# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 10/10/17 for the Period Ending 10/09/17

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| 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): October 9, 2017

# 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 October 9, 2017, InspireMD, Inc. (the "Company") announced the start of patient enrollment in an investigator initiated trial of the Company's CGuard™ EPS in 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 October 9, 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: October 10, 2017

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

**InspireMD Announces the Start of Patient Enrollment in an Investigator Initiated Trial of CGuard™ EPS in Russia**

*CGuard™ Embolic Prevention System (EPS) to be Randomized Against Abbott's RX ACCULINK® Carotid Stent System*

Tel Aviv, Israel—October 9, 2017 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in Embolic Prevention Systems (EPS) / thrombus management technologies and neurovascular devices, today announced the start of patient enrollment in an investigator initiated trial in Russia, entitled: *Independent Randomized Trial in Carotid Artery Revascularization Comparing the Stent (Acculink™) Versus CGuard™EPS.* The objective of the trial is to assess the neuro protection and clinical superiority of the minimally invasive interventional procedure with the CGuard™ EPS versus Abbott's RX ACCULINK® Carotid Stent in subjects at high risk for Carotid Endarterectomy (CEA), a surgical procedure.

The trial is a single center randomized trial with two interventional arms comparing CGuard™ EPS to Acculink™. The trial will enroll 100 consecutive eligible patients with 50 patients in each arm. The primary endpoint of the trial will be new ischemic areas in the brain within 24 to 48 hrs post procedure, and new lesion permanence at 30-days as determined by Diffusion-Weighted Magnetic Resonance Imaging (DWMRI). Each patient will receive clinical and ultrasound follow-up at 1 year. The trial will be conducted at the Center of Vascular and Hybrid Surgery within the Scientific Research Institute of Circulation Pathology in Novosibirsk, which is associated with the Novosibirsk State University, one of Russia's top three universities (QS World University Rankings® 2016). The research will be lead by Professor Andrei Karpenko, the head of the vascular surgery department.

Professor Karpenko commented, "Having been aware of the very impressive data supporting the use of CGuard EPS $^{TM}$ for the treatment of carotid artery stenosis, we are excited to now have the opportunity to evaluate this system versus Abbott's RX ACCULINK® which is widely used in Russia today."

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "We are honored that Professor Karpenko and his team have elected to study CGuard $^{TM}$ EPS in this Vascular Surgeon led clinical trial at the Center of Vascular and Hybrid Surgery within the Scientific Research Institute of Cardiovascular Pathology in Novosibirsk. We understand the first patients have been enrolled and treated in the trial and we look forward to the results at the conclusion of the trial. Once again, we believe that this trial will reinforce our current CGuard $^{TM}$ clinical data, and continue to validate the growing interest and support in CGuard $^{TM}$ across all clinical specialties treating carotid artery disease."

**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 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:**

InspireMD, Inc.
Craig Shore
Chief Financial Officer
Phone: 1-888-776-6804 FREE
Email: craigs@inspiremd.com

Crescendo Communications, LLC
David Waldman
Phone: (212) 671-1021
Email: NSPR@crescendo-ir.com