INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Address	321 COLUMBUS AVENUE BOSTON, MA 02116
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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): October 14, 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 2.02 Results of Operations and Financial Condition.

On October 14, 2014, InspireMD, Inc. (the "Company") issued a press release announcing commercial, development and clinical updates on the MGuard Prime Embolic Protection Systems (EPS) product line and new product programs and hosted a conference call at 8:30am ET to review the updates reported in the press release. During the course of the conference call, the Company announced that the revenue generated from MGuard Prime sales during the three month period ended September 30, 2014 was approximately $220,000, and that the Company's monthly negative cash flow during the three month period ended September 30, 2014 should be slightly less than the Company's historical monthly negative cash flow of $1.3 million to $1.6 million. An archive of the conference call is accessible on the Investor Relations section of the Company's website at www.inspire-md.com/site_en/for-investors and will be accessible for a limited time.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 2.02 in this Current Report on Form 8-K shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

The information required to be disclosed under this Item 7.01 is set forth above under Item 2.02.

Item 8.01 Other Events.

On October 14, 2014, the Company issued a press release announcing commercial, development and clinical updates on the MGuard Prime EPS product line and new product programs. 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 October 14, 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: October 14, 2014

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

Exhibit 99.1

InspireMD Resumes MGuard Prime Sales and Prioritizes DES and Carotid - New Product Programs

—

MGuard Prime commercial re-launch complete in direct markets

Drug Eluting Stent (DES) program advances in development with partners

—

MASTER II trial to suspend enrollment to support DES and Carotid Opportunities

—

Investor conference call this morning at 8:30 a.m. ET

BOSTON, MA – October 14, 2014 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in stent Embolic Protection Systems (EPS), today provided commercial, development and clinical updates on the MGuard Prime coronary EPS product line and positioned the Company to address more efficiently its emerging MGuard and CGuard commercial opportunities.

The Company indicated that it believes all MGuard Prime inventory has been successfully modified and that it is back to full commercial activities in direct markets in Western Europe as of October 10th. Further, all returned distributor inventory has been modified and the majority of its distributor partners have begun shipping product back into hospital accounts. The Company expects direct and distributor based selling to ramp up throughout the fourth quarter of 2014 and to be enhanced by the launch of the CGuard Carotid product.

Positive CGuard first in man (FIM) data was reported last month in the CARENET trial presented at the Transcatheter Therapeutics Meeting (TCT) in Washington DC. CGuard demonstrated 100% procedural success, 0% MACE at 30 days and a significant improvement in reducing new ischemic lesions as measured by diffusion weighted magnetic resonance imaging (dwMRI), as compared to historical controls.

The Company reported today that it has successfully entered the second phase of development work with the first Drug Eluting Stent (DES) candidate via strategic partnership. As previously communicated, the Company expects to bring two viable (CE approved) DES products into an animal testing phase (II) which, if successful, is expected to lead to submission for CE registration of a DES MicoNet platform in the second half of 2015. The initial technical feasibility testing phase (I) of DES candidates had a 100% success rate, enabling the program to progress on schedule with no additional work required prior to commencing the next phase of testing.

In light of current market conditions moving toward continued DES adoption and the delay in enrollment due to the FDA review process, the Company has decided to revise its MGuard strategy for the U.S. This includes the decision not to resume enrollment in the MASTER II trial for the primary endpoints of ST segment resolution and death and target vessel re MI. This decision will allow the Company to direct more resources to the DES program and commercial activities for the MGuard and CGuard. As a result of this change, MASTER II will no longer be an FDA registration trial.

The Company successfully enrolled 310 patients in MASTER II trial prior to suspending enrollment in April due to product manufacturing process changes. The initial clinical analysis of these 310 patients at 30 day follow up showed encouraging clinical results in the MGuard group vs the control group. The Company will continue to follow these 310 MASTER II patients for one year from time of enrollment, and expects to report 30 day data at a major medical meeting in the first quarter of 2015.

Alan Milinazzo, CEO of InspireMD, stated, "On the commercial front, we are now back to full activities in our direct markets outside the US, and we are seeing usage return to pre-Voluntary Field Action (VFA) levels within our existing direct customer base. We will begin shipping product to new customers in our direct markets during this current quarter. Our final post-VFA MGuard Prime commercial milestone will be to return to full commercial activities in all of our distributor markets, which represent the majority of our current customer base. The simultaneous re launch of MGuard Prime with our new CGuard commercial activities should provide our sales channel with positive momentum going into 2015."

Milinazzo continued, “During the past month we have made significant progress on our DES development program. Most importantly, we are ready to begin animal testing of our first DES candidate via partnership and expect to have a DES platform for CE submission in the back half of 2015. Finally, our decision to suspend enrollment in MASTER II and evaluate our interim data will guide our evolving clinical strategy in order to insure that we maximize our clinical investments to help drive adoption of our MGuard and CGuard technology.”

Investor Conference Call
The Company will host a conference call at 8:30 a.m. ET on Tuesday, October 14th to review these updates on its MGuard Prime coronary EPS and business outlook. Participants should call (877) 407-0784 (United States) or (201) 689-8560 (International) and request the InspireMD call or provide confirmation code: 13593465. A live webcast of the call will also be available on the Investor Relations section of the Company’s website at www.inspire-md.com/site_en/for-investors . Please allow 10 minutes prior to the call to visit this site to download and install any necessary audio software.

An archive of the webcast will be available approximately one hour after completion of the live event and will be accessible on the Investor Relations section of the Company’s website at www.inspire-md.com/site_en/for-investors for a limited time. A dial-in replay of the call will also be available to those interested until October 21st. To access the replay, dial (877) 870-5176 (United States) or (858) 384-5517 (International) and enter code: 13593465.

For more information about InspireMD and its offerings, visit www.inspire-md.com .

About Stenting and MGuard™ Prime 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 Prime EPS is integrated with a precisely engineered micro net mesh that is designed to prevent 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 Prime 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 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, (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 and (xiv) the escalation of hostilities in Israel, which could impair our ability to manufacture our products. 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.

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