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 18, 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 18, 2019, InspireMD, Inc. (the "Company") announced that its CGuard™ Embolic Prevention System (EPS) will be featured in two live case transmissions 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 22, 2019, the Company announced results from an initial clinical study of the CGuard™ Embolic Prevention System (EPS) with SmartFit™ technology in a presentation at LINC. 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 18, 2019
99.2	Press release dated January 22, 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 22, 2019

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD's CGuard™ Embolic Prevention System to be Prominently Featured in Live Case Transmissions at LINC, 22 nd to the 25 th January 2019, in Leipzig, Germany

Several Clinical Presentations, Updates, and Panel Discussions on CGuard EPS to also be presented

Tel Aviv, Israel— January 18, 2019 – InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced that its CGuard™ Carotid Embolic Prevention System (EPS) will be featured in two live case transmissions at the Leipzig Interventional Course (LINC) 2019 to be held from January 22nd to the 25th at the Trade Fair Leipzig, Hall 2 in Leipzig, Germany. CGuard™ EPS will also be featured in two panel discussions at the conference.

The two live cases:

Tuesday, 10:57 – 11:22 Live from Bergamo Technical Forum · Room 3
Case 21 – BG 02: male, 64 years (D-V)
Symptomatic left carotid artery disease in a patient with coronary artery disease
Operators: F. Castriota, A. Micari

Tuesday, 16:30 – 18:00 Live from Leipzig Technical Forum · Room 3
Case 27 – LEI 09: female, 56 years (L-K)
Restenosis of the left common carotid artery after TEA
Operators: A. Schmidt, S. Brunlich

Additional presentations featuring CGuard™ EPS will include:

What:	Initial clinical study of the new CGuard™ MicroNet® covered carotid-stent: One size fits all – experimental data and clinical results C. Wissgott, MD, Germany
When:	January 22, 10:27 – 10:33 AM Central European Time
Where:	Room 3 – Technical Forum

What:	PARADIGM-EXTEND prospective academic trial of CGuard™ MicroNet® covered self-expandable stent system: Cumulative 3-year clinical and duplex ultrasound evidence for safety, efficacy and durability of stroke prevention Professor P. Musialek, Poland
When:	January 22, 15:05 – 15:10 PM Central European Time
Where:	Room 7 – Speaker's Room

What:	Intermediate results of a prospective randomized study in carotid artery revascularisation: the Acculink™ stent vs. the mesh covered stent (CGuard™) P. Ignatenko, MD, Russia
When:	January 22, 15:15 – 15:20 PM Central European Time
Where:	Room 7 – Speaker's Room

What: Interim results from a prospective real-world multicentre clinical practice of CAS using the CGuard™ embolic prevention system: the IRONGUARD 2 study W. Mansour, MD, Italy
When: January 22, 15:20 – 15:25 PM Central European Time
Where: Room 7 – Speaker's Room

What: Comparative analysis of carotid artery stenting and carotid endarterectomy in clinical practice Professor Andrey Karpenko, Russia
When: January 22, 15:30 – 15:35 PM Central European Time
Where: Room 7 – Speaker's Room

The CGuard™ Carotid Embolic Prevention System will also be featured at the Company's booth (18c2). InspireMD will be represented by its management, sales and clinical staff and welcomes all enquiries from clinicians and other interested parties.

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 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.

Investor Contacts:

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InspireMD Announces Results from Initial Clinical Study of The CGuard™ Embolic Prevention System (EPS) with SmartFit ™ Technology

"Initial Clinical Study of the New CGuard™ EPS MicroNet® Covered Carotid Stent: 'One Size Fits All'" presented at the LINC 2019 Congress

Tel Aviv, Israel— January 22, 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 details of a new investigator-initiated trial entitled, "Initial Clinical Study of the New CGuard™ EPS MicroNet® Covered Carotid Stent: 'One Size Fits All,'" at the Leipzig Interventional Course (LINC), which is being held January 22-25, 2019 in Leipzig Germany.

Prof. Christian Wissgott, from the Institute for Diagnostic and Interventional Radiology/Neuroradiology, Westkuestenklinikum Heide – Academic Teaching Hospital of the Universities of Kiel, Luebeck and Hamburg, presented his findings using a 10mm diameter CGuard™ EPS with SmartFit™ technology across a broad range of carotid artery diameters, under a differentiated concept of "One Size Fits All."

"One of the keys to successfully treating patients with carotid artery disease is to employ a device that is optimally sized," commented Prof. Wissgott. "With variations of diameters between the common carotid artery (CCA) and the internal carotid artery (ICA), as well as x-ray images giving significant diameter errors due to projection angles, the correct size choice of a carotid stent is frequently challenging. I believe CGuard™ EPS with SmartFit™ technology overcomes this significant challenge."

Prof. Wissgott concluded through in-vitro bench testing that the "One Size Fits All" CGuard™ EPS with SmartFit™ technology demonstrated a near flat chronic outward radial force in the range of 5.5 to 9.0mm diameters, meaning the force against a vessel wall in a 5.5mm vessel and that in a 9.0mm vessel are similar. In the subsequent initial clinical study of 30 consecutive routine patients with a range of carotid artery diameters from 9.0 mm in the CCA to 5.2 mm in the ICA and diameter changes between the CCA and ICA of 2.6mm, Prof. Wissgott demonstrated that, by using a 10mm diameter CGuard™ EPS in all cases, the "One Size Fits All" SmartFit™ technology readily adapts to a range of carotid artery diameter changes and offers additional protection against embolic events that can lead to stroke.

The CGuard™ EPS with SmartFit™ was implanted with 100% technical success with no peri-procedural complications and no major or minor strokes at the six-month follow up. Duplex ultrasound, which measures flow through the carotid artery, confirmed that all ECA (external carotid arteries) were fully patent in all cases. In addition, a subgroup of 10 patients underwent DW-MRI follow-up at 30 days and at six months with no new ipsilateral lesions observed.

Dr. James Barry, President and CEO of InspireMD, Inc., commented, "Prof. Wissgott's in vitro and initial clinical evaluations show the potential of the CGuard™ EPS with SmartFit™ technology to simplify treating patients with carotid artery disease by using a "One Size Fits All" concept for a majority of carotid artery diameters within patients, and between patients, with excellent clinical results. Additionally, the CGuard™ EPS with SmartFit™ does not forshorten when implanted as do many conventional closed-cell stents and next generation double-layer stents. This allows us to offer what we believe is the easiest-to-use carotid device and procedure available on the market today, while most importantly continuing to provide maximum protection against stroke."

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.

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