

INSPIREMD, INC.

FORM 8-K (Current report filing)

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Telephone	(888) 776-6804
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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): December 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 December 18, 2018, InspireMD, Inc. announced the publication of a meta-analysis of four clinical studies involving dual layered and mesh-covered stents in the December 10, 2018 issue of *JACC: Cardiovascular Interventions* . 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 18, 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: December 18, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



**InspireMD Announces Publication of Meta-Analysis Citing Benefits of
Next Generation Mesh-Covered Carotid Stent Systems**

*Analysis includes clinical studies incorporating the Company's MicroNet™-covered stent, the
CGuard™ Embolic Prevention System (EPS)*

Tel Aviv, Israel— December 18, 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 the publication of a meta-analysis of four clinical studies involving dual layered and mesh-covered stents in the December 10, 2018 issue of *JACC: Cardiovascular Interventions*. The analysis concluded that carotid artery disease (CAD) patients treated with mesh-covered stents experienced a 30-day minor stroke rate of 1.25%, lower than 30-day minor stroke rates reported in other widely cited studies, such as CREST and ACT 1, for patients treated with both carotid endarterectomy (CEA) and with those treated with conventional carotid stents. Moreover, CREST and ACT 1 involved lower-risk patient populations as compared to the four studies included in the meta-analysis, which included a higher percentage of high-risk and elderly patients.

“The compelling results of this independent and comprehensive meta-analysis, which includes four studies of high-risk patients treated for carotid artery disease, add to the growing body of evidence that points to superior clinical outcomes with next generation mesh-covered or dual layered devices versus their conventional carotid stent counterparts,” said James Barry, PhD, Chief Executive Officer of InspireMD. “As we continue to expand the commercial availability of our MicroNet™-covered product, CGuard™ EPS, including the submission of a U.S. IDE expected in mid-2019, we welcome additional analyses such as these that further support the positive findings from our own studies with MicroNet-covered products.”

This paper is also the focus of a follow-up article, dated December 12, 2018, that appeared in the publication *Medcape* along with a discussion with a leading European interventional cardiologist, Professor Harald Mudra, MD, Städtisches Klinikum, Munich, Germany, who commented, “I think we are seeing a new milestone with these mesh-covered stents in that we can achieve a very acceptable, low rate of complications and stroke even in high-risk patients. If confirmed in larger and longer trials, these stents could open up a new population for carotid stenting who have previously been thought of as being too high risk for the procedure.”

“We now only use these mesh-covered stents at our center. I am convinced they are superior to conventional carotid stents. The extra layer of mesh keeps the small particles of plaque that can be released during the stenting process from entering the circulation,” Prof. Mudra added.

The full JACC paper can be purchased online here.



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.

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