

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 01/30/20 for the Period Ending 01/29/20

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 29, 2020

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)

(888) 776-6804
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value \$0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

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 January 29, 2020, InspireMD, Inc. (the “Company”) issued a press release announcing that a successful live case featuring the Company’s CGuard™ EPS was presented at the Leipzig Interventional Course (LINC) 2020. 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 No.	Description
--------------------	--------------------

99.1	Press Release dated January 29, 2020
------	--

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 30, 2020

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces Successful Live Clinical Case Transmissions Featuring CGuard™ EPS at the Leipzig Interventional Course (LINC) 2020

Case demonstrates ease-of-use and exceptional patient safety features of CGuard™ EPS

Tel Aviv, Israel — January 29, 2020 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease, today announced that a successful live case featuring CGuard™ EPS was presented at the international LINC conference 2020, which is being held January 28 – 31 in Leipzig, Germany.

“For the third year in a row, we were chosen to showcase CGuard™ EPS in a live case procedure. This again confirms both clinical utility and ease of use of the device relative to alternative stent options and carotid endarterectomy,” said Marvin Slosman, chief executive officer of InspireMD. “Together with the panel discussions and presentations featuring CGuard™ EPS at this year’s LINC conference, the totality of evidence demonstrating CGuard’s safety and efficacy continues to reiterate the value of CGuard as a standard of care treatment for carotid artery disease. We would like to express our thanks to Drs. Micari and Castriota, two world-renowned interventionalists, for again demonstrating superior results of CGuard™ EPS in a real-time clinical setting.”

Live case #17: Symptomatic high-risk carotid artery disease

The live case was conducted by Dr. Antonio Micari and Dr. Fausto Castriota, interventional cardiologists at Humanitas Gavazzeni Hospital, Bergamo, Italy. The 82-year old male patient presented with symptomatic high-risk carotid artery disease and experienced a transient ischemic attack (TIA) with left-sided hemiparesis approximately one month ago. Risk factors included hypertension and hypercholesterolemia. The procedure was successfully performed with CGuard™ EPS, lasted approximately 20 minutes and had an excellent angiographic result.

Following the procedure, Drs. Micari and Castriota commented, “We believe CGuard™ EPS is a game changer in the plaque–stent interaction paradigm.”

About LINC

LINC is a leading global forum for new methods in the field of vascular medicine. LINC brings together medical professionals from different specialties around the world who perform endovascular interventions.

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 symbols NSPR.WS and NSPR.WSB.

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
