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: **October 13, 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	NSPRW	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 October 13, 2021, InspireMD, Inc. (the "Company") issued a press release announcing that the Company received reimbursement approval for its CGuard™ Embolic Prevention System from the French National Authority for Health.

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 October 13, 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: October 13, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Receives Reimbursement Approval for CGuard™ Embolic Prevention System from the French National Authority for Health

Tel Aviv, Israel— October 13, 2021 - InspireMD, Inc. (Nasdaq: NSPR), a global developer of the CGuard™ Embolic Prevention Stent System (EPS) device for the treatment of Carotid Artery Disease (CAD) and stroke prevention, today announced that its CGuard EPS stent system has received a positive opinion from the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDIMTS) of the French National Authority for Health (HAS) regarding reimbursement in France, and the CGuard EPS is being added to the list of reimbursed medical products (LPPR) effective October 25, 2021. This was the final step to full commercial launch of CGuard EPS following CNEDIMTS' positive opinion for reimbursement received by the Company on May 11, 2021 for the treatment of symptomatic and non-symptomatic lesions when surgery is not indicated.

The CGuard® EPS Self-Expanding Carotid Stent is the latest generation open-cell nitinol self-expanding stent with patented MicroNet® mesh technology designed to prevent the risk of early and late embolism.

"This milestone now provides physicians in France with the choice to use CGuard EPS in the treatment of carotid artery disease and stroke prevention. We strive to improve the standard of care in the treatment of carotid artery disease, by moving away from surgical endarterectomy towards less invasive options such as the CGuard EPS Carotid Stent System. We believe that the unique and proprietary design of our system, is the most advanced and safest stent system on the market today," said Marvin Slosman, CEO of InspireMD.

Andrea Tommasoli, Senior VP Global Sales and Marketing commented, "We worked closely with HAS for over a year to gain reimbursement approval, and its opinion validated the efficacy and safety of use of the CGuard EPS carotid stent based on our unmatched and expanding portfolio of clinical evidence and the results of our extensive clinical research program. The expansion of CGuard into France represents further progress in our efforts to grow the geographic reach of our commercial products as we continue to establish CGuard as the carotid device of choice among physicians across the world that treat carotid disease."

The CGuard® carotid stent, is commercially established in 33 markets to date, adding France to our growing global expansion.

ClinicalTrials.gov Identifier: NCT04900844

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 its belief that the unique and proprietary design of its system is the most advanced and safe stent system on the market today and that the expansion of CGuard into France represents further progress in its efforts to grow the geographic reach of its commercial products. 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 filings with the SEC. 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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