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): May 16, 2013

InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-35731	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 May 16, 2013, InspireMD, Inc. (the "Company") issued a press release announcing that it will present six-month results from the MASTER (MGuard for Acute ST Elevation Reperfusion) trial of its MGuard™ Embolic Protection Stent. The results will be presented on May 23, 2013 at EuroPCR, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions, at the Palais Des Congrès in Paris. The results will also be presented through a conference call and webcast on the same date.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated May 16, 2013

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: May 20, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated May 16, 2013

InspireMD to Announce Six-Month Results from the MGuard™ Embolic Protection Stent (EPS) MASTER Trial at EuroPCR

- Strong Conference Presence to Include Presentations/Educational Events Featuring the MGuard™ Embolic Protection Stent -

- Company to Host Conference Call on Thursday, May 23 rd to Review MASTER Data -

BOSTON and TEL AVIV, Israel, MAY 16, 2013 -- InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), the leader in embolic protection stents, today announced a robust schedule of educational events and data presentations at EuroPCR, culminating in the first presentation of 6-month results from the MASTER (**M** Guard for **A** cute **ST E** levation **R** eperfusion) trial of the Company's MGuard™ Embolic Protection Stent (EPS).

EuroPCR is the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions (EAPCI) and takes place in Paris, at the Palais Des Congrès, from May 21-24, 2013.

Gregg W. Stone M.D., the MASTER study chairman and the Director of the Cardiovascular Research and Education Center for Interventional Vascular Therapy at New York-Presbyterian Hospital/Columbia University Medical Center, said, "In these STEMI patients, embolic protection is an unmet need that is not addressed by current bare metal or drug eluting coronary stents. The clinical evidence supporting the benefits of using the MGuard EPS stent in STEMI patients continues to grow. This year's EuroPCR meeting will add important new data underlining the protective benefits of MGuard EPS six months post-procedure."

InspireMD STEMI Symposium
Thursday, May 23, 2013
12:00 CET, Room 242AB

The Embolic Protection Stent - Beyond current techniques:
A More Effective Solution in STEMI Primary PCI

The InspireMD symposium will be chaired by Jean Fajadet, M.D., Co-Director, Interventional Cardiology Unit, Clinique Pasteur, Toulouse, France and Jose P. S. Henriques M.D., Academic Medical Center Amsterdam, Netherlands. Additional speakers include Drs., Antonio Colombo, Ran Kornowski, Chaim Lotan and Sigmund Silber. The highlight of the symposium will be the first presentation of 6-month results from the MASTER (**M** Guard for **A** cute **ST E** levation **R** eperfusion) trial of the Company's MGuard™ Embolic Protection Stent (EPS).

A summary of additional MGuard EPS educational events and data presentations at EuroPCR follows. All times are in Central European Time. In addition to attending these presentations, EuroPCR participants can learn more about MGuard EPS at the InspireMD booth (#P14).

Tuesday, May 21st, 2013

12:30-14:00 **Interventional strategies for thrombus management in STEMI** , Room 253
13:45-13:55 The use of self-expanding stents and mesh-based stents by D. Dudek

14:30-15:30 **Use of adjunctive imaging during PCI in ACS** , Room 342B
14:45-14:55 OCT guided treatment of persistent thrombus in a mesh-covered stent, by A. Thury

15:30-16:30 **Primary PCI for STEMI: prevention of thrombus embolism** , Room 253
16:00-16:10 The use of an embolic protection stent in a STEMI case of recurrent no-reflow
16:15-16:25 Mesh-covered stent for STEMI patient: patent side branch after stent coverage

16:45-18:15 **Clot, too much clot, new clots: primary PCI for STEMI** , Room 253
17:15-17:25 Resolving a blinded primary PCI by C. Cafri
18:00-18:10 The use of an embolic protection stent in a highly thrombotic STEMI case by B. Varshitzky

16:45-18:15 **How to prevent distal embolization during PCI of diseased saphenous vein graft** , Room 352A
17:30-17:40 The use of an embolic protection stent in a complex STEMI saphenous vein graft case, by I. Herz
18:00-18:10 Treating in-stent restenosis in saphenous vein graft with embolic protection stent, by I. Herz

Wednesday, May 22nd, 2013

14:10-15:40 **Interactive case corner #7**
Integrated approach with OCT, mesh-covered stent and drug-eluting balloon for late failure of DES by M.F. Brancati

16:45-18:15 **Moderated posters 3**
17:51-18:15 Efficacy of an embolic protection stent as a function of symptom onset to balloon time in STEMI patients: a MASTER trial sub study by D. Dudek

16:45-18:15 **Abstract: Impact of thrombus aspiration device on the results of primary PCI** , Room 243
18:02-18:09 Efficacy of an embolic protection stent as a function of thrombus size in STEMI patients: a MASTER trial sub study by R. Costa

Thursday, May 23rd, 2013

10:45-11:45 **Management of intra-coronary thrombus during primary PCI** , Room 352B
11:30-11:40 Extensive thrombotic material protrusion successfully treated with a mesh covered stent by A. Gholoobi

12:00-13:00 **Corner PCI of totally occluded saphenous vein graft,** Abstract & Case Corner
12:15-12:25 STEMI due to vein graft occlusion: new opportunities with new devices, by C. Cafri

14:10-15:40 **New challenges for high-risk primary PCI in 2013,** Room 253
14:55-15:00 Case presentation: primary PCI in STEMI - What to do if standard thrombectomy and regular stent does not seem to be enough, by B. Mrevlje

14:10-15:40 **Up-to-date primary PCI technique,** Room 252AB
15:25-15:35 Novel approaches: self-expanding, mesh covered stent, no stent, by R.J. Van Geuns

“The depth and breadth of our activities at EuroPCR reflect InspireMD’s commitment to addressing unmet needs in interventional cardiology and establishing MGuard EPS as the industry standard for coronary stents,” said Alan W. Milinazzo, President and Chief Executive Office of InspireMD. “The MASTER trial represents a critical milestone in the evolution of the company and we are looking forward to engaging the cardiology community in a dialogue about its implications for clinical practice at the InspireMD STEMI Symposium on May 23 rd .”

Conference Call and Webcast Details

InspireMD will host a conference call and webcast to review 6-month MASTER trial data on Thursday May 23, 2013 at 8:00 ET, 14:00 CET. To access the call, participants should dial the following numbers:

- U.S. and Canada: +1-888-417-8516
- Paris: +33-08-00-90-26-40
- International: +1-719-325-2144

A live webcast will be available at www.inspiremd.com. An archived webcast will be available for 30 days.

About Stenting and MGuard™ EPS

Standard stents were not 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 integrates 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 with regard to ST segment resolution, 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’s mission is to utilize its proprietary MGuard technology to make its products the industry standard for stents and to provide a superior solution to the key clinical issues of current stenting: embolic showers, restenosis, and late stent thrombosis.

InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD’s common stock is quoted on the NYSE MKT under the ticker symbol NSPR.
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.

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 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.

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