

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 03/30/17 for the Period Ending 03/30/17

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
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): March 30, 2017

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35731

(Commission
File Number)

26-2123838

(IRS Employer
Identification No.)

4 Menorat Hamaor St.
Tel Aviv, Israel

(Address of principal executive offices)

6744832

(Zip Code)

Registrant's telephone number, including area code: (888) 776-6804

(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))
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Item 8.01 Other Events.

On March 30, 2017, InspireMD, Inc. announced the launch of its CGuard™ EPS at the ICCA Stroke Conference 2017 held March 24th-25th at the Vishnevskiy Institute of Surgery of the Ministry of Public Health in Moscow, Russia. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated March 30, 2017

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: March 30, 2017

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces Commercial Launch of CGuard™ EPS in the Russian Federation at the ICCA Stroke Event In Moscow

BOSTON, MA—March 30, 2017 - InspireMD, Inc. (NYSE MKT:NSPR) (NYSE MKT:NSPR.WS) (“InspireMD” or the “Company”), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced the launch of its CGuard™ Embolic Prevention System (EPS) at the ICCA Stroke Conference 2017 held March 24th-25th at the Vishnevskiy Institute of Surgery of the Ministry of Public Health in Moscow, Russia. As previously announced, the Company recently signed an agreement with Nerin Assets OU (“Nerin”), a leading regional distributor, covering the Russian Federation to distribute CGuard™ EPS

“We were extremely pleased with the attendance and enthusiastic interest in the presentations, panel discussions and case presentations on CGuard™ EPS at the ICCA Stroke event,” commented Agustin Gago, EVP and Chief Commercial Officer of InspireMD. “Russia is a key market for us, with the highest rate of cerebrovascular disease in Europe. Carotid Artery Stenting (CAS) case numbers nearly doubled from 2014 to 2015 and as the trend towards CAS vs Carotid Endarterectomy (CEA) or surgery increases, we expect further growth. CGuard™ is also very well suited for transradial procedures, whereby the device is inserted through the wrist—a procedure that is rapidly gaining traction in Russia and throughout Europe, as it reduces cost and hospital stay. With the CGuard EPS officially going on sale in the Russian Federation through our distribution partner Nerin Assets OU, we look forward to capturing significant market share in the months to come.”

Mr. Daniel Golubtsov, Managing Director of Nerin Assets OU, added, “As we could see at the ICCA Stroke in Moscow, the CGuard™ EPS has the potential to be recognized as best in class. We are excited to have officially launched the product and are confident it will become a success and add significant value to our product offering.”

Dr Bernhard Reimers, Director of the Clinical and Invasive Cardiology Unit at the Humanitas Hospital, Milan, commented, “I was pleased to see InspireMD here to actively support this event with presentations and especially challenging case reports in stroke resolution. Being a user of the CGuard™ myself, it reinforces my view that carotid artery stenting with CGuard™ will increasingly become the treatment of choice in stroke and its prevention”

Dr Volkov Sergey Vladimirovich, Head of the Endovascular Treatment and Diagnostics Department at the Treatment and Rehabilitation Centre in Moscow, stated, “When treating patients, I am very pleased with the long-term performance and superior safety of CGuard, which addresses the risk of distal embolization by preventing plaque protrusion through the stent. Having utilized CGuard™ through transradial (wrist) catheterization, this technology helps ensure a safer, more cost-effective and patient friendly procedure versus surgery.”

About ICCA Stroke

ICCA Stroke is an interdisciplinary and interactive course with leading experts in the field, recorded cases, step by step presentations, debates and hands-on workshops on catheter-based treatment of acute stroke.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary 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™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR and certain warrants are quoted on the NYSE MKT under the ticker symbol NSPR.WS.

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 Annual Report on Form 10-K 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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