INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/05/12 for the Period Ending 11/05/12

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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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): November 5, 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 7.01 Regulation FD Disclosure.

On November 5, 2012, InspireMD, Inc. issued a press release announcing that the randomized 432-patient MASTER trial of its embolic protective MGuard [TM] stent will be published in the November 6, 2012 print edition of the peer-reviewed *Journal of American College of Cardiology*, Vol. 60, No. 19 . A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

The information in this Current Report and the accompanying exhibits is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Certain statements contained in the press release and the presentation constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a number of risks and uncertainties. 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 InspireMD, Inc.'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 Transition Report on Form 10-KT For the transition period from January 1, 2012 to June 30, 2012 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated November 5, 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: November 5, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated November 5, 2012.

Positive Results Of InspireMD's MASTER Trial To Be Published
On November 6 In *Journal Of American College Of Cardiology*

432-Patient Study of New MGuard™ Stent Met
Primary Endpoint; Significantly Improved
Likelihood of Heart Attack Survival

TEL AVIV, ISRAEL NOV. 5 – InspireMD, Inc. ("InspireMD" or the "Company") (OTC: NSPR) announced today that the randomized 432-patient MASTER trial of its embolic protective MGuard stent will be published in the November 6, 2012 print edition of the peer-reviewed *Journal of American College of Cardiology*, Vol. 60, No. 19.
The online version of the paper, authored by Gregg W. Stone, MD and others, appeared a week ago Wednesday (October 24) at:
http://content.onlinejacc.org/article.aspx?articleid=1377008,
coinciding with Dr. Stone's presentation of the findings at the Late Breaking Clinical Trials session of the 24th Annual Transcathater Cardiovascular Therapeutics (TCT) scientific meeting in Miami, October 22-26 .

The findings showed the novel MGuard EPS provided a statistically and clinically significant acute advantage and, as a result, may hold the potential to lower the incidence of adverse sequela and prolong survival of heart attack victims.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the Food and Drug Administration (FDA) at this time. The Company plans to initiate a FDA approval study in 1Q 2013.

The study met its primary endpoint (proportion of patients with ST segment resolution of ≥ 70%, measured at 60 to 90 minutes post procedure), showing the MGuard EPS was significantly superior to the control arm of bare metal and drug eluting stents in the treatment of heart attack patients.

--Significantly more patients treated with the MGuard EPS achieved complete ST resolution (a measure of blood flow restoration to the heart muscle) compared to the control arm (57.8% vs. 44.7%, P=0.008), a relative improvement of 29 percent.

--The MGuard EPS showed a significant improvement in coronary artery blood flow compared with the control, including: (1) superior rates of restoring normal blood flow (TIMI-3 flow) (91.7% vs. 82.9%, P=0.006, a relative improvement of 10.6%); and (2) significantly less incomplete blood flow (TIMI-0/1 flow) post PCI (1.8% vs. 5.6%, P=0.01, a relative improvement of 67.9%).

Although the study's secondary endpoints were not powered for statistical significance, they showed positive trends.

--The trial showed a trend toward lower mortality (0% vs. 1.9%, P=0.06) at 30 days and smaller infarct size as measured by post procedure cardiac MRI (17.1gr vs. 22.3gr, p=0.27) in the MGuard EPS arm versus control.

--There was no difference between the groups in the secondary endpoint of myocardial blush grade, which is an angiographic measure of blood flow to the cardiac muscle (MBG2/3 83.9% vs. 84.7%, P=0.81).

The MASTER (**MG** uard for **A** cute **ST E** levation **R** eperfusion) trial randomized 432 patients to MGuard EPS (217) and 216 to either bare metal stents (60%) or drug eluting stents (40%). Fifty centers in nine countries participated in the trial. Patients are being followed for one year.

Dr. Stone, the study's chairman, is the Director of the Cardiovascular Research and Education Center for Interventional Vascular Therapy at New York-Presbyterian Hospital/Columbia University Medical Center.

About Stenting and MGuard EPS
Standard stents weren't 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, 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 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 quoted on the OTC under the ticker symbol NSPR.

About MGuard™ Embolic Protection Coronary Stent
MGuard™ EPS 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 EPS is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is CE Mark approved. MGuard™ is not approved for sale in the U.S. by the U.S. Food and Drug Administration 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 From 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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