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): **May 9, 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 May 9, 2025, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 31, 2025. 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 May 9, 2025 (furnished herewith pursuant to Item 2.02)
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: May 9, 2025

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

Exhibit 99.1

InspireMD Reports First Quarter 2025 Financial Results

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Management to host investor conference call today, May 9th, at 8:30am ET

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Miami, FL — May 9, 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 first quarter ended March 31, 2025.

Business Highlights:

- Continued engagement 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. Optimistic for an anticipated approval in the third quarter of 2025
- Advanced commercial infrastructure and operational readiness ahead of anticipated U.S. launch
- Continued enrollment with excellent pace in the CGUARDIANS II pivotal study of the CGuard Prime carotid stent system for use during TCAR procedures

Marvin Slosman, CEO of InspireMD, commented: "In the first quarter we continued to drive commercial adoption of our technology in our served markets, while laying a strong operational and strategic foundation for upcoming transformational milestones. With a clear roadmap for commercial expansion and a disciplined focus on execution, we've built and trained a world-class commercial team—ready to execute at scale upon potential FDA PMA approval. We're energized by the momentum and confident in the opportunities on the horizon."

"We continue to work interactively with the FDA and are optimistic for an anticipated approval of CGuard Prime in the third quarter of 2025. Despite dynamics within the agency and the timing of our audit in February, we are confident the remaining items will be successfully completed. I am excited about the transformative milestones ahead as we work to bring this innovative technology to patients in the U.S. and drive the next chapter of InspireMD's growth," Mr. Slosman concluded.

Financial Results for the First Quarter Ended March 31, 2025

For the first quarter of 2025, total revenue increased by $18,000, or 1.2%, to $1,529,000 from $1,511,000 during the first quarter of 2024. This increase was driven by continued adoption of our CGuard technology in existing markets, offset by the impact of foreign exchange and distributors managing CGuard inventory levels in anticipation of CGuard Prime approval in Europe.

Gross profit for the first quarter of 2025 remained constant at $292,000, compared to the gross profit of the first quarter of 2024.

Total operating expenses for the first quarter of 2025 were $11,752,000, an increase of $4,046,000, or 52.5% compared to $7,706,000 for the first quarter of 2024. This increase was primarily due to higher salaries and share-based compensation tied to U.S. sales force expansion ahead of FDA approval. Additional increases stemmed from CGuard Prime launch preparation, U.S. facility rent, and CFO recruitment fees.

Financial income, net for the first quarter of 2025 was $294,000, a decrease of $88,000 or 23.0% compared to $382,000 for the first quarter of 2024. This decrease was primarily due to less interest income from investments in marketable securities and money market funds.

Net loss for the first quarter of 2025 totaled $11,166,000 or $0.22 per basic and diluted share, compared to a net loss of $7,032,000, or $0.21 per basic and diluted share, for the same period in 2024.

As of March 31, 2025, cash and cash equivalents and marketable securities were $26,086,000 compared to $34,637,000 as of December 31, 2024.

Conference Call and Webcast Details

Management will host a conference call at 8:30 am ET today, May 9th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Friday, May 9th at 8:30 a.m. ET

Domestic:	1-800-579-2543
International:	1-785-424-1789
Conference ID:	IMD1Q25
Webcast:	Webcast Link – Click Here

https://viavid.webcasts.com/starthere.jsp?ei=1713642&tp_key=1c3c464032

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.

Investor Contacts:

Craig Shore
Chief Financial Officer
InspireMD, Inc.
888-776-6804
craigs@inspiremd.com

Webb Campbell
Gilmartin Group LLC
Webb@gilmartinir.com
investor-relations@inspiremd.com

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS[1]
(U.S. dollars in thousands, except share and per share data)

	Three months ended March 31,	
	2025	**2024**
Revenues	$ 1,529	$ 1,511
Cost of revenues	1,237	1,219
Gross Profit	292	292
Operating Expenses:		
Research and development	4,059	2,625
Selling and marketing	2,750	1,237
General and administrative	4,943	3,844
Total operating expenses	11,752	7,706
Loss from operations	(11,460)	(7,414)
Financial Income, net	294	382
Net Loss	$ (11,166)	$ (7,032)
Net loss per share – basic and diluted	$ (0.22)	$ (0.21)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	49,993,509	34,242,976

CONDENSED CONSOLIDATED BALANCE SHEETS(2)
(U.S. dollars in thousands, except share and per share data)

	March 31, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,383	$ 18,916
Marketable securities	13,703	15,721
Accounts receivable:		
Trade, net	1,580	1,572
Other	763	682
Prepaid expenses	893	1,060
Inventory	2,822	2,570
Total current assets	32,144	40,521
Non-current assets:		
Long term deposit	430	426
Property, plant and equipment, net	2,736	2,371
Operating lease right of use assets	2,225	2,360
Funds in respect of employee rights upon retirement	1,137	1,129
Total non-current assets	6,528	6,286
Total assets	$ 38,672	$ 46,807

	March 31, 2025	December 31, 2024
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,727	$ 1,254
Other	5,640	6,424
Total current liabilities	7,367	7,678
Long-term liabilities:		
Operating lease liabilities net of current maturities	1,639	1,796
Liability for employee rights upon retirement and others	1,321	1,247
Total long-term liabilities	2,960	3,043
Total liabilities	$ 10,327	$ 10,721
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2025 and December 31, 2024; 29,752,661 and 26,611,033 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	3	3
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2025 and December 31, 2024; 1,718 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	*	*
Additional paid-in capital	293,014	289,589
Accumulated deficit	(264,672)	(253,506)
Total equity	28,345	36,086
Total liabilities and equity	$ 38,672	$ 46,807

(1) All 2025 financial information is derived from the Company's 2025 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; all 2024 financial information is derived from the Company's 2024 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All March 31, 2025financial information is derived from the Company's 2025 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2024 financial information is derived from the Company's 2024 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.