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): August 7, 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 August 7, 2017, InspireMD, Inc. announced the publication of the independent study entitled, "One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents, transforms the carotid revascularization field," in the Advances in Interventional Cardiology Journal 2017. 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 August 7, 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: August 7, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Publication of an Independent Clinical Review Authored by Leading U.S. and European Physicians Supporting Safety Advantages of Mesh-Covered Carotid Stents

Comprehensive Review of Clinical Trial Data Supports the Safety and Efficacy of Carotid Artery Stenting (CAS) Versus Carotid Endarterectomy (CEA)

Mesh Covered Carotid Devices Transforming the CAS Field

Highlights Key Advantages of CGuard™ EPS Versus Conventional Stents Including Better Patient Outcomes

Tel Aviv, Israel—August 7, 2017 - InspireMD, Inc. (NYSE MKT:NSPR) (NYSE MKT:NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced the publication of the independent study entitled, " One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents, transforms the carotid revascularization field, " in the Advances in Interventional Cardiology Journal 2017. The paper illustrates that carotid artery stenting (CAS) has the potential to be an equally safe, but less invasive, alternative to the surgical carotid endarterectomy (CEA) procedure. A link to the full article is available on the InspireMD website .

The paper was co-authored by Dr Piotr Musiałek, Department of Cardiac and Vascular Diseases, Jagiellonian University, School of Medicine, John Paul II Hospital, Krakow, Poland, Professor L. Nelson Hopkins and Professor Adnan H. Siddiqui, both of the Departments of Neurosurgery and Radiology, School of Medicine and Biomedical Sciences, University at Buffalo, State University of New York, Jacobs Institute, Gates Vascular Institute Kaleida Health, Buffalo, New York, USA.

The review finds that data from more than 550 patients in mesh-covered and dual layered carotid device clinical studies show an overall 30-day complication rate of ~1% with near-elimination of post-procedural events. This data, combined with other historical data on patients with symptomatic and asymptomatic carotid stenosis confirming no difference between CAS and CEA long term stroke risk, serve to illustrate the potential transformation of the carotid revascularization field.

Additional highlights from the paper include:

- CGuard™ EPS' open cell stent design together with SmartFit technology provides superior conformability compared to other next generation carotid devices, even in torturous lesions;
- MicroNet covering has a very small pore size, thus provides maximum protection from protruding plaque;
- CGuard™ EPS has a better radial force than current alternatives, and this, together with the open stent design, allows it to conform effectively to the vessel wall;
- Current alternatives have no known tapered version of their stent, so unlike CGuard ^{TM} EPS, the operator needs to make measurements and calculations to ensure proper coverage of the lesion as there is considerable foreshortening.

Dr Jim Barry, CEO of InspireMD, commented, "This review paper, yet again, continues to underline the mounting evidence for treating carotid artery disease with the next generation carotid devices, both safely and less invasively, thereby reducing the need for surgery. We are especially pleased that the review highlights CGuard ™ EPS' clinical data, compared to its competitors, making it the clearly preferred choice of the authors."

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 MKT under the ticker symbol NSPR and certain warrants are quoted on the NYSE MKT 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