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): October 7, 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.)**

4 Menorat Hamaor St. Tel Aviv, Israel	**6744832**
(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 October 7, 2024, InspireMD, Inc. (the "Company") issued a press release titled "InspireMD Announces Approval of Investigational Device Exemption (IDE) Application for CGUARDIANS II Pivotal Study of the CGuard Prime 80cm Carotid Stent System". 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 October 7, 2024, the Company announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Investigational Device Exemption (IDE) Application to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80cm Carotid Stent System during transcarotid revascularization (TCAR) procedures.

Exhibit Number	Description
99.1	Press release, dated October 7, 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: October 7, 2024

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

Exhibit 99.1

InspireMD Announces Approval of Investigational Device Exemption (IDE) Application for CGUARDIANS II Pivotal Study of the CGuard Prime 80cm Carotid Stent System

Miami, Florida — October 7, 2024 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for the prevention of stroke, today announced that the U.S. Food and Drug Administration (FDA) has approved the company's Investigational Device Exemption (IDE) Application to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80cm Carotid Stent System during transcarotid revascularization (TCAR) procedures.

In February 2024, InspireMD announced that Patrick Geraghty, M.D., professor of surgery and radiology, section of vascular surgery at Washington University School of Medicine in St. Louis, MO, and Patrick Muck, M.D., program director and chief of vascular surgery at Good Samaritan Hospital in Cincinnati, OH, have agreed to act as lead investigators for the trial.

Marvin Slosman, Chief Executive Officer of InspireMD, stated, "The approval of our CGUARDIANS II IDE is an important milestone and a significant step forward in our mission to serve the broadest range of physician and patient needs with a comprehensive set of tools that can deliver our best-in-class carotid stent system, CGuard Prime, for both CAS and TCAR procedures. The CGUARDIANS II study is intended to facilitate approval of the use of CGuard Prime in an optimized TCAR version and indication."

"In parallel, we continue to advance development of our comprehensive next generation TCAR Neuroprotection System, SwitchGuard NPS. Each of these initiatives helps pave the way, once approved, for us to initiate commercial sales and strive for market leadership in the United States. Our mission to improve stroke prevention and carotid disease management with our CGuard platforms continues as we build our company toward U.S. expansion and global success. Additionally, as we previously announced, we are thrilled to have Dr. Patrick Geraghty and Dr. Patrick Muck as co-principal investigators for the study, as well as a world class group of investigators committed to the trial's success," Mr. Slosman concluded.

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 one-year results from such trial presented at LINC 2024, the C-GUARDIANS II trial, including the timing of its commencement, as well as the timing and outcome of any subsequent results, potential FDA approval, or potential launch or commercialization in the U.S. or elsewhere. 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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