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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): September 8, 2020

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)

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, par value $0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

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 September 8, 2020, InspireMD, Inc. (the "Company") issued a press release reporting that it has received approval from the U.S. Food and Drug Administration (FDA) of its Investigation Device Exemption (IDE), thereby allowing the Company to proceed with a pivotal study of its CGuard™ Carotid Stent System, CARENET-III, for prevention of stroke in patients in the United States.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated September 8, 2020

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: September 8, 2020

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

Exhibit 99.1

InspireMD Announces Approval of Investigational Device Exemption (IDE) for Pivotal Study of CGuard Carotid Stent System

IDE Approval to Pave the Way for Pivotal Study of CGuard System for Carotid Artery Disease and Stroke Prevention in the United States

Tel Aviv, Israel — September 8, 2020 – InspireMD, Inc. (NYSE American: NSPR), the developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease (CAD), today announced the U.S. Food and Drug Administration ("FDA" or "the Agency") has granted approval for the company to proceed with a pivotal study of the CGuard™ Carotid Stent System, CARENET-III, for prevention of stroke in patients in the United States.

"This is a key milestone in the history of our company as it helps pave the way for us to initiate a clinical trial of CGuard EPS for addressing Carotid Artery Disease and preventing stroke in the United States market. This will be the first U.S.-based study of CGuard which is a cornerstone of our global expansion plans," said Marvin Slosman, InspireMD's CEO. "A pivotal trial of this kind requires significant preparation and allocation of resources and we have already begun to move pieces into place in order to plan the initiation of our CARENET-III study. The FDA approval of the IDE represents an important step in enabling us to conduct a pivotal clinical trial to demonstrate the potential for CGuard EPS against carotid artery disease, which accounts for more than 6.2 million deaths worldwide, and a cost burden of more than $34 billion in the U.S. alone."

The CARENET-III study would be a 315-subject study with up to 40 U.S. institutions. The company will provide additional details as plans advance.

About the CGuard® EPS

The CGuard® Embolic Protection System is an advanced platform solution designed to deliver the flexibility of the traditional open-cell stent with advanced protection from peri-procedural and post-procedural embolic events caused by plaque prolapse through the stent strut that can lead to stroke. CGuard's unique MicroNet® technology mitigates the prolapse and associated embolization and has shown superior clinical outcomes for patients against alternative carotid stent types, conventional or next-generation double-layer stents, as well as invasive procedures such as endarterectomy, a major surgical procedure. InspireMD's CGuard™ has created a new dimension in the protected treatment of carotid artery disease with the potential to truly establish a new standard of care for the management of carotid artery disease and stroke prevention.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for carotid stenting 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 and NSPR.WSB.

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) the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy; (v) intense competition in the medical device industry from much larger, multinational companies, (vi) product liability claims, (vii) product malfunctions, (viii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (ix) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (x) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (xi) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xii) our reliance on single suppliers for certain product components, (xiii) 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 (xiv) 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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