INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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): September 17, 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 September 17, 2018, InspireMD, Inc. (the "Company") announced issuance of two new U.S. patents covering the Company's proprietary MicroNet™ stent jacket combined with a stent scaffold and related drug eluting technologies. 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 September 17, 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: September 17, 2018

By: */s/ James Barry*

Name: James Barry, Ph.D.

Title: Chief Executive Officer

InspireMD Announces Issuance of Two New U.S. Patents Covering Proprietary MicroNet™ Stent Jacket and Related Drug Eluting Technology

Patents further strengthen intellectual property surrounding Company's lead commercial product, CGuard™ EPS

InspireMD remains on track to submit an Investigational Device Exception (IDE) with FDA in mid-2019

Tel Aviv, Israel— September 17, 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 that the United States Patent and Trademark Office (USPTO) has issued US Patents 10,070,976 and 10,070,977 covering InspireMD's proprietary MicroNet™ stent jacket combined with a stent scaffold and related drug eluting technologies. MicroNet is a key differentiator of InspireMD's commercial products, including the company's lead product, CGuard™ EPS, for the prevention of stroke in patients being treated for carotid artery disease. The claims also cover MGuard Prime™ EPS for patients being treated for acute myocardial infarction.

"We are pleased that the USPTO has recognized this unique technology that we believe can revolutionize the field of vascular stenting in general, but more importantly, prevent stroke in patients with carotid artery disease," said James Barry, PhD, Chief Executive Officer of InspireMD. "Conventional stenting in patients being treated for carotid artery disease allows for the protrusion of plaque through the stent struts and into the blood vessel in up to 65% of cases, significantly increasing the risk of stroke and other complications post-procedure. However, our novel MicroNet stent jacket technology acts as a safety net that prevents debris from passing through the mesh, resulting in significantly lower complication rates versus conventional stenting. These patents also strengthen and broaden our overall product and technology portfolio with the inclusion of claims covering drug eluting technologies. Combining MicroNet with drug eluting capabilities would be a key differentiating feature of our coronary stent product, MGuard Prime EPS, and any other drug eluting stent product, creating what we believe are broad potential applications in the coronary drug eluting stent market."

Dr. Barry continued, "We look forward to further executing on our growth strategy, which includes the expansion of our commercial footprint, both in countries where we have established distribution as well as new geographies. We are also working to submit a U.S. investigational device exception (IDE) for CGuard EPS to FDA expected in mid-2019 as we begin the process of accessing the U.S. Market."

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for Carotid Stenting 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