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): February 6, 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.)

3 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 February 6, 2012, InspireMD, Inc. (the "Company") issued a press release reporting clinical data from an investigator-sponsored controlled randomized trial of its MGuard™ product. A copy of this press release is included herein as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of InspireMD, Inc., dated February 6, 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: February 8, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of InspireMD, Inc., dated February 6, 2012

InspireMD Announces Positive Clinical Data From Trial of MGuard™

Data shows significant improvement in microvascular reperfusion for MGuard™ vs. bare metal stents

TEL AVIV, Israel, Feb. 6, 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, announced positive clinical results from an investigator-sponsored controlled randomized trial conducted in Chile. The study showed that acute ST-elevation myocardial infarction (STEMI) patients who underwent coronary angioplasty with MGuard™ exhibited statistically significant improvement in microvascular reperfusion criteria compared with those treated with traditional bare metal stents (BMS).

The study was presented in Washington, D.C., at the Cardiovascular Research Technologies conference by lead investigator Dr. Dante Lindefjeld. "Every perfusion parameter measured in our study displayed superior outcomes in the MGuard™ group compared to the BMS group," said Dr. Lindefjeld when asked about his presentation. "Additional randomized trials are now appropriate to gather more data about the role of MGuard™ in clinical use. I'm personally pleased to be the investigator who completed the first randomized trial for MGuard™."

Eli Bar, CTO and Vice President of Research and Development at InspireMD, commented, "The results of this 40-patient study add to the growing body of data about MGuard's efficacy. The continued work of independent investigators such as Dr. Lindefjeld and his colleagues is important in evaluating the value of MGuard™ and in creating greater awareness of the product among cardiologists. We will continue to study MGuard™ to generate further data about its safety and efficacy."

MICAMI MGuard™ Trial Design and Results

Dr. Lindefjeld's study was known as the MICAMI (MIcrovascular Coronary Flow Comparison in Acute Myocardial Infarction Angioplasty) MGuard™ trial. It was designed to investigate if use of MGuard™ could reduce distal embolization of thrombus/platelet aggregates and thereby improve coronary and myocardial reperfusion in STEMI patients.

Forty patients with STEMI referred for primary PCI were enrolled at three centers in Chile and randomized to receive either MGuard™ or BMS treatment. The endpoints, analyzed by blinded experts, were TIMI flow grade, myocardial blush grade, TIMI frame count and the percentage of patients with optimal result. Baseline measurements of clinical, angiographic and procedural variables were not significantly different between groups. The elapsed time from onset of AMI was also comparable for both groups.

Key findings from the trial:

- 18 patients (90%) in the MGuard™ group achieved Blush grade 3 compared with 10 patients (50%) in the BMS group ($p = 0.006$)*.
- Median Blush grade value for MGuard™ patients was 3.0 (optimal result) versus 2.5 for BMS patients ($p = 0.006$)*.
- Measurement of corrected TIMI frame count showed a benefit in favor of MGuard™ (mean cTFC: MGuard™ 19.65 $\pm$ 4.07 vs. BMS 27.35 $\pm$ 7.15, $p < 0.001$*, cTFC mean difference MGuard™ - BMS 7.7, CI 95%: 3.94 to 11.46).
- 17 patients (85%) in the MGuard™ group achieved successful angioplasty (as defined by cTFC $\leq$ 23) compared with only 6 (30%) in the BMS group ($p < 0.001$)*.
- Final TIMI flow grade was not significantly different between the 2 groups.
- There were 2 cases of acute stent thrombosis (one for each group) at 30 days follow up, and no clinical events at 6 months.

*p values were calculated using a 2 sided test

About MGuard™ Coronary Stent

MGuard™ presents a novel combination of 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 provides 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).

MGuard™ is currently being investigated in the multi-center, international MASTER (MGuard™ for Acute ST Elevation Reperfusion) trial. This 432 patient study has been designed to evaluate the MGuard™ stent compared to commercially-approved BMS or DES products in STEMI patients undergoing primary angioplasty. Results are expected in the second half of 2012. Plans for a registration study in the US are also at an advanced stage.

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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