INSPIREMD, INC.

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report: **July 26, 2021**

InspireMD, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-35731	**26-2123838**
(Commission File Number)	(IRS Employer Identification No.)
4 Menorat Hamaor St. **Tel Aviv, Israel** (Address of Principal Executive Offices)	**6744832** (Zip Code)

(888) 776-6804
(Registrant's Telephone Number, Including Area Code)

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 each exchange on which registered
Common Stock, par value $0.0001 per share	NSPR	The Nasdaq Capital Market LLC
Series B Warrants, exercisable for one share of Common Stock	NSPRZ	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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, 2021, InspireMD, Inc. (the "Company") issued a press release announcing the initial enrollment and completion of the first cases of the Company's C-Guardian trial of its CGuard™ Embolic Prevention Stent System.

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 July 23, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: July 26, 2021

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

Exhibit 99.1

InspireMD Enrolls and Treats First Patients at Ballad Health System in U.S. Registration C-Guardian Clinical Trial of CGuard EPS

Tel Aviv, Israel— July 23, 2021 - InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) device for the treatment of Carotid Artery Disease (CAD) and stroke prevention, today announces the initiation of enrollment and successful completion of the first cases of the Company's U.S. registration C-Guardian trial of CGuard EPS.

The first patients, who were under the care of principal investigator, Chris Metzger, M.D., system chair of clinical research at Ballad Health System in Eastern Tennessee, were successfully implanted with the CGuard EPS stent device. These are the first of 315 patients who are expected to be enrolled in the trial and treated with CGuard EPS in the treatment of carotid artery stenosis in symptomatic and asymptomatic patients undergoing carotid artery stenting.

"I believe that the initiation of this trial marks an important milestone for the potential approval of CGuard EPS and the potential of CGuard EPS in advancing the treatment of CAD and stroke prevention," commented Dr. Metzger. "The wealth of clinical evidence and real-world experience outside the U.S. in the approved served markets with CGuard, demonstrating positive outcomes for patients was very compelling, which drew us to lead this trial to advance the CGuard EPS in the U.S. We are thrilled to participate in such an important effort to bring next generation devices to the growing therapeutic effort of treating CAD."

InspireMD CEO, Marvin Slosman, added, "This milestone marks the beginning of what we consider to be the next step in our journey of establishing CGuard EPS as the leading stent device for treatment of CAD and the transition from surgical intervention to endovascular therapy. The U.S. market has been a priority for our company and we believe that the C-Guardian trial will potentially pave the way to CGuard becoming available to physicians and their patients to realize the ongoing results from our current 33 served global markets. We are grateful to Dr. Metzger and the Ballad Health System for leading this effort and their commitment to advancing our collective goals to improve patient outcomes and stroke prevention."

InspireMD Director, and renowned Cardiologist and Carotid expert, Dr. Gary Roubin, shared, "I am thrilled to contribute to the realization of this important milestone for InspireMD and encouraged to see the many years of advancing the treatment of Carotid Artery Disease take another step with the potential of having CGuard available to the medical community in the U.S."

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.

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. For example, the Company is using forward-looking statements when it discusses the number of expected patients to be enrolled in the trial, that the initiation of the trial marks an important milestone for the potential approval of the CGuard EPS and towards advancing the treatment of CAD and stroke prevention, and that the initiation of the trial marks the beginning of the next step in the Company's journey towards CGuard EPS being utilized in the U.S. 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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