society of Cardiology (ESC).

About InspireMD , Inc.

InspireMD is a medical device company focused 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 listed on the OTC BB 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, including the Company's Registration Statement on Form S-1 filed with the SEC on April 25, 2012. Investors and security holders are urged to read these documents free of charge on the SEC's web site at 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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