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): **December 20, 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 December 20, 2023, Inspire MD, Inc. (the "Company") issued a press release titled "InspireMD Announces Issuance of Key U.S. Patent Covering its SwitchGuard™ Neuroprotection System". 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 December 20, 2023 the Company announced the issuance of U.S. Patent No. 11,844,893, titled, "Shunts with Blood Flow Indicators." The patent covers key aspects of the Company's SwitchGuard™ Neuroprotection System (NPS) along with future features in development that are expected to enable the treating physician to visualize flow through the system. The Company expects to submit an Investigational Device Exemption (IDE) to the FDA in 2024, which, if approved, would allow the company to initiate a clinical trial to support the clearance of the SwitchGuard™ NPS coupled with CGuard Prime

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated December 20, 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: December 20, 2023

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

Exhibit 99.1

InspireMD Announces Issuance of Key U.S. Patent Covering Its SwitchGuard™ Neuroprotection System

Reflects continued focus on adding intellectual property to support the strategic direction of the Company to provide a complete solution set for the treatment of carotid artery disease and the prevention of stroke

Tel Aviv, Israel, and Miami, Florida — December 20, 2023 – InspireMD (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for the prevention of stroke, announced today the issuance of U.S. Patent No. 11,844,893, titled, "Shunts with Blood Flow Indicators."

The patent covers key aspects of the company's SwitchGuard™ Neuroprotection System (NPS) along with future features in development that are expected to enable the treating physician to visualize flow through the system. The SwitchGuard™ NPS is designed to allow the physician to reverse blood flow to the brain during a carotid artery stenting procedure, including Transcarotid Artery Revascularization (TCAR) or other neurovascular procedures. The SwitchGuard™ NPS is designed to prevent embolic debris generated during the procedure from traveling to the brain, passing the blood through the filter housed within the SwitchGuard before returning it to the patient, to minimize blood loss during the procedure.

In October 2023, the Centers for Medicare and Medicaid Services (CMS) expanded coverage for carotid artery stenting (CAS) and TCAR to include both asymptomatic and standard risk patients at either high- or standard- risk for carotid endarterectomy (surgery). The broader availability of these less invasive options should better enable physicians to tailor treatment plans to the needs of individual patients.

Marvin Slosman, Chief Executive Officer of InspireMD, stated, "The issuance of this patent demonstrates our continued priority to develop and build on our robust intellectual property to support our innovations, while expanding our product portfolio for optimal patient outcomes in the treatment of carotid artery disease with the utmost safety in mind. This coupled with our CGuard Prime Carotid Stent System should provide clinicians with innovation and safety during carotid revascularization procedures and minimize the risk of stroke."

InspireMD expects to submit an Investigational Device Exemption (IDE) to the FDA in 2024, which, if approved, would allow the company to initiate a clinical trial to support the clearance of the SwitchGuard™ NPS coupled with CGuard Prime.

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, 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.

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