

INSPIREMD, INC.

FORM 8-K (Current report filing)

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Telephone	(888) 776-6804
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Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
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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): June 18, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On June 18, 2018, InspireMD, Inc. announced that study results on its CGuard™ EPS were presented at the 10th International Congress of the Polish Society for Vascular Surgery by Dr. Jan Jakub Kesik and by Prof. Piotr Szopiński. 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.

On June 20, 2018, InspireMD, Inc. announced that CGuard™ EPS was featured at the SBHCI Congress, sponsored by the Brazilian Society of Hemodynamics and Interventional Cardiology, which took place in Curitiba, Brazil from June 13-15, 2018. A copy of the press release is attached as Exhibit 99.2 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 June 18, 2018
99.2	Press release dated June 20, 2018

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: June 21, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD's CGuard™ EPS Prominently Featured at the 10th International Congress of the Polish Society for Vascular Surgery

Study results presented from 46 patients treated over two years with zero complications

President of the Polish Society for Vascular Surgery presented clinical cases illustrating the advantages of CGuard™ EPS

Tel Aviv, Israel— June 18, 2018 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced that study results on its CGuard™ EPS were presented at the 10th International Congress of the Polish Society for Vascular Surgery by Dr. Jan Jakub Kęsik. Dr. Kęsik, from Lublin Medical University Hospital, presented an overview study of his experience with CGuard™ EPS, which included 46 patients with 100% procedural success, 0% clinical complications, 0% MACNE, and 0% instent restenosis. The presentation featured the advantages of the CGuard™ EPS covered with the company's proprietary MicroNet™ PET fiber versus the metallic dual layer Roadsaver® and other conventional carotid stents.

Additionally, Prof. Piotr Szopiński, President of the Polish Society for Vascular Surgery also spoke about his positive experiences with CGuard™ EPS and presented pre-recorded illustrative carotid procedures performed with the product. The Company's local distributor in Poland, Arteriae Sp., also hosted a booth that featured CGuard™ EPS at the conference that was well attended.

“We are pleased with the continued and growing favorable response to CGuard™ EPS by vascular surgeons as was seen at the 10th International Congress of the Polish Society for Vascular Surgery,” commented James Barry, PhD, Chief Executive Officer of InspireMD. “We appreciate the support from Dr. Kęsik and Professor Szopiński who are both vascular surgeons and highlighted the advantages of CGuard™ EPS in their respective presentations. Dr. Kęsik's study, which included 46 patients with zero complications, adds to the growing body of evidence supporting the advantages of CGuard™ EPS versus conventional and alternative stents. This is just another example of how CGuard™ EPS is becoming a primary solution for surgeons who might otherwise be considering surgery for their patients with carotid artery disease.”

The 10th International Congress of the Polish Society for Vascular Surgery is one of the premier European medical conferences covering the field of vascular surgery with over 400 attendees. The event was hosted by the Polish Society of Vascular Surgery, an organization aimed at advancements in the field of vascular surgery, dissemination of knowledge and the exchange of experiences among individuals and organizations in the field.

About InspireMD, Inc.

InspireMD seeks to utilize its patented 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 American under the ticker symbol NSPR and certain warrants are quoted on the NYSE American 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.

Investor Contacts:

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InspireMD's CGuard™ EPS Featured at the SBHCI Congress in Brazil

Tel Aviv, Israel— June 20, 2018 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced that CGuard™ EPS was featured at the SBHCI Congress, sponsored by the Brazilian Society of Hemodynamics and Interventional Cardiology, which took place in Curitiba, Brazil from June 13-15, 2018. The Congress hosted approximately 1,200 participants including doctors from across Brazil and Central and South America.

As part of the scientific sessions, Dr. Antonio Micari, MD, PhD of Maria Cecilia Hospital, in Cotignola, Italy, presented “How to Minimize Complications, the Safe Carotid Artery Stenting (CAS), Step by Step.” Dr. Micari discussed the importance of selecting the right type of stent to minimize the risks of complications in CAS procedures. He presented CGuard™ EPS as the carotid embolic protection stent system of choice. In addition to his presentation he also showed a challenging and successful case that utilized the CGuard™ EPS which employs the company's patented MicroNet™ PET fiber and SmartFit™ Technology.

“We are pleased to have had CGuard™ EPS featured so prominently at the SBHCI Congress in Brazil, which included over a thousand attendees from across Central and South America,” commented James Barry, PhD, Chief Executive Officer of InspireMD. “We particularly appreciate the continued support from Dr. Micari from Maria Cecilia hospital, one of the leading endovascular surgery facilities in Italy and one of the leaders in the world doing more than 40,000 endovascular procedures per year. Regional congresses such as SBHCI are central to our strategy as we expand our footprint and generate awareness among both key opinion leaders and leading physicians in Latin America.”

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