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): September 27, 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 September 27, 2012, InspireMD, Inc. issued a press release announcing that the initial results from its MGuard™ for Acute ST Elevation Reperfusion (MASTER) Trial will be presented by Gregg M. Stone, MD, the MASTER Trial's chairman, on October 24, 2012 at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation, in Miami, Florida. 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 September 27, 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: October 3, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated September 27, 2012.

Results Of InspireMD's MASTER Stent Trial Scheduled For
Late Breaking Trials Session At TCT In Miami, FL Oct. 24

Trial Studied Performance Of MGuard™ Embolic Protection Stent (EPS) In 433 Patients Undergoing Emergency Treatment For Heart Attacks

TEL AVIV, Israel, Sept. 27, 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 Infraction announced today that Gregg W. Stone, MD will present initial results of the 433-patient randomized MASTER trial on October 24, 2012 at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation, in Miami, Florida (October 22-26).

InspireMD previously announced (on August 20) that the MASTER (***M*** *Guard for* ***A*** *cute* ***ST E*** *levation* ***R*** *eperfusion)* trial demonstrated a positive outcome in patients suffering heart attacks when compared to commercially-approved bare metal or drug-eluting stents.

Presentation of detailed findings by Dr. Stone, the study's Chairman, is scheduled for the Late Breaking Trials session in the main arena on Wednesday October 24 at 11:40 AM under the title "A Prospective, Randomized Trial of PET Micronet Mesh-Covered Stent vs. Standard Stents in Patients with ST-Segment Elevation Myocardial Infarction."

"The TCT conference is one of the world's premier events for new data and developments in interventional cardiology", said Robert Ratini, InspireMD's vice president of sales and marketing. "We are honored that the committee found the MASTER trial important enough for inclusion in the prestigious Late Breaking Clinical Trials session. We are hopeful this will broaden clinical awareness and adoption of our MGuard Embolic Protection Stent for the benefit of our customer physicians and their patients"

MASTER is the first Company-sponsored randomized clinical study comparing the MGuard™ Embolic Protection Stent to commercially-approved bare metal or drug-eluting stents in heart attack patients undergoing primary percutaneous coronary intervention (PPCI).

Eleven earlier single arm studies and one 40-patient physician-sponsored randomized trial showed the MGuard™ embolic protection stent to be effective in restoring blood flow.

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 wall of the blocked artery, preventing debris from falling in to the bloodstream and causing a potentially fatal downstream blockage.

Approximately 850,000 heart attack patients worldwide are expected to receive stents this year, accounting for $1.7 billion of stent sales, or nearly 30 percent of the $6.0 billion global stent market.

Plans for a U.S. FDA registration trial of the MGuard™ embolic protection stent are underway, with patient enrollment expected to begin during the first quarter of 2013.

About TCT

Transcatheter Cardiovascular Therapeutics (TCT) is the annual scientific symposium of the Cardiovascular Research Foundation. TCT gathers leading medical researchers and clinicians from around the world to present and discuss the latest developments in the field.

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1991, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new technologies, drugs and therapies in interventional cardiovascular medicine.

For more information about CRF, visit www.crf.org .

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™ Embolic Protection 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.

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, its 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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