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): January 23, 2019

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 January 23, 2019, InspireMD, Inc. (the "Company") announced that two successful live cases featuring CGuard™ Embolic Prevention System (EPS) were presented at the Leipzig Interventional Course (LINC) 2019, which is being held January 22-25 in Leipzig, Germany. 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.

On January 24, 2019, the Company announced the presentation of positive interim results from an investigator-initiated study of CGuard™ EPS at the LINC 2019. A copy of the press release is attached as Exhibit 99.2 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 23, 2019
99.2	Press release dated January 24, 2019

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 24, 2019

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Two Successful Live Clinical Case Transmissions Featuring CGuard ™ EPS at the Leipzig Interventional Course (LINC) 2019

Cases demonstrate ease-of-use of CGuard™ EPS in two challenging clinical situations physicians face when treating carotid artery disease

Tel Aviv, Israel — January 23, 2019 – 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 two successful live cases featuring CGuard™ EPS were presented at LINC 2019, which is being held January 21 – 23 in Leipzig, Germany.

"The live demonstrations of CGuard™ EPS at this year's LINC conference, a major international interventional conference covering the latest innovations in vascular medicine, allowed attending physicians to see first-hand the simplicity of the CGuard EPS procedure as conducted by world renowned interventional cardiologists and angiologists," said Dr. James Barry, President and Chief Executive Officer of InspireMD. "It is immensely gratifying to once again have CGuard™ EPS chosen by these leading interventionalists to be prominently featured in two live case transmissions today at LINC 2019."

Live case #1: Patient with Symptomatic Left Carotid Artery Disease and Concomitant Coronary Artery Disease

The first live case was conducted by Dr. Antonio Micari and Dr. Fausto Castriota, interventional cardiologists at Humanitas Gavazzeni Hospital, Bergamo, Italy. The patient had stable angina over the prior twelve months, with one hospital admission for one transient ischemic attack (TIA) approximately one month ago. The risk factors included hypertension, hypercholesterolemia and critical left interior carotid artery (LICA) stenosis with evidence of soft plaque. The procedure was successfully performed with the 8mm x 40mm CGuard™ EPS, lasted approximately 20 minutes and had an excellent angiographic result.

Following the procedure, Drs. Micari and Castriota commented, "This patient presented with multiple co-morbidities, including a history of transient ischemic attacks, and a large amount of soft plaque that significantly increases the chance of embolization associated with conventional carotid stents. There were no adverse events during the procedure. At this early stage, it appears that CGuard™ EPS offers superior patient protection where conventional carotid stents may not."

Live case #2: Restenosis of the Left Common Carotid Artery after TEA

The second live case was conducted by Drs. Andre Schmidt and Matthias Ullrich of Universitaetsklinikum of Leipzig, in Leipzig, Germany. The patient was symptomatic with a high grade stenosis of the right common carotid artery, likely caused by post radiation and open surgery due to a parotid tumor, and had dizziness. The risk factors included hypertension, hyperlipidemia and the patient is a former smoker. The patient received a 8mm x 40mm CGuard™ EPS and the case also lasted approximately 20 minutes with an excellent angiographic result.

Following the procedure, Drs. Schmidt and Ullrich commented, "We were very happy with the performance of the CGuard in today's challenging case that is not seen in everyday practice. It continues to reinforce our positive impressions of this innovative product and we look forward to continuing to implement it in our practice."

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 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 Presentation of Interim Data from Investigator-Initiated Study Comparing CGuard™ EPS with a Conventional Open-Cell Carotid Stent

CGuard™ EPS shows encouraging interim results verses a conventional carotid stent in absence of any adverse clinical events in the CGuard™ arm

Data presented at the LINC 2019 Congress in Leipzig, Germany

Tel Aviv, Israel — January 24, 2019 – 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 the presentation of positive interim results from an investigator-initiated study of CGuard™ EPS. The presentation, entitled, "The **SIBERIA** Trial – CGuard™ MicroNet® Covered **S** tent vs. Accul **I** nk™: **B** asal, 30d DW-MRI and 1y Clinical **E** valuation in 100 **R** andom **I** zed p **A** tients," is occurring at the Leipzig Interventional Course (LINC), which is being held January 22-25, 2019 in Leipzig Germany.

Dr. A. Karpenko and Dr. P. Ignatenko from the Siberian Federal Biomedical Research Center, Russia, presented interim data from their first 50 patients in an independent, randomized clinical trial designed to ultimately include 100 consecutive patients with symptomatic and asymptomatic carotid artery disease. The patients are randomly assigned (1:1) into two treatment groups: 50 patients will receive the CGuard™ EPS MicroNet® mesh covered stent and 50 patients will receive a conventional carotid stent. The primary endpoints are the incidence and volume of new lesions within the brain after carotid stenting using diffusion weighted magnetic resonance imaging (DW-MRI) peri-procedurally and at 30 days.

At the protocol-mandated interim analysis, after recruiting the first 50 patients in the study, the results at one month show that, despite having patients with higher risk factors in the CGuard™ group compared to the conventional carotid stent arm, the CGuard™-treated patients had a significantly lower incidence of multiple lesions in the brain (16% vs 44%), and a lower incidence of large cerebral lesions (24% vs 40%). Finally, major adverse clinical events after 30 days occurred in the conventional carotid stent arm but not in the CGuard™ EPS-treated patients (12% vs 0%).

Dr. Karpenko commented, "We are excited that despite the higher-risk patient profile in the CGuard™ group, the interim results show a significant reduction of cerebral embolization while patient outcomes suggest a clinically-relevant benefit of the CGuard™ EPS. This mandated interim analysis gives us confidence to continue enrolling patients in this trial and extending the data-set in this potentially important advancement in the stroke prevention field."

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