

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 12/05/17 for the Period Ending 12/05/17

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): December 5, 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 December 5 , 2017, InspireMD, Inc. announced the preliminary 24 month follow-up results in the PARADIGM 101 Clinical Study utilizing CGuard™ EPS. 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 December 5 , 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: December 5, 2017

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



**InspireMD Announces Preliminary 2 Year Follow-up Results from the
PARADIGM Clinical Study Using CGuard™ EPS**

No procedure or device related adverse events at 24 months

*Results presented at the 2017 VEITHsymposium in New York
and ICI Meeting 2017 in Tel Aviv*

Tel Aviv, Israel—December 5, 2017 - InspireMD, Inc. (NYSE AMER: NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced the preliminary 24 month follow-up results in the PARADIGM 101 Clinical Study utilizing CGuard™ EPS. Dr. Piotr Musialek, Department of Cardiac and Vascular Diseases, John Paul II Hospital, Kraków, Poland, presented the long-term follow-up at the 2017 VEITH Symposium in New York on November 16th, 2017 and the ICI Meeting 2017 in Tel Aviv on December 4, 2017.

PARADIGM-101 is an investigator-led clinical study evaluating the use of CGuard™ EPS in 101 consecutive all-comer patients with symptomatic or high-risk asymptomatic carotid artery stenosis. The data presented illustrate that no periprocedural or postprocedural intervention related death, major stroke, or myocardial infarction had occurred in the study patients at 24-month follow-up.

These excellent results in PARADIGM-101 are consistent with the other CGuard™ EPS Trials, including CARENET, IRON-GUARD, WISSGOTT Study and CASANA Study. The PARADIGM study long-term preliminary results further confirm the sustained benefits of CGuard™ out to two years and make it a potential permanent therapeutic protection option for all-comer patients with carotid artery disease.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, “We are excited to see Prof. Musialek’s report out on the long-term follow-up data from the PARADIGM study, which represents the longest known clinical follow-up with any such carotid devices to date. This is just another piece of data that continues to reinforce the potential benefits of CGuard EPS. The 24 month follow-up data from this trial simply confirms the sustained long term benefit CGuard could provide to patients with carotid artery disease.”

The 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 5-day event features rapid-fire presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques.

The ICI Meeting 2017 is the premier international conference for innovations in cardiovascular systems (heart, brain and peripheral vessels) and high-tech life science companies.

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
