INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/24/12 for the Period Ending 05/24/12

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
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): May 24, 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 24, 2012, InspireMD, Inc. issued a press release announcing the completion of enrollment in its MASTER (MGuard™ for Acute ST Elevation Reperfusion) 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 24, 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 24, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated May 24, 2012.

FOR IMMEDIATE RELEASE

INSPIREMD ANNOUNCES ENROLLMENT COMPLETION IN MASTER TRIAL

Milestone Reached in MGuard ™ Clinical Development, Results Expected 3Q 2012

Tel Aviv, Israel – May 24, 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 Infarctions, today announced that is has completed enrollment in the MASTER (MGuard™ for Acute ST Elevation Reperfusion) trial. The Company is on track to release preliminary top line results in the third quarter of 2012.

Eli Bar, CTO and Vice President of Research and Development of InspireMD, commented: "This is an important milestone in the clinical development of MGuard™. The timely completion of enrollment has been achieved one month ahead of schedule. Completion of the MASTER trial is a key component of our plan to establish MGuard™ as the standard of care for Acute MI patients."

The MASTER Trial is a multinational randomized controlled trial designed to evaluate the MGuard™ and MGuard Prime Coronary Stents compared with the standard of care , bare metal stents (BMS) or drug eluting stents (DES), for acute ST-elevation myocardial infarction (STEMI) patients. It has enrolled 432 patients in a two-arm, parallel design study. The primary endpoint is complete ST segment resolution. Clinical follow-up will continue for one year and important secondary endpoints such as TIMI (Thrombolysis In Myocardial Infarction) flow, MBG (Myocardial Blush Grade) and MACE (Major Adverse Cardiac Events) will be measured. Sub-studies include infarct size measured by cardiac MRI, as well as restenosis by invasive angiographic follow-up at 13 months.

The MASTER Trial is being conducted in 50 centers in nine countries: Germany, Hungary, Israel, Poland, Czech Republic, France, Ireland, Brazil and South Africa. Dr. Gregg Stone, Director of Cardiovascular Research and Education, Columbia University in New York, is the study chairman. The trial's principal investigators are Prof. Alexandre Abizaid of the Institute Dante Pazzanese de Cardiologia in São Paulo Brazil; Prof. Dariusz Dudek from Jagiellonian University in Krakow, Poland; and Prof. Sigmund Silber of University of Munich, Germany. Detailed results from the trial are expected to be submitted for presentations at interventional cardiology meetings in the second half of the year.

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 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 December 22, 2011. 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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