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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 (Date of earliest event reported): **January 31, 2024**

**InspireMD, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**001-35731**  
(Commission  
File Number)

**26-2123838**  
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

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**Item 7.01 Regulation FD Disclosure.**

On January 31, 2024, InspireMD, Inc. (the “Company”) issued a press release titled “InspireMD Receives CE Mark Recertification Under EU’s New Medical Device Regulation (MDR) Regulatory Framework”. 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 8.01 Other Events.**

On January 31, 2024, the Company announced that it has received CE Mark recertification under the European Union’s new Medical Device Regulation (MDR) regulatory framework.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release, dated January 31, 2024 (furnished herewith pursuant to Item 7.01)</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: January 31, 2024

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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### **InspireMD Receives CE Mark Recertification Under EU's New Medical Device Regulation (MDR) Regulatory Framework**

**Tel Aviv, Israel, and Miami, FL — January 31, 2024** – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Carotid Stent System (EPS) for the prevention of stroke, today announced that it has received CE Mark recertification under the European Union's new Medical Device Regulation (MDR) regulatory framework. MDR replaced the previous MDD framework, which had governed the approval and marketing of medical devices in the EU until May of 2021.

Marvin Slosman, chief executive officer of InspireMD, stated, "The transition from MDD to MDR has been challenging and has required us, and others in the medical device industry, to be comprehensive and persistent in our approach to addressing changes in requirements, timelines, and priorities during this process. We are very pleased to have now received formal recertification of our CE Mark under MDR, allowing us to continue to work to make CGuard EPS the standard of care for carotid artery revascularization in our existing commercial territories while also advancing our new product pipeline using the pathway provided under MDR."

"In parallel, our work on the Premarket Approval Application (PMA) for the C-GUARDIANS U.S. IDE trial continues to progress nicely, and we look forward to primary endpoint results in mid-2024, followed by submission of the final module of the PMA application to FDA in the second half of this year. We continue to aggressively work toward multiple value creating milestones, including the potential U.S. approval of the CGuard Prime EPS stent system in the first half of 2025," 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](http://www.inspiremd.com).

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## 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, as well as the timing and outcome of any subsequent results, the EFS, 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:

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