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): January 23, 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 January 23, 2012, InspireMD, Inc. (the "Company") issued a press release summarizing certain of the Company's accomplishments in 2011 and goals for 2012. 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 January 23, 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: January 23, 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 January 23, 2012

FOR IMMEDIATE RELEASE

INSPIREMD PROVIDES CORPORATE UPDATE, PLANS FOR 2012

- **MASTER Trial enrollment continues on schedule**
- **FDA Registration Trial scheduled to start in 2012**
- **Achievement of 2012 goals will expand, transform Company**
- **Preliminary 2011 revenues reported**

Tel Aviv, Israel – January 23, 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 its business objectives for 2012 and reviewed its achievements in 2011. InspireMD stents are based on the Company's proprietary MicroNet™ platform technology.

The Company said its major objective in the next year is to leverage its MASTER Trial results to commercialize the MGuard™ stent technology globally. The market for stents in the treatment of Acute Myocardial Infarction is approximately $1.8 billion. The MASTER Trial, a multinational randomized controlled trial designed to evaluate the MGuard ™ Coronary Stent compared with the standard of care for acute ST-elevation myocardial infarction (STEMI) patients, is progressing well and enrolling on schedule, the Company reported. Preliminary results are expected in the third quarter.

A second major objective in the next year is to initiate a U.S. registration study, the Company said. Discussions with the U.S. Food and Drug Administration are taking place actively with the objective of initiating this study later this year. The Investigational Device Exemption (IDE) application that would enable this trial to begin is planned for submission soon, the Company said.

"Achievement of our objectives for 2012 would literally transform our Company," said Ofir Paz, InspireMD's Chief Executive Officer. "Our larger goal is to establish MGuard ™ as the new standard of care in the interventional treatment of Acute MI."

Mr. Paz added: "In 2011, InspireMD made significant progress in planning, initiating and enrolling patients into the MASTER Trial and in expanding the international commercial presence of MGuard ™ . There appears to be significant interest in MGuard ™ within the global physician community."

The MGuard ™ Coronary Stent is now available in Europe, Asia and Latin America through InspireMD's distributor network. The Company said that in 2012 it will aggressively pursue additional registrations and contracts in new areas, with the goal of fostering further brand name recognition. Plans for infrastructure expansion, including the addition of manufacturing capacity and hiring of key senior personnel, are also at an advanced stage.

2011 Achievements

- Initiated MASTER Trial comparing MGuard ™ with standard of care in STEMI patients. As of January 23rd 2012, 150 patients (out of 432 planned) have been enrolled.
- Presented positive three-year follow up data of MGuard Multicenter Experience in STEMI patients at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in San Francisco, CA. This study showed approximately 50% reduction of MACE (Major Adverse Cardiac Events) compared to patients stented with conventional bare metal stent (BMS) or drug eluting stent (DES) products.
- Expanded the international presence of MGuard ™ through distributors in South Africa, India and Russia. MGuard ™ is currently approved and sold via distributors in more than 30 countries.
- Enrollment reached over 600 patients in the ongoing International registries.
- Doubled MGuard ™ production levels to meet the ongoing increase in demand .
- Commenced trading as a public company in the United States on the Over-the-Counter Bulletin Board (OTCBB) .
- Concluded a series of financings in which the Company raised an aggregate of approximately $12 million of cash.
- Elected Sol J. Barer, Ph.D. as Chairman of the Board of Directors, and elected Paul Stuka and Eyal Weinstein as independent directors.

2012 Goals and Objectives

- Complete the Master Trial and report results (2H, 2012) at a major interventional cardiology meeting.
- Initiate and commence enrollment in the FDA Registration trial of MGuard ™ .
- Obtain CE Mark approval for MGuard Carotid ™ product.
- Initiate clinical study for MGuard Carotid ™ .
- Expand commercial and manufacturing infrastructure in anticipation of MGuard ™ demand, including the hiring of key senior executives.
- Pursue additional registrations and distribution contracts in new countries.

MASTER Trial Enrollment on Track, Primary Endpoint Data Expected in Third Quarter

The MASTER (MGuard ™ for Acute ST Elevation Reperfusion) randomized trial seeks to enroll 432 patients in a two-arm, parallel design study. The objective is to evaluate the MGuard™ stent compared to commercially-approved BMS or DES products in achieving myocardial reperfusion in primary angioplasty for the treatment of STEMI patients. 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, myocardial blush grade and MACE will be measured. Additional sub-studies for cardiac MRI and invasive angiography are planned as well. Dr. Gregg Stone, Director of Cardiovascular Research and Education, Columbia University in New York, is the study chairman.

Eli Bar, CTO and Vice President of Research and Development of InspireMD, commented: “We are pleased that enrollment in the MASTER Trial is advancing on schedule and we anticipate completing enrollment in the second quarter of 2012.” He added: “The intent of the MASTER Trial is to provide additional supportive data based on a large, multi-national randomized trial.”

The MASTER Trial is being conducted in 12 countries: Germany, Hungary, Israel, Poland , Canada, Czech Republic, France, the Netherlands, Ireland, Serbia, Brazil and South Africa. It is actively enrolling patients in 32 centers. The trial’s principal investigators are Prof. Alexandre Abizaid, Prof. Dariusz Dudek and Prof. Sigmund Silber. Detailed results from the trial are expected to be submitted for presentations at interventional cardiology meetings in the second half of the year.

Plans for U.S. Registration of MGuard ™ Underway

InspireMD is advancing its regulatory strategy for U.S. FDA approval for MGuard ™ with a trial that is scheduled to begin in the second half of 2012. This trial will consist of patients undergoing primary revascularization for Acute Myocardial Infarction (AMI) who will be randomized to undergo PCI (Percutaneous Coronary Intervention) with either the MGuard Prime System or the comparator Abbott Vision BMS stent.

The primary efficacy endpoint will be a myocardial blush score of 3, with a successful outcome based on superiority of MGuard ™ to the BMS stent. The primary safety endpoint will be non-inferiority Target Vessel Failure (TVF) with secondary endpoints including ST-segment resolution at 60 minutes and MACE at 30 days, 6 and 12 months. Dr. Donald Cutlip, Executive Director of Clinical Investigation at the Harvard Clinical Research Institute, will provide scientific leadership of the FDA Registration trial.

2011 Preliminary Shipment and Revenue Results

Unaudited preliminary shipments of the MGuard ™ Coronary Stent system for 2011 increased approximately 78% compared to 2010. Unaudited preliminary revenues for 2011 were approximately $6 .0 million, compared to $4.9 million in 2010, an increase of approximately 21%. These numbers have not yet been audited by PWC, InspireMD’s external auditors. Final audited numbers for the year will be announced when the Company reports year-end 2011 earnings in March.

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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