INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/20/14 for the Period Ending 05/20/14

Address	321 COLUMBUS AVENUE
	BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

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 20, 2014

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.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(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 20, 2014, InspireMD, Inc. (the "Company") issued a press release announcing that the Company will present the results of its 12-month follow-up from its MASTER (MGuard for Acute ST Elevation Reperfusion) trial at the EuroPCR 2014 Conference to be held from May 20 to May 23, 2014 in Paris, France.

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 20, 2014

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, 2014

By: /s/ Craig Shore

Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated May 20, 2014

For Immediate Release

InspireMD to Showcase Embolic Systems with MicroNet ™ Technology and Results from MASTER I Trial at EuroPCR Conference

Company to Present at European Symposium Titled MGuard™ Embolic Protection Stent: The Importance of Thrombus Management in STEMI Primary PCI

BOSTON, MA – May 20, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection systems, today announced that it will be attending EuroPCR 2014 , the leading cardiovascular event in Europe. The conference will take place in Paris, France from May 20-23, 2014.

Each year, more than120 companies from the cardiovascular industry, including device and equipment manufacturers, attend EuroPCR. This event allows attendees to discover new products and R&D projects as well as interact with practitioners and industry partners to further development and innovation in the cardiovascular field.

During the event, InspireMD will share the results of its 12-month follow-up from its MASTER Trial for the first time in Europe at a symposium titled "MGuard Embolic Protection Stent: The Importance of Thrombus Management in STEMI Primary PCI," which will be attended by world-renowned faculty. The symposium will focus on the importance of thrombus management in primary PCI for STEMI patients, provide an update on relevant clinical data on device selection in STEMI treatment and showcase real-life examples of how device selection can influence the outcome of STEMI patients.

Throughout the meeting, presenters will discuss data from InspireMD's 12-month MASTER (MGuard for Acute ST Elevation Reperfusion) trial demonstrating that the MGuard outperformed bare metal and drug eluting stents in all-cause mortality in ST segment elevation myocardial infarction (STEMI) patients. Further, the MASTER trial achieved its primary endpoint in complete ST-segment resolution at 60-90 minutes post-procedure, which is historically a strong predictor of mortality. The secondary endpoint continued to show lower mortality rates with MGuard use as opposed to the control group.

"When we presented the MASTER I trial findings in Q4 in the United States, they were extremely well received, as the data suggested that InspireMD's MGuard EPS offers STEMI patients a higher likelihood of survival at 12 months than standard bare metal and drug eluting stents," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "We look forward to sharing this information with the European cardiology community for the first time at EuroPCR and we anticipate a similarly positive reception."

InspireMD will also be speaking with investigators about the CARENET (CARotid Embolic protection study using microNET) multi-center European clinical trial using the CGuard™ carotid embolic protection system ("EPS"). The proprietary CGuard carotid EPS uses the same patented MicroNet™ technology featured on its MGuard Prime™ coronary system. This protects patients from plaque debris and blood clots breaking off and traveling distally in the arteries which can lead to life threatening strokes. The size, or aperture, of the MicroNet 'pore' is only 150-180 microns in order to maximize protection against plaque and thrombus.

Milinazzo continued, "We remain on track to complete enrollment in the CARENET study and interest among physicians here at EuroPCR remains very high. We believe the CGuard and the associated CARENET trial will be of great interest to physicians treating patients with carotid artery disease worldwide."

For more information about InspireMD and its offerings, as well as additional 12-month results, visit www.inspire-md.com.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard ™) and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT 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, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) 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 (xiii) 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-KT 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.

Investor Contacts:
Todd Fromer / Garth Russell
KCSA Strategic Communications
Phone: 212-896-1215 / 212-896-1250
Email: tfromer@kcsa.com / grussell@kcsa.com

Media Contact:
Samantha Wolf
KCSA Strategic Communications
212-896-1220
swolf@kcsa.com