INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/22/17 for the Period Ending 08/17/17

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): August 17, 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard.

On August 17, 2017, InspireMD, Inc. (the " ***Company*** ") received a notice from NYSE Regulation indicating that the Company does not meet continued listing standards of the NYSE American LLC (the " ***NYSE American*** ") as set forth in Part 10 of the NYSE American Company Guide (the " ***Company Guide"***). Specifically, the Company is not in compliance with Section 1003(a)(iii) of the Company Guide because the Company reported stockholders' equity of less than $6 million as of June 30, 2017, and net losses in its five most recent fiscal years ended December 31, 2016. As a result, the Company has become subject to the procedures and requirements of Section 1009 of the Company Guide.

The Company must submit a plan of compliance to NYSE Regulation by September 17, 2017, addressing how it intends to regain compliance with Section 1003(a)(iii) of the Company Guide by February 17, 2019. If the plan is accepted by NYSE Regulation, the Company may be able to continue its listing during the plan period, during which time the Company will be subject to periodic review to determine whether it is making progress consistent with the plan.

If the Company does not submit a plan, or if the plan is not accepted by NYSE Regulation, delisting proceedings will commence. Furthermore, if the plan is accepted but the Company is not in compliance with the continued listing standards by February 17, 2019, or if it does not make progress consistent with the plan during the plan period, the NYSE American will initiate delisting proceedings.

The NYSE Regulation notice also included an early warning of the Company's potential noncompliance with Section 1003(a)(iv) of the Company Guide because the uncertainty regarding the Company's ability to generate sufficient cash flows and liquidity to fund operations raises substantial doubt about its ability to continue as a going concern.

The Company's management is reviewing its options to address the deficiencies and expects to submit a compliance plan on or before the deadline set by the NYSE American.

Item 8.01 Other Events.

On August 22, 2017, the Company issued a press release announcing posting of video testimonials about its CGuard ^{TM} Embolic Prevention System from several European key opinion leaders on the Company's website. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

On August 22, 2017, the Company issued a press release announcing the receipt of the NYSE Regulation notice described in Item 3.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated August 22, 2017
99.2	Press release dated August 22, 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 22, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Shares CGuard ™ EPS Video Testimonials
from European Key Opinion Leaders

Tel Aviv—August 22, 2017 - InspireMD, Inc. (NYSE AMER:NSPR) (NYSE AMER:NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced it has posted video testimonials about its CGuard ™ Embolic Prevention System from several European key opinion leaders on its website: http://www.inspiremd.com/en/kol-testimonials/

Featured testimonials include:

- Dr. Alberto Cremonesi, Chief of the Cardiovascular Department at Maria Cecilia Hospital, Cotignola, Italy
- Dr. Antonio Moreno, Chief Medical Officer of Endovascular Intervention World MEDICA, Madrid, Spain
- Dr. Bernhard Reimers, Clinical and Invasive Cardiology Unit Director at Humanitas Research Hospital, Milan, Italy
- Prof. Ralf Kolvenbach, Head of the Cardiovascular Diseases Department, Medical Director of the Catholic Hospitals, Duesseldorf, Germany
- Prof. Piotr Musialek, Jagiellonian University Department of Cardiac & Vascular Diseases, Krakow, Poland

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "We are honored that such respected clinicians from the fields of vascular surgery, interventional cardiology and interventional neuroradiology across Europe are willing to publicly endorse our very promising technology. These testimonials provide detailed and diverse clinical views on the advantages of the CGuard Embolic Prevention System, as described by those who use it routinely in their daily practices to improve patient outcomes."

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:

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InspireMD Announces Notification of NYSE AMERICAN Listing Deficiency and Expectation to Regain Compliance

Tel Aviv – August 22, 2017 — InspireMD, Inc. (NYSE AMER: NSPR) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced it received a letter from the NYSE American on August 17, 2017 indicating that InspireMD does not meet a certain NYSE American LLC (the "NYSE American") continued listing standard as set forth in Part 10, Section 1003(a)(iii) of the Company Guide of the NYSE American, due to the fact the Company had reported stockholders' equity of less than $6 million as of June 30, 2017 and had net losses in its five most recent fiscal years ended December 31, 2016. The Exchange's notice has no immediate effect on the listing of the Company's common stock on the Exchange. The Company's management is reviewing its options to address the deficiency and expects to submit a compliance plan to the NYSE American on or before September 17, 2017, the deadline set by the Exchange, addressing how it intends to regain compliance with Sections 1003(a)(iii) of the Company Guide by February 17, 2019.

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