

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): July 23, 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 July 23, 2018, InspireMD, Inc. announced that it has established its first two Centers of Excellence at leading hospitals in Europe. 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 July 23, 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: July 24, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces Opening of First Two CGuard™ EPS Centers of Excellence

Tel Aviv, Israel— July 23, 2018 - InspireMD, Inc. (NYSE AMER: 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 it has established its first two Centers of Excellence (COE) at leading hospitals in Europe.

The first COE is at the Augusta Hospital Clinic for Vascular Surgery in Düsseldorf, Germany and is led by Prof. Ralf Kolvenbach, Head of the Cardiovascular Diseases Department and Medical Director of the Catholic Hospitals. Prof. Kolvenbach is one of the leading vascular surgeons in Germany and treats a significant number of patients suffering from carotid artery disease. The second COE is at the Maria Cecilia Hospital, in Cotignola, Italy and is led by Dr. Alberto Cremonesi, Chief of the Cardiovascular Department and a leading interventional cardiologist in Italy, also treating a large number of patients suffering from carotid artery disease.

The Augusta Hospital Clinic for Vascular Surgery and Maria Cecilia Hospital recently held their first workshop, which covered the indications and strategies for the use of CGuard™ EPS. This included lectures and proctoring of live cases to illustrate the advantages of the minimally invasive carotid artery revascularization procedures using CGuard™ EPS versus endarterectomy, which is the more commonly utilized surgical approach.

“We are privileged to have established these first two CGuard™ EPS Centers of Excellence at two of the leading hospitals in Germany and Italy, which are key markets for CGuard,” commented James Barry, PhD, Chief Executive Officer of InspireMD. “COEs are a key element in our broader strategy to educate and convert vascular surgeons and interventionalist away from the more invasive surgical carotid endarterectomy procedure and towards CGuard™ EPS in the treatment of patients with carotid artery disease given the sustained safety and embolic and stroke prevention benefits clinically seen with the CGuard™ EPS. Converting physicians away from treating carotid artery disease with surgery will result in a significant increase in the addressable market for our product, which we believe is a billion-dollar product category in carotid artery procedures alone. The goal of these COEs is to train, educate and share experiences among both surgeons and interventionalists to incorporate CGuard™ EPS into their daily practice as the system of choice for carotid revascularization and stroke prevention. We look forward to announcing additional COEs as we continue to execute on our strategy.”

Agustin Gago, EVP and Chief Commercial Officer of InspireMD, noted, “The initial workshops held at both the Augusta Hospital Clinic for Vascular Surgery and at the Maria Cecilia Hospital were well attended and illustrate the growing interest among vascular surgeons as well as interventionalists in CGuard™ EPS, which utilizes our patented MicroNet® technology.”

About InspireMD, Inc.

InspireMD has developed the CGuard™ Embolic Protection System to aid vascular surgeons and other medical specialists to guard against the debilitating effects of stroke caused by carotid artery disease, one of the highest risk factors of this condition. CGuard™ EPS, with its patented MicroNet® and SMARTFIT™ technologies, provides a minimally invasive, safe and effective alternative to surgery and other interventions with their associated risk factors. InspireMD intends to pursue further applications of its platform MicroNet® technology in neurovascular, coronary and peripheral artery procedures.

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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