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): December 9, 2024

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.)**

6303 Waterford District Drive, Suite 215 Miami, Florida	**33126**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (888) 776-6804

(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 each exchange on which registered**
Common Stock, $0.0001 par value per share	NSPR	The Nasdaq Capital Market

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 7.01. Regulation FD Disclosure.

On December 9, 2024, InspireMD, Inc. (the "Company") issued a press release titled "InspireMD Announces First Patient Enrolled in the CGUARDIANS II Pivotal Study of the CGuard Prime Carotid Stent System in Transcarotid Artery Revascularization Procedures (TCAR)". A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference in this Item 7.01.

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 8.01. Other Events.

On December 9, 2024, the Company announced that the first patient has been enrolled in the Company's CGUARDIANS II clinical trial evaluating its CGuard Prime Carotid Stent System in patients undergoing carotid artery stenting via the Transcarotid Artery Revascularization (TCAR) approach.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated December 9, 2024
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: December 9, 2024

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

Exhibit 99.1

InspireMD Announces First Patient Enrolled in the CGUARDIANS II Pivotal Study of the CGuard Prime Carotid Stent System in Transcarotid Artery Revascularization Procedures (TCAR)

Study represents a significant step forward in Company's mission to serve the broadest set of physician and patient needs with best-in-class CAS and TCAR solutions

Miami, Florida — December 9, 2024 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for the prevention of stroke, today announced that the first patient has been enrolled in the company's CGUARDIANS II clinical trial evaluating its CGuard Prime Carotid Stent System in patients undergoing carotid artery stenting via the Transcarotid Artery Revascularization (TCAR) approach. The patient was enrolled by Dr. Patrick Muck at Good Samaritan Hospital, part of the TriHealth System in Cincinnati, Ohio. Dr. Muck serves as both the site principal investigator as well as a co-lead investigator of the CGUARDIANS II study.

Marvin Slosman, Chief Executive Officer of InspireMD, commented, "As we approach potential FDA approval of CGuard Prime with a CAS indication in the first half of next year, we are thrilled to have initiated the CGUARDIANS II study that, if successful, will address an ever-expanding TCAR market of roughly 30,000 procedures performed in the U.S. this year. I would like to thank Dr. Muck for helping us achieve this initial and critical enrollment milestone, and I look forward to the efficient execution of this important study as we work to enable the use of CGuard Prime in the broadest application, offering patients and physicians this next generation stenting platform, which has demonstrated best-in-class clinical outcomes in rigorous clinical studies and with over 60,000 devices sold to date."

Dr. Patrick Muck, program director and chief of vascular surgery at Good Samaritan Hospital in Cincinnati, Ohio stated, "As we begin this study of CGuard Prime in a TCAR setting, we value tremendously the prior data from the C-GUARDIANS PMA, the real-world results of this implant and its potential to advance patient care through these unmatched clinical results. The protective qualities of the MicroNet mesh offer patients the sustainable protection which is so important in both short- and long-term outcomes of this procedure. We look forward to the efficient enrollment of this study, contribution from the team of investigators and working with InspireMD on this important program."

CGUARDIANS II is a prospective, multi-center, single arm pivotal study that aims to enroll a minimum of 50 evaluable patients. The objective of this study is to evaluate acute device success and technical success of the CGuard Prime when used in conjunction with an FDA-cleared TCAR neuro-protection system in patients at high risk for adverse events from carotid endarterectomy.

More information on the study can be found at: NCT06653387

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. Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's or directors' expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation, including potential U.S. commercial 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 our 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.

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