# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 11/28/18 for the Period Ending 11/28/18

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| 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): November 28, 2018

## 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 November 28, 2018, InspireMD, Inc. announced that its CGuard™ Embolic Prevention System (EPS) has been granted regulatory approval by the Australian Therapeutic Goods Administration for commercial sale and reimbursement in Australia. 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 Number | Description |
|---|---|
| 99.1 | Press release dated November 28, 2018 |

**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 28, 2018

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

**InspireMD Announces Regulatory and Reimbursement Approval of CGuard™ Embolic Prevention System in Australia**

*Commercial Launch to Occur Immediately*

**Tel Aviv, Israel— November 28, 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 its novel CGuard™ Embolic Prevention System (EPS) has been granted regulatory approval by the Therapeutic Goods Administration (Part of the Australian Government's Department of Health) for commercial sale and reimbursement in Australia. Launch will commence immediately in collaboration with InspireMD's local distribution partner, Diverse Devices Pty Ltd., of Sydney.

"Regulatory approval of CGuard™ EPS in Australia represents an important step toward our goal of expanding commercial availability into new territories, and the Asia-Pacific region represents a significant opportunity for our Company," said James Barry, PhD, Chief Executive Officer of InspireMD. "With 22 million residents, Australia ranks third behind only Japan and China in terms of total healthcare spending. More significantly, however, is that Australia's Therapeutic Goods Administration sets a very high bar in terms of regulatory and reimbursement approval of new medical devices. We believe our approval reflects not only the agency's recognition of CGuard's differentiating features versus conventional carotid stents, but also the need for safer treatments for carotid artery disease. We are eager to begin offering this novel technology to patients in Australia imminently."

Aidan McEvoy, Director of Diverse Devices Pty Ltd., commented, "At Diverse Devices, we strive to bring the latest technologies to health care professionals across Australia, and we are pleased to add CGuard™ EPS to our portfolio of the most innovative stent products available on the market today."

**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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