

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 03/27/18 for the Period Ending 03/27/18

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

**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): March 27, 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

(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 March 27, 2018, InspireMD, Inc. announced that it has received regulatory approval for the CGuard™ Embolic Prevention System and MGuard Prime™ in Peru. 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 March 27, 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: March 27, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



**InspireMD Receives Regulatory Approval for both CGuard™ EPS
and MGuard Prime™ in Peru**

Tel Aviv, Israel— March 27, 2018 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced that it has received regulatory approval for the CGuard™ Embolic Prevention System (EPS) and MGuard Prime™ in Peru. The approval was granted by Peru’s Ministry of Health.

In May of 2017 the company announced it had entered into an exclusive distribution agreement with Dispositivos Medicos E.I.R.L, a leading medical device distributor in Peru. The two companies have collaborated since the initial agreement in order to successfully secure this regulatory approval. Sales for both products, CGuard™ EPS and MGuard Prime™, will commence immediately in Peru.

Maximiliano Arboleda, General Manager of Dispositivos Medicos E.I.R.L, commented, “We have been working closely with InspireMD in order to educate key opinion leaders and top hospital chains in preparation for marketing clearance, which we have now secured. The clinical data from both of these products is quite impressive and we expect our physicians to start using the products very quickly.”

“We are excited to officially launch our commercial efforts in Peru following an extensive regulatory review and approval by the Peruvian health authorities,” said Agustin Gago, EVP and Chief Commercial Officer of InspireMD. “The approval of both CGuard™ EPS and MGuard Prime™ in Peru is further recognition of the importance of our products and supports our expansion into Latin America. With a population of more than 30 million and solid GDP growth, Peru is an attractive market and Dispositivos Medicos E.I.R.L is a great partner, as it represents many of the leading global medical device manufacturers in Peru.”

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.

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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