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: **November 4, 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 November 3, 2021, InspireMD, Inc. (the "Company") issued a press release announcing the publication of the 12-month results of the Company's CGuard™ EPS SIBERIA Trial in the Journals of the American College of Cardiology.

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 November 3, 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: November 4, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Publication of 12-Month Results of CGuard™ EPS SIBERIA Trial in *Journals of the American College of Cardiology: Cardiovascular Interventions*

Tel Aviv, Israel— November 3, 2021 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of Carotid Artery Disease (CAD), today announced that results from the investigator-initiated SIBERIA randomized clinical trial of CGuard EPS, that evaluated the peri-procedural and 30-day silent brain infarcts associated with the use of its MicroNet™ covered stent (CGuard) versus a conventional "workhorse" open-cell Acculink™ nitinol stent were published this week. The principal investigator study was published in Journals of the American College of Cardiology (JACC) and is titled *Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization*.

The main findings of the study included:

- CGuard MicroNet-covered carotid stent, in relation to a first-generation stent:
  - reduced 4.5-fold the magnitude of peri-procedural silent brain infarcts volume; and
  - abolished post-procedural silent infarcts, that were on-going with the first-generation stent.
- This data constitute level 1 evidence in favor of a CGuard MicroNet-covered stent in demonstrating reduction of cerebral infarcts in neuroprotective CAS versus Acculink.

This randomized control study evaluated 30-day silent brain infarcts associated with the use of the Acculink conventional open-cell nitinol stent vs the CGuard MicroNet-covered stent. The Micronet-covered stent significantly reduced periprocedural cerebral embolism, showing an average of 57% reduction in lesion per patient (171 mm^3 vs 73 mm^3 ($P = 0.017$)) and a 4.5 fold reduction in total volume of periprocedural lesions (701 mm^3 vs 157 mm^3 ($P = 0.007$)) when compared to Acculink. Additionally, postprocedural (48 hours to 30 day) cerebral was abolished by the MicroNet covered stent, while it was ongoing with the conventional, first-generation carotid stent.

"We are very pleased with the results of the SIBERIA trial and the subsequent publication, as the first randomized, controlled clinical trial to directly compare CGuard EPS head-to-head against a widely used conventional stent," said Marvin Slosman, Chief Executive Officer of InspireMD. "The study highlights our growing body of real-world clinical evidence as well as scientific evidence showing the superiority of the CGuard device in preventing brain embolization. This proprietary technology has the potential to change the standard of care and help physicians make better treatment decisions for the management of stroke and overall carotid artery disease. We are excited to further demonstrate the technology behind CGuard EPS with our C-Guardians registrational trial in the United States, for which we are currently enrolling patients."

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 Nasdaq under the ticker symbol NSPR, and certain warrants are quoted on the Nasdaq under the symbol NSPRZ.

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", "scheduled" or similar words. For example, the company is using forward-looking statements when it discusses that the study highlights growing evidence of the superiority of the CGuard device in preventing brain embolization and that the technology has the potential to change the standard of care and help physicians make better treatment decisions for the management of stroke and overall carotid artery disease. 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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