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): August 20, 2012

InspireMD, Inc.

(Exact name of registrant as specified in its 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 August 20, 2012, InspireMD, Inc. issued a press release announcing results from its MGuard™ for Acute ST Elevation Reperfusion (MASTER) 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 August 20, 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: August 20, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated August 20, 2012.

InspireMD Announces Positive Results From MGuard™ Stent MASTER Trial For Emergency Treatment Of Heart Attack Patients

TEL AVIV, Israel, August 20, 2012 -- InspireMD, Inc. (OTCBB: NSPR) (the "Company" or "InspireMD"), a medical device company focusing on the development and commercialization of its proprietary MGuard™ embolic protection stent platform technology for use in patients with Acute Myocardial Infarctions, announced today that a multi-center randomized trial of its MGuard™ embolic protection stent demonstrated a positive outcome in treating patients suffering heart attacks when compared to commercially-approved bare metal or drug-eluting stents.

Detailed results will be presented at the upcoming Transcatheter Cardiovascular Therapeutics (TCT) meeting in Miami (October 22-26, 2012).

“We have reached a key milestone in the history of InspireMD,” said Ofir Paz, the Company’s chief executive officer. “We look forward to presenting detailed results of the MGuard™ MASTER trial at the TCT in October.”

The MASTER *(**M** Guard for **A** cute **ST E** levation **R** eperfusion)* trial enrolled 433 patients in nine countries and was designed to evaluate the MGuard™ embolic protection stent compared to commercially-approved bare metal or drug-eluting stents in heart attack patients undergoing primary percutaneous coronary intervention (PCI).

Heart attacks are the leading cause of death in the industrialized world. Approximately 3.2 million stenting procedures are expected to be performed worldwide in 2012, of which 850,000, or about 26 percent, will be for patients having heart attacks. Stents for heart attack patients are expected to represent $1.8 billion of stent sales, or nearly 30 percent of the $5.9 billion global stent market.

The MGuard™ embolic protection stent is a coronary stent integrated with a proprietary micronet technology. The micronet is designed to hold plaque and thrombus in place against the blocked artery’s wall, preventing debris from entering the bloodstream.

Plans for a U.S. FDA registration trial are underway, with patient enrollment expected to begin by year end.

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".

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 is integrated with the stent. The MGuard™ is designed 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).

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 Annual Report on Form 10-K 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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