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 (Date of earliest event reported): **August 31, 2023**

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

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 7.01 Regulation FD Disclosure.

On August 31, 2023, InspireMD, Inc. (the "Company") issued a press release titled "InspireMD Announces Abstract of 30-Day Results from the C-Guardians U.S. Investigational Device Exemption (IDE) Clinical Trial Accepted for Presentation at VIVA23". A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated August 31, 2023 (furnished herewith pursuant to Item 7.01)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 31, 2023

By: */s/ Amir Kohen*
Name: Amir Kohen
Title: Interim Chief Financial Officer

Exhibit 99.1

InspireMD Announces Abstract of 30-Day Results from the C-Guardians U.S. Investigational Device Exemption (IDE) Clinical Trial Accepted for Presentation at VIVA23

Tel Aviv, Israel, and Miami, Florida — August 31, 2023 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for the prevention of stroke, today announced that an abstract detailing upcoming 30-day results from its C-Guardians U.S. IDE clinical trial has been accepted for presentation as a late-breaking clinical trial at the Vascular InterVentional Advances Annual Meeting (VIVA23), which is being held October 30 through November 2 in Las Vegas.

Presentation details:

Title:	**30-Day Results from the C-Guardians Pivotal Trial of the CGuard™ Carotid Stent System**
Presenter:	Chris Metzger, M.D., System Chair of Clinical Research at Ballad Health System and lead investigator of the C-Guardians trial
Date:	Wednesday, November 1, 2023
Time:	10:45am-12:00pm PT (1:45pm-3:00pm ET)

Marvin Slosman, chief executive officer of InspireMD, stated, "We are very pleased that an abstract detailing our 30-day follow-up data from our C-Guardians IDE trial has been accepted for presentation at this year's VIVA conference, which is among the most important gatherings of endovascular specialists each year. We believe CGuard™ EPS, with its novel MiroNet™ technology, offers next-level neuroprotection that translates into superior short- and long-term patient outcomes, something we aim to demonstrate with this important trial. We also look forward to sharing one-year data from C-Guardians in the second half of next year that, if positive, may support a Premarket Approval Application (PMA) and allow us to potentially launch the CGuard Prime EPS stent system in the U.S. in the first half of 2025."

About C-Guardians

The C-Guardians clinical trial is evaluating the safety and efficacy of the CGuard™ Carotid Stent System for the treatment of carotid artery stenosis. The study, which completed enrollment in June 2023, enrolled 316 patients across 25 trial sites in the U.S. and Europe.

The trial includes both symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS). The primary endpoint includes the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the Clinical Events Committee (CEC) adjudication or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication. The performance goal will be considered to have been met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is <11.6% and the p-value is <0.025.

The company anticipates primary endpoint results from the study in H2 2024.

About VIVA

VIVA (Vascular InterVentional Advances) is a global educational event for specialists caring for patients with vascular disease. VIVA brings together attendees and faculty specializing in vascular surgery, interventional cardiology, interventional radiology, vascular medicine, neurointervention/neurosurgery, and cardiothoracic surgery, offering a uniquely comprehensive educational experience with access to some of the best minds in endovascular care.

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.

We routinely post information that may be important to investors on our website. For more information, please visit www.inspiremd.com.

Forward-looking Statements

This press release contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding the future. 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. Examples of such statements include, but are not limited to, statements relating to the C-Guardians U.S. IDE clinical trial, including 30-day results from such trial and that such results will be available to presented as a late-breaking clinical trial at VIVA23, as well as the timing and outcome of any subsequent results, PMA or potential launch. 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 our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern; our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; market acceptance of our products; an inability to secure and maintain regulatory approvals for the sale of our products; negative clinical trial results or lengthy product delays in key markets; our ability to maintain compliance with the Nasdaq listing standards; our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products; our ability to adequately protect our intellectual property; our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; entry of new competitors and products and potential technological obsolescence of our products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with our research and products and potential product liability claims; product malfunctions; price increases for supplies and components; insufficient or inadequate reimbursement by governmental and other third-party payers for our products; our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful; adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions; 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; the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk. 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:

Craig Shore
Chief Financial Officer
InspireMD, Inc.
888-776-6804
craigs@inspiremd.com

Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com
investor-relations@inspiremd.com