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 14, 2024**

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 2.02 Results of Operations and Financial Condition

On May 14, 2024, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 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 May 14, 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: May 14, 2024

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

Exhibit 99.1

InspireMD Reports First Quarter 2024 Financial Results and Provides Business Update

- Generated first quarter 2024 CGuard EPS revenue of $1.51 million, an increase of 22.0% over the first quarter of 2023 -

- Announced that an abstract detailing one-year outcomes from the C-GUARDIANS IDE clinical trial of CGuard™ Prime has been accepted for presentation at LINC 2024, to be held May 28-31 -

- Named Patrick Geraghty, M.D. and Patrick Muck, M.D. as lead principal investigators for the Company's CGUARDIANS II clinical trial for Transcarotid Artery Revascularization (TCAR), as well as Dr. William Gray, as advisor to the company -

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Management to host investor conference call today, May 14, at 8:30am ET

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Tel Aviv, Israel and Miami, FL — May 14, 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 first quarter ended March 31, 2024.

First Quarter 2024 and Recent Developments:

- Generated CGuard revenue in the first quarter 2024 of $1.51 million, a 22.0% increase over the first quarter of 2023.
- Sold 2,553 CGuard EPS stent systems in the first quarter of 2024, as compared to 2,033 in the first quarter of 2023, an increase of 25.6%.
- Announced that an abstract of the one-year outcomes from its C-GUARDIANS IDE clinical trial of the CGuard™ Prime Carotid Stent System for the treatment of carotid artery stenosis has been accepted for presentation at the Leipzig Interventional Course (LINC) 2024, which is being held May 28-31, in Leipzig, Germany.
    - Presentation of one-year results follows an earlier abstract of 30-day results from C-GUARDIANS which were presented at the Vascular InterVentional Advances Annual Meeting (VIVA23) and the VEITH Symposium in November 2023.
    - The 30-day results demonstrated that patients with carotid artery stenosis and at high risk for carotid endarterectomy (CEA) had an overall major adverse event rate (death, stroke or myocardial infarction, or DSMI) of 0.95% from procedure through 30 day follow up when treated with carotid artery stenting (CAS) using CGuard.
    - The announcement of one-year results from C-GUARDIANS will potentially trigger the first of four $17.9 million financing tranches per the transformational private placement of up to $113.6 million that the company announced in May 2023.

- Named Patrick Geraghty, M.D., professor of surgery and radiology, section of vascular surgery at Washington University School of Medicine in St. Louis, MO, and Patrick Muck, M.D., program director and chief of vascular surgery at Good Samaritan Hospital in Cincinnati, OH, as lead principal investigators for the Company's CGUARDIANS II clinical trial of its SwitchGuard™ neuroprotection system for use with CGuard Prime in TCAR procedures.

- Announced recertification of the Company's CE Mark under the European Union's new Medical Device Regulation (MDR) regulatory framework.

- Announced the appointment of medical technology executive Pete Ligotti as Executive Vice President and General Manager of North America.

Marvin Slosman, CEO of InspireMD, commented: "Our first quarter results reflect continued momentum and share gains in our served CE Mark territories, including total revenue of $1.51 million that increased 22.0% year-over-year. We sold more than 2,500 stents during the quarter, up 25.6% year-over-year and bringing our real-world experience with the CGuard EPS stent platform to over 50,000 stents sold to date, a noteworthy milestone for our company.

"At the same time, we remain acutely focused on advancing our ongoing C-GUARDIANS PMA clinical trial through to completion for U.S. market approval. Recall that the 30-day results that were presented at last year's VIVA23 and VEITH Symposium showed that stenting with CGuard in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%. These are best-in-class results from any carotid pivotal trial conducted to date and form the foundation of our 'stent first' strategy.

"We were very pleased to have recently announced that an abstract of the one-year results from C-GUARDIANS will be presented at the LINC conference in Germany later this month. This key milestone will potentially allow us to file a Premarket Approval (PMA) application with the FDA later this year and give us line-of-sight to potential approval in the first half of 2025.

"I am very pleased with our progress, including building our core business as well as advancing our clinical trials and new product pipeline, anticipating and preparing for a launch of our best-in-class carotid platforms in the U.S. in 2025," Mr. Slosman concluded.

Financial Results for the First Quarter Ended March 31, 2024

For the first quarter of 2024, total revenue increased 22.0%, to $1,511,000, from $1,239,000 during the first quarter of 2023. This increase was predominantly driven by growth in existing markets.

Gross profit for the first quarter of 2024 decreased by $81,000, or 21.6%, to $292,000, compared to a gross profit of $373,000 for the first quarter of 2023. This decrease resulted primarily from higher training costs of new hires to build capacity for anticipated increased volume requirements. Gross margin (gross profit as a percentage of revenue) decreased to 19.4% during the three months ended March 31, 2024, from 30.1% during the three months ended March 31, 2023.

Total operating expenses for the first quarter of 2024 were $7,706,000, an increase of $2,952,000, or 62.1% compared to $4,754,000 for the first quarter of 2023. This increase was primarily due to higher share-based compensation resulting from the recognition of grants made during the second quarter of 2023 and the first quarter of 2024.

Total financial income for the first quarter of 2024 was $382,000, an increase of $257,000 or 205.6% compared to $125,000 for the first quarter of 2023. This increase was primarily due to a $264,000 increase in interest income from investments in marketable securities, money market funds and short-term bank deposits.

Net loss for the first quarter of 2024 totaled $7,032,000, or $0.21 per basic and diluted share, compared to a net loss of $4,256,000, or $0.53 per basic and diluted share, for the same period in 2023.

As of March 31, 2024, cash, cash equivalents and marketable securities were $34.0 million compared to $39.0 million as of December 31, 2023.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, May 14th, 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, May 14th at 8:30 a.m. ET

Domestic:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13745786
Call me™	Link here
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 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. 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 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

Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

investor-relations@inspiremd.com

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

	Three months ended March 31,	
	2024	**2023**
Revenues	$ 1,511	$ 1,239
Cost of revenues	1,219	866
Gross Profit	292	373
Operating Expenses:		
Research and development	2,625	1,843
Selling and marketing	1,237	788
General and administrative	3,844	2,123
Total operating expenses	7,706	4,754
Loss from operations	(7,414)	(4,381)
Financial Income, net	382	125
Net Loss	$ (7,032)	$ (4,256)
Net loss per share – basic and diluted	$ (0.21)	$ (0.53)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,242,976	8,093,340

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

	March 31, 2024	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,389	$ 9,640
Marketable securities	24,561	29,383
Accounts receivable:		
Trade, net	1,187	1,804
Other	483	648
Prepaid expenses	531	578
Inventory	2,360	2,106
Total current assets	38,511	44,159
Non-current assets:		
Property, plant and equipment, net	1,186	1,060
Operating lease right of use assets	1,366	1,473
Funds in respect of employee rights upon retirement	965	951
Total non-current assets	3,517	3,484
Total assets	$ 42,028	$ 47,643

	March 31, 2024	December 31, 2023
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 659	$ 939
Other	4,218	5,081
Total current liabilities	4,877	6,020
Long-term liabilities:		
Operating lease liabilities	914	1,038
Liability for employees rights upon retirement	1,150	1,084
Total long-term liabilities	2,064	2,122
Total liabilities	$ 6,941	$ 8,142
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2024 and December 31, 2023; 23,412,385 and 21,841,215 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	2	2
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2024 and December 31, 2023; 1,718 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	*	*
Additional paid-in capital	263,618	261,000
Accumulated deficit	(228,533)	(221,501)
Total equity	35,087	39,501
Total liabilities and equity	$ 42,028	$ 47,643

(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 March 31, 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 and Exchange Commission.