INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 01/19/18 for the Period Ending 01/16/18

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): January 16, 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 3.01, Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On January 16, 2018, InspireMD, Inc. (the "Company") received notification (the "Deficiency Letter") from the NYSE AMERICAN LLC ("NYSE American") that the Company is not in compliance with certain NYSE American continued listing standards (the "Listing Standards"). This was in addition to our prior disclosed non-compliance with Sections 1003(a)(ii)-(iii) of the NYSE American Company Guide.

The Deficiency Letter states that the Company's shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the NYSE American Company Guide, the NYSE American staff determined that the Company's continued listing is predicated on it effecting a reverse stock split of its common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 16, 2018. The Company intends to regain compliance with the Listing Standards by undertaking a measure or measures that are for the best interests of the Company and its stockholders, including potentially effecting a reverse stock split.

The Company filed a definitive proxy statement with the Securities and Exchange Commission on December 26, 2017, with respect to a special meeting of the Company's stockholders scheduled to be held on February 7, 2018, to consider, among other items, the authorization of the board of directors, in its discretion but prior to the annual meeting of the Company's stockholders in 2018, to amend the Amended and Restated Certificate of Incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio in the range of 1-for-25 to 1-for-50, such ratio to be determined by the board of directors (the "Reverse Stock Split Proposal"). There can be no assurance that the Company's stockholders will approve the Reverse Stock Split Proposal. Further, there can be no assurance that the market price of the Company's new common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of the Company's common stock outstanding before the reverse stock split, and there is no assurance that the Company's common stock will not trade at levels viewed as abnormally low for a substantial period of time and lead the NYSE American to immediately suspend trading in our common stock . In the interim, as discussed below, the Company will continue to actively pursue its business in the hopes that such actions will increase stockholder value and raise the price of its common stock. The Company cannot assure that its actions will demonstrate compliance.

The Company's common stock will continue to be listed on the NYSE American while it attempts to regain compliance with the Listing Standards, subject to the Company's compliance with other continued listing requirements, as described in prior filings. The Deficiency Letter does not affect the Company's business operations or its Securities and Exchange Commission reporting requirements.

Item 8.01 Other Events.

On January 19, 2018, the Company issued a press release announcing publication of an independent imaging study demonstrating the advantages of CGuard ^{TM} EPS in reducing stent plaque prolapse in carotid artery stenting patients and disclosing receipt of the notice from the NYSE American. 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 January 19, 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: January 19, 2018

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Publication of an Independent Imaging Study Highlighting the Advantages of CGuard™ EPS Compared to Another Next Generation Carotid Stent

Tel Aviv, Israel— January 19, 2018 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced the publication of an independent observational study conducted by Tomoyuki Umemoto, MD and colleagues in the December 2017 issue of the journal EuroIntervention demonstrating the advantage of CGuard™ EPS in reducing stent plaque prolapse (vascular tissue or thrombus protruding through the stent and into the carotid artery following stenting that is vulnerable to embolizing into the brain) in carotid artery stenting patients.

The aim of this study was to compare plaque prolapse after carotid artery stenting (CAS) with CGuard™ versus a competing device as assessed by optical coherence tomography (OCT), a technique that performs high definition images inside of the artery. A series of sixteen consecutive patients undergoing CAS were enrolled in the study. A total of 248 cross-sectional OCT images (166 images for CGuard ^{TM} and 82 for the competing device) were analyzed to assess the incidence of plaque prolapse.

As introduction to this OCT study, an editorial appeared in the same EuroIntervention issue, authored by Professor Piotr Musialek, Jagiellonian University Department of Cardiac & Vascular Diseases, John Paul II Hospital, Krakow, Poland, and Prof Eugenio Stabile, Division of Cardiology, Department of Advanced Biomedical Sciences, University of Naples "Federico II", Naples, Italy. The editorial authors state: "With conventional carotid stenting, plaque prolapse occurs via the 'cheese-grater' effect." They go on to highlight the permanent protective role of CGuard™ EPS, the unique MicroNet™ covered carotid stent, which already demonstrated neuro-protection in the CARENET Study. The editorial authors noted that the competing device had a two-fold greater risk of plaque prolapse compared with CGuard™ in the OCT frames analysis.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "We are pleased to see another study conducted on CGuard™ EPS that was again, focused on proving out the mechanism of the protective properties of MicroNet™ in the treatment of carotid artery disease. While this observational study was conducted on a limited number of patients, it was encouraging to see that CGuard™ EPS continues to perform as advertised in the clinical setting. Moreover, the fact that yet another independent clinical investigation was conducted and the investigators saw it fit to once again publish further validates the interest in CGuard™ EPS and the future the device holds for potentially preventing catastrophic events that can occur with conventional carotid artery stents."

EuroIntervention is a monthly peer-reviewed journal of interventional cardiovascular medicine that has become one of the benchmarks in its field. EuroIntervention is the official journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). The Journal is endorsed by the European Society of Cardiology (ESC) and has a distinguished European and International editorial board led by Prof Patrick W. Serruys from the Erasmus MC, Rotterdam.

The Company also announced that it has received notice from the NYSE American LLC (the "NYSE American") pursuant to Section 1003(f)(v) of the NYSE American's Company Guide that, due to the Company's current low selling share price, the Company's continued listing on the NYSE American is contingent upon the Company effecting a share consolidation or otherwise demonstrating a sustained improvement in its share price within the next six months but not longer than July 16, 2018 (or such longer period as may be agreed to by the NYSE American).

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.

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