INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/29/18 for the Period Ending 11/29/18

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): November 29, 2018

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	6744832
(Address of principal executive offices)	(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 November 29, 2018, InspireMD, Inc. announced details from several presentations of updated data from its CGuard™ Embolic Prevention System (EPS) registries at the recent Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium) in New York. 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 November 29, 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: November 29, 2018

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

InspireMD Announces Positive Long-Term Safety and Efficacy Data from Ongoing CGuard™ EPS Registries at the Recent 45th Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium)

Tel Aviv, Israel— November 29, 2018 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of carotid artery disease, today announced details from several presentations of updated CGuard™ EPS data at the recent VEITHsymposium in New York. The results of three separate registries confirm the long-term benefits of CGuard™ EPS in preventing late embolic events.

In his presentation, Piotr Musialek, MD, DPhil, Jagiellonian University Professor of Cardiovascular Medicine, Jagiellonian University Dept. of Cardiac & Vascular Diseases, John Paul II Hospital, Krakow, Poland, presented an update of his ongoing PARADIGM-Extend clinical trial of "all comers" with high-risk carotid stenosis in 251 patients treated with CGuard™ EPS.

Professor Musialek noted, "CGuard™ EPS delivers excellent safety and efficacy both during the procedure and at long-term 36-month follow-up. This is especially encouraging as this is an "all comers" registry which includes patients with high-risk carotid lesions such as aneurysms, dissections or highly calcified lesions. I am not aware of any other device that has demonstrated such sustained long-term benefits."

Also, during the VEITHsymposium, Professor Christian Wissgott, Director at Westküstenklinikum Heide, Heide, Germany, presented positive six-month follow-up data on 70 consecutive patients treated with CGuard™ EPS, which mirror Professor Musialek's results. Among the findings, CGuard™ EPS demonstrated a 100% technical success rate. Additionally, there were no pre-interventional complications observed, and no peri- or post-interventional strokes observed. At six months, no intrastent restenosis was observed, and DWI-MRI data from 29 of the 70 patients detected no new ipsilateral lesions in the brain after thirty days and six months.

Commenting on the results, Professor Wissgott stated, "The novel CGuard™ EPS with the combination of an open-cell nitinol stent and a micro-mesh cover leads to the prevention of post-procedural embolic events. The CGuard™ is easy and safe to implant due to its very smooth wall adaption to the vessel wall and lack of foreshortening."

Finally, Laura Capoccia, MD, PhD, Assistant Professor of Vascular Surgery University, Vascular Surgeon, Vascular and Endovascular Surgery Division, Department of Surgery, Rome, Italy and Francesco Speziale, MD, Vascular and Endovascular Surgery Division, Department of Surgery, University of Rome, presented an update on the ongoing IRONGUARD 2 Multicenter Prospective Registry Study of 342 patients with severe carotid stenosis. Again, the presentation, which included data from 15 centers, showed no major stroke, no permanent neurologic symptoms, no restenosis and no neurologic deaths in 51 of the 342 patients who completed one-year follow-up.

Dr. Jim Barry, Chief Executive Officer of InspireMD, commented, “The findings from these ongoing studies in Poland, Germany and Italy further highlight the long-term clinical benefits of CGuard™ EPS in preventing embolic events in patients undergoing minimally-invasive procedures for stroke treatment. These are three separate clinical studies across geographies and clinical specialties with highly positive and consistent long term results. This clearly differentiates CGuard™ EPS from other technologies on the market and, we believe, represents a significant advancement in treatment of carotid artery disease.”

Copies of the presentations can be found at www.inspiremd.com.

About VEITHsymposium

VEITHsymposium provides vascular surgeons, interventional radiologists, interventional cardiologists and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease. The Event features presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for treatment of carotid artery disease by providing outstanding acute results and durable stroke free long-term outcomes.

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:

Craig Shore
Chief Financial Officer
InspireMD, Inc.
888-776-6804
craigs@inspiremd.com

Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com