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): **March 12, 2025**

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	**6744832**
(Address of Principal Executive Offices)	(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 2.02 Results of Operations and Financial Condition.

On March 12, 2025, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the fourth quarter and year ended December 31, 2024. A copy of this 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 2.02 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 March 12, 2025
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: March 12, 2025

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

Exhibit 99.1

InspireMD Reports Fourth Quarter and Full Year 2024 Financial Results

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Management to host investor conference call today, March 12th, at 8:30am ET

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Miami, FL — March 12, 2025 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Prime carotid stent system for the treatment of carotid artery disease and prevention of stroke, today announced financial and operating results for the fourth quarter and full year ended December 31, 2024.

Recent Business Highlights:

- Engaged with the U.S. Food and Drug Administration (FDA) on the Premarket Approval (PMA) application for the CGuard Prime carotid stent system in the U.S. ahead of an anticipated first half 2025 approval
- Announced approval of and enrolled first patients in the CGUARDIANS II pivotal study of the CGuard Prime carotid stent system for use during TCAR procedures
- Established headquarters in Miami, Florida, to optimally support the anticipated U.S. commercial launch of CGuard Prime in the first half of 2025, if approved
- Achieved quarterly revenue and unit records of $1.95M and 3.5K respectively in served markets

Marvin Slosman, CEO of InspireMD, commented: "2024 was a year of tremendous progress at InspireMD. We advanced CGuard Prime, our best-in-class carotid implant, toward potential U.S. approval by submitting our PMA application to the FDA. We also initiated the CGUARDIANS II pivotal study for its use in the large and growing TCAR market — an important step in expanding our development pipeline."

"We continue to see a clear path toward a potential CGuard Prime launch in the first half of 2025, pending approval. We are working closely with the FDA to support the review process and look forward to bringing this innovative technology to patients in the U.S. I look forward to key clinical, regulatory, and commercial milestones in the months ahead, particularly the potential U.S. approval and commercial launch of CGuard Prime," Mr. Slosman concluded.

Financial Results for the Fourth Quarter Ended December 31, 2024

For the fourth quarter of 2024, total revenue increased by $188,000, or 10.7%, to $1,949,000, from $1,761,000 during the fourth quarter of 2023. This increase was predominantly driven by growth in new and existing markets.

Gross profit for the fourth quarter of 2024 decreased by $36,000, or 7.1%, to $469,000, compared to a gross profit of $505,000 for the fourth quarter of 2023. This decrease in gross profit resulted from an increase in cost of goods sold. This increase was primarily due to an increase in material and labor costs, driven mainly to higher sales volume, and increased compensation expense for new and current employees. The increase of cost of goods sold was offset by an increase of the revenues as described above.

Total operating expenses for the fourth quarter of 2024 were $9,836,000, an increase of $3,523,000, or 55.8% compared to $6,313,000 for the fourth quarter of 2023. This increase was primarily due to increases in expenses related to salaries and share-based compensation as we continue to expand our US personnel and sales force in anticipation of FDA approval. In addition, there was an increase of expenses due to clinical, regulatory and development expenses related to our expected launch into the TCAR (transcarotid revascularization) market and CGuard Prime product preparation expenses for the anticipated U.S. commercial launch, offset by a reduction in clinical trial expenses associated with the C-GUARDIANS FDA Study as the one-year follow-up finalized in the second quarter of 2024.

Financial income, net for the fourth quarter of 2024 was $252,000, a decrease of $216,000 or 46.1% compared to $468,000 for the fourth quarter of 2023. This decrease was primarily due to less interest income from investments in marketable securities and money market funds.

Net loss for the fourth quarter of 2024 totaled $9,174,000 or $0.19 per basic and diluted share, compared to a net loss of $5,405,000, or $0.16 per basic and diluted share, for the same period in 2023.

As of December 31, 2024, cash and cash equivalents and marketable securities were $34,637,000 compared to $39,023,000 as of December 31, 2023.

Financial Results for the Full Year Ended December 31, 2024

For the twelve months ended December 31, 2024, revenue increased by $804,000, or 13.0%, to $7,009,000, from $6,205,000 during the twelve months ended December 31, 2023. This increase was driven by growth in existing and new markets.

Gross profit for the twelve months ended December 31, 2024, decreased by 16.7%, or $301,000, to $1,506,000, compared to a gross profit of $1,807,000 for the same period in 2023. This decrease in gross profit resulted from an increase in cost of goods sold. This increase was primarily due to an increase in material and labor costs, driven mainly to higher sales volume, and increased compensation expense for new and current employees. In addition, there was an increase of other cost of goods sold related to miscellaneous expenses. The increase of cost of goods sold was offset by an increase of the revenues as described above.

Gross margin (gross profits as a percentage of revenue) decreased to 21.5% during the year ended December 31, 2024, from 29.1% during the year ended December 31, 2023, driven by the factors mentioned above.

Total operating expenses for the twelve months ended December 31, 2024, were $35,009,000, an increase of $12,059,000, or 52.5% compared to $22,950,000 for the twelve months ended December 31, 2023. This increase was primarily due to increases in expenses related to salaries and share-based compensation as we expand our US personnel and sales force in anticipation of FDA approval. In addition, an increase of expenses for clinical, regulatory and development expenses related to our expected launch into the TCAR (transcarotid revascularization) market, CGuard Prime product preparation expenses for the anticipated U.S. commercial launch, offset by a reduction in clinical trial expenses associated with the C-GUARDIANS FDA Study as the one-year follow-up finalized in the second quarter of 2024.

Financial income, net for the twelve months ended December 2024, was $1,557,000, an increase of $265,000 or 20.5% compared to $1,292,000 for the twelve months ended December 31, 2023. The increase in financial income primarily resulted from an increase in interest income from investments in marketable securities and money market funds.

Net loss for the twelve months ended December 31, 2024, totaled $32,005,000, or $0.76 per basic and diluted share, compared to a net loss of $19,916,000, or $0.82 per basic and diluted share, for the twelve months ended December 31, 2023.

Conference Call and Webcast Details

Management will host a conference call at 8:30 am ET today, March 12th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Wednesday, March 12th at 8:30 a.m. ET

Domestic:	1-800-579-2543
International:	1-785-424-1789
Conference ID:	IMD4Q24
Webcast:	Webcast Link – Click Here

https://viavid.webcasts.com/starthere.jsp?ei=1710071&tp_key=533cb06aa3

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 future events, future financial performance, strategies, expectations, competitive environment and regulation, including potential FDA approval and potential U.S. commercial launch. 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 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; substantial doubt about our ability to continue as a going concern; significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; 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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CONSOLIDATED STATEMENTS OF OPERATIONS [1]
(U.S. dollars in thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2024	**2023**	**2024**	**2023**
Revenues	$ 1,949	$ 1,761	$ 7,009	$ 6,205
Cost of revenues	1,480	1,256	5,503	4,398
Gross Profit	469	505	1,506	1,807
Operating Expenses:				
Research and development	3,693	2,035	13,634	7,981
Selling and marketing	1,915	1,309	6,069	3,865
General and administrative	4,228	2,969	15,306	11,104
Total operating expenses	9,836	6,313	35,009	22,950
Loss from operations	(9,367)	(5,808)	(33,503)	(21,143)
Financial income, net	252	468	1,557	1,292
Loss before tax expenses	(9,115)	(5,340)	(31,946)	(19,851)
Tax expenses	59	65	59	65
Net Loss	$ (9,174)	$ (5,405)	(32,005)	$ (19,916)
Net loss per share – basic and diluted	$ (0.19)	$ (0.16)	$ (0.76)	$ (0.82)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	48,889,766	33,937,425	41,928,360	24,268,181

CONSOLIDATED BALANCE SHEETS [2]
(U.S. dollars in thousands)

	December 31, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 18,916	$ 9,640
Marketable securities	15,721	29,383
Accounts receivable:		
Trade, net	1,572	1,804
Other	682	648
Prepaid expenses	1,060	578
Inventory	2,570	2,106
Total current assets	40,521	44,159
Non-current assets:		
Long term deposit	426	-
Property, plant and equipment, net	2,371	1,060
Operating lease right of use assets	2,360	1,473
Funds in respect of employee rights upon retirement	1,129	951
Total non-current assets	6,286	3,484
Total assets	$ 46,807	$ 47,643

	December 31, 2024	December 31, 2023
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,254	$ 939
Other	6,424	5,081
Total current liabilities	7,678	6,020
Long-term liabilities:		
Operating lease liabilities	1,796	1,038
Liability for employee rights upon retirement and others	1,247	1,084
Total long-term liabilities	3,043	2,122
Total liabilities	10,721	8,142
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2024 and 2023; 26,611,033 and 21,841,215 shares issued and outstanding at December 31, 2024 and 2023, respectively	3	2
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2024 and 2023; 1,718 shares issued and outstanding at December 31, 2024 and 2023, respectively	*	*
Additional paid-in capital	289,589	261,000
Accumulated deficit	(253,506)	(221,501)
Total equity	36,086	39,501
Total liabilities and equity	$ 46,807	$ 47,643

(1) All 2024 financial information for the twelve months ended December 31, 2024 is derived from the Company's 2024 audited financial statements and all financial information for the twelve months ended December 31, 2023 is derived from the Company's 2023 audited financial statements, included in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2024 filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2024 and 2023 is derived from the Company's unaudited, financial statements.

(2) All December 31, 2024 financial information is derived from the Company's 2024 audited financial statements and all December 31, 2023 financial information is derived from the Company's 2023 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2024 filed with the Securities and Exchange Commission.