
**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): **August 6, 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.

Item 2.02 Results of Operations and Financial Condition

On August 6, 2024, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the three and six months ended June 30, 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 August 6, 2024 (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: August 6, 2024

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



**InspireMD Reports Second Quarter 2024 Financial Results and Provides
Business Update**

- Announced positive outcomes from the C-GUARDIANS IDE clinical trial of the CGuard™ Prime carotid stent system demonstrating a one-year primary endpoint event rate of 1.95%, the lowest for any carotid stent or embolic protection device pivotal trial –

- On track to submit a Premarket Approval (PMA) application to the FDA this quarter -

- Raised gross proceeds of \$17.9 million from full exercise of Series H warrants triggered by announcement of C-GUARDIANS data -

—
Management to host investor conference call today, August 6th, at 8:30am ET

Tel Aviv, Israel and Miami, FL — August 6, 2024 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the treatment of carotid artery disease (CAD) and prevention of stroke, today announced financial and operating results for the second quarter ended June 30, 2024.

Second Quarter 2024 and Recent Developments:

- Announced one-year outcomes from the C-GUARDIANS IDE clinical trial of CGuard™ Prime demonstrating a primary endpoint event rate of **1.95%** through one year, the lowest such event rate for any carotid stent or embolic protection device pivotal clinical trial.
 - Announced the full exercise of 12.9 million Series H warrants issued pursuant to the transformational public financing of up to \$113.6 million announced in May 2023. The Series H warrants were exercised primarily into pre-funded warrants and resulted in gross proceeds of \$17.9 million, or \$16.9 million after fees.
 - Generated second quarter 2024 CGuard EPS revenue of \$1.74 million, an increase of 5.4% over the second quarter of 2023, on 2,969 CGuard stents sold, up nearly 6% over the second quarter of 2023.
 - Engaged with a leading MedTech search firm, The Mullings Group, to accelerate build-out of world-class operations and commercial teams in the United States.
 - Announced completion of enrollment in groundbreaking CREST-2 clinical trial, with 23 patients in the stenting arm treated with CGuard, the only investigational device allowed by FDA for inclusion in the trial.
 - Advanced preparation activities for initiation of the CGUARDIANS II Transcarotid Arterial Revascularization (TCAR) clinical trial in the back half of 2024.
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Marvin Slosman, CEO of InspireMD, commented: “The clear highlight since our last quarterly report was the announcement of best in class one-year outcomes data from our pivotal C-GUARDIANS clinical trial of the CGuard Carotid Stent System, which was designed to support a Premarket Approval (PMA) application to FDA later this year. The data demonstrated a primary endpoint event rate of 1.95% through one year, the lowest such rate for any carotid stent or embolic protection device pivotal clinical trial, thus adding to the significant body of data that we have compiled demonstrating the outstanding performance of CGuard both short- and long-term. With these results in hand, we intend to proceed with a PMA application in the back half of this year while continuing to build out a world-class US commercial infrastructure in anticipation of FDA approval in the first half of 2025.

“In parallel, we continued to advance development of our pipeline of carotid intervention and stroke prevention tools, including our SwitchGuard NPS TCAR solution, and we remain on track to initiate our CGUARDIANS II clinical trial in the back half of this year. By uniquely developing solution sets for both CAS and TCAR utilizing our best-in-class CGuard Prime stent implant, we believe we are well positioned for the ongoing paradigm shift toward an endovascular ‘stent first’ approach. I am very pleased with our continued progress and look forward to a productive back half of the year,” Mr. Slosman concluded.

Financial Results for the Second Quarter ended June 30, 2024

For the three months ended June 30, 2024, revenue increased by \$90,000, or 5.4%, to \$1,739,000, from \$1,649,000 for the three months ended June 30, 2023. This increase was driven by growth in existing and new markets, partially offset by a reduction in clinical trial revenue driven by the conclusion of C-GUARDIANS enrollment in June 2023.

For the three months ended June 30, 2024, gross profit (revenue less cost of revenues) decreased by \$160,000, or 32.6%, to \$331,000, from \$491,000 during the three months ended June 30, 2023. This decrease in gross profit resulted from an increase in material and labor costs mainly due to compensation expense for new and current employees, higher sales volume, additional space to build capacity for anticipated increased volume requirements and additional training expenses offset by an increase in revenues. Gross margin (gross profits as a percentage of revenue) decreased to 19.0% during the three months ended June 30, 2024, from 29.8% during the three months ended June 30, 2023, driven by the factors mentioned above.

Total operating expenses for the second quarter of 2024 were \$8,591,000, an increase of \$2,785,000, or 48.0%, compared to \$5,806,000 for the second quarter of 2023. This increase was primarily due to an increase in compensation and development expenses with the vast majority being non-cash share-based compensation-related expenses.

Net loss for the second quarter of 2024 totaled \$7,909,000, or \$0.22 per basic and diluted share, compared to a net loss of \$5,077,000, or \$0.24 per basic and diluted share, for the same period in 2023.

As of June 30, 2024, cash, cash equivalents and marketable securities were \$47.2 million compared to \$39.0 million as of December 31, 2023. This includes the full exercise of Series H Warrants, raising gross proceeds of \$17.9 million, related to the announcement of one-year follow up from the C-GUARDIANS pivotal trial.

Financial Results for the Six Months ended June 30, 2024

For the six months ended June 30, 2024, revenue increased by \$362,000, or 12.5%, to \$3,250,000, from \$2,888,000 for the six months ended June 30, 2023. This sales increase was due to growth in existing and new markets, partially offset by a reduction in clinical trial revenue due to the completion of C-GUARDIANS enrollment in June 2023.



For the six months ended June 30, 2024, gross profit (revenue less cost of revenues) decreased by 27.9%, or \$241,000, to \$623,000, compared to \$864,000 for the same period in 2023. This decrease in gross profit resulted from an increase in material and labor costs mainly due to compensation expense for new and current employees, higher sales volume, additional space to build capacity for anticipated increased volume requirements and additional training expenses offset by an increase of the revenues.

Total operating expenses for the six months ended June 30, 2024, were \$16,297,000, an increase of \$5,737,000, or 54.3% compared to \$10,560,000 for the six months ended June 30, 2023. This increase was primarily due to an increase in compensation and development expenses with the vast majority being non-cash share-based compensation-related expenses.

Net loss for the six months ended June 30, 2024, totaled \$14,941,000, or \$0.43 per basic and diluted share, compared to a net loss of \$9,333,000, or \$0.64 per basic and diluted share, for the six months ended June 30, 2023.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, August 6, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Tuesday, August 6th at 8:30 a.m. ET

Domestic:	1-800-445-7795
International:	1-785-424-1699
Conference ID:	IMD2Q24
Webcast:	Webcast Link – Click Here

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 revenue growth. 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; 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 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.

Investor Contacts:

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CONSOLIDATED STATEMENTS OF OPERATIONS⁽¹⁾

(U.S. dollars in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenues	\$ 1,739	\$ 1,649	\$ 3,250	\$ 2,888
Cost of revenues	1,408	1,158	2,627	2,024
Gross Profit	331	491	623	864
Operating Expenses:				
Research and development	3,401	1,993	6,026	3,836
Selling and marketing	1,445	892	2,682	1,680
General and administrative	3,745	2,921	7,589	5,044
Total operating expenses	8,591	5,806	16,297	10,560
Loss from operations	(8,260)	(5,315)	(15,674)	(9,696)
Financial income	351	238	733	363
Net Loss	\$ (7,909)	\$ (5,077)	\$ (14,941)	\$ (9,333)
Net loss per share – basic and diluted	\$ (0.22)	\$ (0.24)	\$ (0.43)	\$ (0.64)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	35,877,926	21,074,187	35,060,451	14,619,622



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

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 28,385	\$ 9,640
Marketable securities	18,778	29,383
Accounts receivable:		
Trade, net	1,307	1,804
Other	450	648
Prepaid expenses	717	578
Inventory	<u>2,206</u>	<u>2,106</u>
Total current assets	<u>51,843</u>	<u>44,159</u>
Non-current assets:		
Property, plant and equipment, net	1,595	1,060
Operating lease right of use assets	1,257	1,473
Funds in respect of employee rights upon retirement	<u>964</u>	<u>951</u>
Total non-current assets	<u>3,816</u>	<u>3,484</u>
Total assets	<u>\$ 55,659</u>	<u>\$ 47,643</u>

INSPIREMD

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	927	939
Other	6,038	5,081
Total current liabilities	<u>6,965</u>	<u>6,020</u>
Long-term liabilities:		
Operating lease liabilities	786	1,038
Liability for employees rights upon retirement	1,145	1,084
Total long-term liabilities	<u>1,931</u>	<u>2,122</u>
Total liabilities	<u>8,896</u>	<u>8,142</u>
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at June 30, 2024 and December 31, 2023; 25,196,479 and 21,841,215 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	3	2
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at June 30, 2024 and December 31, 2023; 1,718 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	*	*
Additional paid-in capital	283,202	261,000
Accumulated deficit	(236,442)	(221,501)
Total equity	<u>46,763</u>	<u>39,501</u>
Total liabilities and equity	<u>\$ 55,659</u>	<u>\$ 47,643</u>



(1) 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; all 2023 financial information is derived from the Company's 2023 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All June 30, 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. 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, 2023 filed with the Securities
