

# INSPIREMD, INC.

## **FORM 8-K** (Current report filing)

Filed 11/13/18 for the Period Ending 11/13/18

|             |   |
|-------------|---|
| 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   |

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): November 13, 2018

**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)

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

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(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.

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**Item 8.01 Other Events.**

On November 13, 2018, InspireMD, Inc. announced that its CGuard™ Embolic Prevention System will be featured in several presentations at the Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium), which is being held November 13-17 in New York. 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

| <b>Exhibit<br/>Number</b> | <b>Description</b>                                     |
|---------------------------|--|
| 99.1                      | <a href="#">Press Release, dated November 13, 2018</a> |

**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: November 13, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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**InspireMD Announces Upcoming Presentations at the 45th Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium)**

**Tel Aviv, Israel— November 13, 2018** – 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 the Company’s CGuard™ Embolic Prevention System will be featured in several podium presentations during the upcoming VEITHsymposium, which is being held November 13-17 in New York.

Details of the presentations are as follows:

**Thursday November 15<sup>th</sup> :**

**INTERNATIONAL GUEST FACULTY PROGRAM**

Location: Sutton Parlor Center, 2nd Floor

***Title: Clinical Results And Mechanical Properties Of A MicroNet Covered Carotid-Stent (CGUARD)***

Time: 15:37 PM - 15:42 PM

Presenter(s): Christian Wissgott, MD, Assistant Director at Westküstenklinikum Heide, Heide, Germany.

**Friday, November 16<sup>th</sup> :**

**NEW AND IMPROVED TECHNOLOGY AND TECHNIQUES FOR CAROTID TREATMENT AND CAS: MESH COVERED STENTS AND TRANSCERVICAL TRANSCAROTID ARTERY REVASCULARIZATION (TCAR)**

Location: Grand Ballroom East, 3rd Floor

Moderators: Frank J. Veith, MD / Wesley S. Moore, MD

**MESH COVERED STENTS**

***Title: Update on the Three Mesh Covered Stents For CAS: What Are the Differences Between Them And What Is The Status Of Their Safety And Efficacy***

Time: 8:00 AM - 8:05 AM

Presenter(s): Max Amor, MD, Interventional Cardiologist, University of Medicine – Nancy, Director, Cardiovascular Department, Clinic Louis Pasteur Essey-Lès-Nancy, Essey-Lès-Nancy, France

***Title: Update on Results with the C-Guard MicroNet Mesh Covered Stent for CAS (From Inspire MD): Does It Prevent Strokes: Does It Cause ISR Or Other Long-Term Problems: Can It Have Value in Other Vascular Beds***

Time: 8:06 AM - 8:11 AM

Presenter(s): Piotr Musialek, MD, DPhil, Jagiellonian University Professor of Cardiovascular Medicine, Jagiellonian University Dept. of Cardiac & Vascular Diseases, Consultant in Vascular Medicine and Cardiology, John Paul II Hospital, Krakow, Poland, Krakow, Poland

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**Title: *Why A Reinvigoration of CAS Is Justified by Better Embolic Protection And Newer Mesh Covered Stents; OCT Proves It***

Time: 8:54 AM - 8:59 AM

Presenter(s): Carlo Setacci, MD, Professor of Vascular Surgery, University of Siena Director, Vascular and Endovascular Surgery Unit University of Siena, Siena, Italy

**CAROTID TOPICS RELATED TO NEW DEVELOPMENTS, IMPROVED TECHNIQUES AND TECHNOLOGY, CAS VS. CEA AND CAROTID BODY TUMORS**

Moderators: Ali F. AbuRahma, MD / Wesley S. Moore, MD

**Title: *Midterm Comparative Results of CAS With 2 Mesh Covered Stents – The C-Guard (InspireMD) And The Roadsaver (Terumo)***

Time: 1:24 PM - 1:29 PM

Presenter(s): Maria Antonella Ruffino, MD, EBIR, Vascular Interventional Radiologist, Vascular Radiology - AOU Cittu della Salute e della Scienza di Torino, Torino, Italy

**Saturday, November 17<sup>th</sup> :**

**HOT CAROTID AND VERTEBRAL TOPICS – TOO GOOD TO MISS (4 ½ MINUTE FAST PACED TALKS)**

Location: Grand Ballroom East, 3rd Floor

Moderators: Frank J. Veith, MD / Enrico Ascher, MD

**Title: *Results of A Multicenter Italian Registry Of Real World CAS With The C-Guard Mesh Covered Stent: The IRONGUARD 2 Study***

Time: 1:20 PM - 1:25 PM

Presenter(s): Laura Capoccia, MD, PhD, Assistant Professor of Vascular Surgery University

Vascular Surgeon, Vascular and Endovascular Surgery Division, Department of Surgery, Rome, Italy

Francesco Speciale, MD, Vascular and Endovascular Surgery Division, Department of Surgery, “Paride Stefanini” “Sapienza”, University of Rome

**About VEITHsymposium**

VEITHsymposium provides vascular surgeons, interventional radiologists, interventional cardiologists and other vascular specialists with a unique and exciting format to learn the most current information about what is new and important in the treatment of vascular disease. The Event features presentations from world renowned vascular specialists with emphasis on the latest advances, changing concepts in diagnosis and management, pressing controversies and new techniques.

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**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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