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): June 10, 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 June 10, 2020, InspireMD, Inc. (the "**Company**") issued a press release announcing the publication of the results of its PARADIGM trial in the *EuroIntervention* journal. In that trial, 101 unselected consecutive real-life patients were treated with the Company's CGuard™ MicroNET covered stent for carotid stenosis and were monitored for postprocedural neurologic events for a period of 12 months. The results displayed sustained protection against any such neurologic events. A copy of that 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 June 10, 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: June 10, 2020

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

Exhibit 99.1

InspireMD Announces Publication of 12-Month Results of CGuard™ EPS PARADIGM Trial in *EuroIntervention*

Results indicate that 12 months after carotid intervention the CGuard EPS MicroNET-covered stent delivers sustained protection against postprocedural neurologic events

Tel Aviv, Israel — June 10, 2020 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease treatment, announced today that 12-month PARADIGM trial results have been published in the *EuroIntervention* journal. The paper, entitled, "Routine MicroNET™ covered embolic prevention stent system use for consecutive symptomatic and increased stroke-risk asymptomatic carotid stenosis revascularization: Twelve-month outcomes from the PARADIGM study," details the results of 101 unselected consecutive real-life patients treated with the CGuard™ MicroNET covered stent for carotid stenosis and the 12-month prevention of postprocedural neurologic events.

101 unselected consecutive patients for carotid revascularization were enrolled in the PARADIGM trial. At 30 days, only one adverse event occurred (a minor transient stroke with no other strokes, myocardial infarctions, or deaths. Furthermore, these study results show that no strokes occurred between 30 days and twelve months.

"PARADIGM evaluates CGuard™ in unselected consecutive patients for carotid revascularization, with higher clinical standards, and constitutes a reference for future carotid stenting studies," said Marvin Slosman, Chief Executive Officer of InspireMD. "This is substantiated by a new paper in *EuroIntervention,* a prestigious medical journal covering the latest advancements in vascular intervention. The risk of peri-procedural or post-procedural stroke in the treatment of carotid stenotic lesions has long been a significant obstacle to more widespread adoption of less invasive stenting as an alternative to surgery for carotid revascularization. We believe these new data demonstrate the sustained safety of our unique CGuard™ EPS system incorporating proprietary MicroNet™ technology. Data such as these are integral to our ongoing efforts to make CGuard™ the eventual standard of care because of the many clinical benefits of CGuard™.

"Our present work indicates that an effective MicroNET™-covered stent protection against post-procedural neurologic events extends at least mid-term in the absence of any procedure- or device-related issues," stated Dr. Piotr Musialek, co-author of the paper and lead investigator of the PARADIGM study.

EuroIntervention is an international peer-reviewed journal whose aim is to create a community of high-quality research and education in the field of percutaneous cardiovascular interventions. *EuroIntervention* is the official Journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI).

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for the 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 symbols 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) 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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