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 3, 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 3, 2020, InspireMD, Inc. (the "**Company**") issued a press release that included updated data regarding the results of a large, long-term PARADIGM-EXTEND study involving the Company's CGuard™ Embolic Prevention System (EPS). The data was included in a presentation made as part of the European Society of Cardiology 2020 Carotid Update e-presentation at the European Society of Cardiology (ESC) Congress 2020. The study is an investigator-driven, on-going study performed with CGuard Carotid stent for primary and secondary stroke prevention in a large, consecutive all-comers population, with 5 years (60 months) follow-up.

The results tracked 480 patients who completed the 30-day follow-up. There were no peri-procedural major strokes or death among those 480 patients. The total death/stroke /myocardial incidence at 30 days was 1.04% (5/480) due to two minor strokes, one myocardial infarction and two stent-unrelated deaths. 354 of the 480 patients completed a 12-month follow-up, with only one patient experiencing in-stent restenosis, constituting only 0.28% (1/354) of those participating. At the 12-month follow-up, there were no other device-related adverse clinical events. For the 46 patients who completed the 60-month follow-up period, there was only one more case of in-stent restenosis and no additional cases of device-related stroke.

A copy of the press release including the updated data from the study 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 3, 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 3, 2020

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

Exhibit 99.1

InspireMD Announces the European Society of Cardiology 2020 "Best Poster Award" for Updated Data from the PARADIGM-EXTEND Study

Tel Aviv, Israel — September 3, 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 announces the award for Best ESC Congress Poster for the presentation of updated data from the large, long-term PARADIGM-EXTEND study of the CGuard™ Embolic Prevention System (EPS), as part of the European Society of Cardiology 2020 Carotid Update e-presentation at the European Society of Cardiology (ESC) Congress 2020. PARADIGM/EXTEND is an investigator-driven on-going study performed with CGuard Carotid stent for primary and secondary stroke prevention in a large, consecutive all-comers population, with 5 years (60 months) follow-up.

PARADIGM-EXTEND current results for 480 patients of the expected total of 550 that completed the 30-day follow-up were presented. There were no peri-procedural major strokes or death. The total death/stroke /myocardial incidence at 30 days was 1.04% (5/480) due to two minor strokes, one myocardial infarction and two stent-unrelated deaths. In the study, 354/480 patients completed the 12-month follow-up with only 1 patient experiencing in-stent restenosis, 0.28% (1/354). At the 12-month follow-up there were no other device-related adverse clinical events. Finally, 46/480 patients completed the 60-month follow-up period with one more case of in-stent restenosis and no additional cases of device-related stroke.

The lead investigator of the study and ESC Congress presenter was Prof Piotr Musialek, Jagiellonian University Department of Cardiac & Vascular Diseases John Paul II Hospital, Kraków, Poland. Prof Musialek stated, "In consecutive all-comer patients, CGuard EPS stent nearly abolished, in an unprecedented magnitude, stroke risk in relation to carotid restenosis. Based on the PARADIGM-EXTEND and other accumulated clinical data on CGuard's safety and efficacy, in our ESC 2020 Carotid Update Lecture we indicated that increasing the use of the MicroNet-covered stent demonstrates a fundamental change in the carotid revascularization paradigm, with significantly larger proportions of patients now able to benefit from this technology and a percutaneous procedure rather than surgery."

"The results from this investigator-driven initiative and resulting recognition of best poster, continue to demonstrate that CGuard provides extended safety and stroke prevention efficacy when added to optimized medical therapy. We continue to prioritize patient care by focusing on measuring evidence that confirms the superiority of CGuard EPS in preventing neurovascular events. Recognition of this data through acknowledgement of this sort builds confidence and awareness within the physician community. Our global expansion strategy and intention to bring CGuard to the United States builds on the foundation of real-world experience and results. We believe the novel MicroNet technology, which is at the heart of the CGuard system, provides a clear differentiator in terms of prevention of additional ischemic events and restenosis," said Marvin Slosman, InspireMD's CEO. "We are grateful to Professor Musialek and Jagiellonian for their work on the PARADIGM-EXTEND study, and we look forward to sharing further results of this study and other key milestones as we continue to follow patients' outcomes."

The ESC Congress 2020 is being held digitally from August 29-September 2, 2020 and can be accessed via https://www.escardio.org/Congresses-&-Events/ESC-Congress.

About the PARADIGM-EXTEND Study

The PARADIGM-EXTEND study was designed to evaluate long-term clinical efficacy and safety of the CGuard system's use in 550 consecutive carotid revascularization patients. The study is an all-comer, all-referrals-tracked study with no exclusion criteria other than a lack of Neurovascular Team-determined indication. Clinically asymptomatic patients were to receive revascularization only in case of increased-stroke-risk characteristics. Adverse events are independently adjudicated. To date, 480 patients (39-87 years, 60% symptomatic, 142 women) with 514 arteries crossed the first follow-up window of 30 days.

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.

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