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 6, 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 March 6, 2024, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the fourth quarter and year ended December 31, 2023. 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 6, 2024
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 6, 2024

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

Exhibit 99.1

InspireMD Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides Business Update

- Record fourth quarter 2023 CGuard EPS revenue of $1.76 million increased 71.6% over fourth quarter 2022 -

- Announced positive 30-day data from the Company's ongoing U.S. Investigational Device Exemption (IDE) clinical trial, C-GUARDIANS, designed to support U.S. approval of CGuard Prime -

- Named Patrick Geraghty, M.D. and Patrick Muck, M.D. as lead principal investigators for the Company's C-GUARDIANS II clinical trial of its SwitchGuard™ NPS 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, March 6, at 8:30am ET

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Tel Aviv, Israel and Miami, FL — March 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 fourth quarter and full-year ended December 31, 2023.

Fourth Quarter 2023 and Recent Developments:

- Generated record CGuard revenue in the fourth quarter 2023 of $1.76 million, a 71.6% increase over the fourth quarter of 2022.
- Sold 3,107 CGuard EPS stent systems in the fourth quarter of 2023, as compared to 1,781 in the fourth quarter of 2022, an increase of 74.5%.
- Announced presentation of positive 30-day results from the C-GUARDIANS U.S. clinical trial of CGuard EPS at the Vascular InterVentional Advances Annual Meeting (VIVA23) and the VEITH Symposium. The 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 the CGuard EPS.
- Announced re-certification of the Company's CE Mark under the European Union's new Medical Device Regulation (MDR) regulatory framework.
- 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 C-GUARDIANS II clinical trial of its SwitchGuard™ neuroprotection system for use with CGuard Prime in TCAR procedures.
- Appointed William Gray, M.D., system chief of the cardiovascular division at Main Line Health in Wynnewood, PA and professor of medicine at Thomas Jefferson University in Philadelphia, PA, as an advisor to the Company.
- Announced a strategic agreement with the Jacobs Institute at the State University of New York at Buffalo, and Dr. Adnan Siddiqui, Vice-Chairman and Professor of Neurosurgery, to execute an Early Feasibility Study (EFS) evaluating the CGuard EPS carotid stent to treat severe carotid stenosis or occlusion, in conjunction with thrombectomy, in patients presenting with acute ischemic stroke and tandem lesions.
- Announced support for the Centers for Medicare and Medicaid Services' (CMS) final National Coverage Determination expanding coverage for CAS to include both asymptomatic and standard risk patients, significantly expanding the U.S. CAS addressable market.
- 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: "We delivered another strong quarter of sales growth in our approved CE Mark territories while at the same time advancing our U.S. clinical trial and product development pipeline. Our total revenue of $1.76 million represents a record quarter and an increase of nearly 72% over the comparable period in 2022. Notably, we sold over 3,100 stents, up more than 74% year-over-year and bringing our real-world experience to more than 48,000 stents sold to date. The receipt of formal recertification of our CE Mark under the EU's new Medical Device Regulation (MDR) regulatory framework just a few weeks ago allows us to now leverage the new product development pathway and the latest regulatory certification provided under MDR.

"Also during the quarter, we were extremely pleased to report 30-day follow-up data from our C-GUARDIANS clinical trial at VIVA23 and the VEITH Symposium, which are among the most important annual gatherings of specialists who treat vascular disease. The data 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% from procedure through 30 days, which compares favorably to both surgery and alternative stenting options and represents best in class results to date of any pivotal trial of carotid intervention. We remain on track to report 12-month follow-up data mid-year, followed by the submission of our Premarket Approval (PMA) application.

"Finally, we made progress advancing our new product pipeline by announcing the lead PIs for our upcoming C-GUARDIANS II clinical trial of our SwitchGuard NPS for use with CGuard Prime in TCAR procedures. We also announced an agreement with Jacobs Institute to conduct an early feasibility study of CGuard Prime to treat patients with acute ischemic stroke and tandem lesions.

"We believe InspireMD is uniquely positioned with a best-in-class implant and solutions to support both CAS and TCAR procedures, with line-of-sight to significant clinical and regulatory catalysts this year and next," Mr. Slosman concluded.

Financial Results for the Fourth Quarter Ended December 31, 2023

For the fourth quarter of 2023, total revenue increased 71.6%, to $1,761,000, from $1,026,000 during the fourth quarter of 2022. This increase was predominantly driven by the CE Mark recertification which occurred subsequent to the end of the fourth quarter 2022.

Gross profit for the fourth quarter of 2023 increased by $307,000, or 155.1%, to $505,000, compared to a gross profit of $198,000 for the fourth quarter of 2022. This increase resulted from higher revenue and a decrease in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 28.7% during the three months ended December 31, 2023, from 19.3% during the three months ended December 31, 2022.

Total operating expenses for the fourth quarter of 2023 were $6,313,000, an increase of $1,179,000, or 23.0% compared to $5,134,000 for the fourth quarter of 2022. This increase was primarily due to increases in expenses related to the salaries and share-based compensation offset by a reduction in clinical trial expenses as we near completion of the C-GUARDIANS trial.

Total financial income for the fourth quarter of 2023 was $468,000, an increase of $349,000 or 293% compared to $119,000 for the third quarter of 2022. This increase was primarily due to a $349,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Net loss for the fourth quarter of 2023 totaled $5,405,000, or $0.16 per basic and diluted share, compared to a net loss of $4,845,000, or $0.60 per basic and diluted share, for the same period in 2022.

As of December 31, 2023, cash, cash equivalents, short-term bank deposits and marketable securities were $39.0 million compared to $17.8 million as of December 31, 2022.

Financial Results for the full year ended Dec 31, 2023

For the twelve months ended December 31, 2023, total revenue increased by $1,034,000, or 20.0%, to $6,205,000, from $5,171,000 during the twelve months ended December 31, 2022. This increase was driven by a 21.1% increase in sales of CGuard EPS, to $6,205,000 during the twelve months ended December 31, 2023, from $5,123,000 during the twelve months ended December 31, 2022. This sales increase was mainly due to growth in existing and new markets.

Gross profit for the twelve months ended December 31, 2023, increased by $690,000, or 61.8%, to $1,807,000, compared to a gross profit of $1,117,000 for the twelve months ended December 31, 2022. This increase in gross profit resulted from higher revenue and a decrease in write-off and miscellaneous expenses. Gross margin increased to 29.1% during the twelve months ended December 31, 2023, from 21.6% during the twelve months ended December 31, 2022.

Total operating expenses for the twelve months ended December 31, 2023 were $22,950,000, an increase of $3,120,000, or 15.7% compared to $19,830,000 for the twelve months ended December 31, 2022. This increase was primarily due to increases in expenses related to salaries and share-based compensation offset by a reduction in clinical and product development expenses.

Total financial income for the twelve months ended December 2023, was $1,292,000, an increase of $1,042,000 or 417% compared to $250,000 for the twelve months ended December 31, 2022. This increase was primarily due to a $1,152,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Net loss for the twelve months ended December 31, 2023 totaled $19,916,000, or $0.82 per basic and diluted share, compared to a net loss of $18,491,000, or $2.35 per basic and diluted share, for the twelve months ended December 31, 2022.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, March 6th, 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 6th at 8:30 a.m. ET

Domestic:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13744173
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.

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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,	
	2023	**2022**	**2023**	**2022**
Revenues	$ 1,761	$ 1,026	$ 6,205	$ 5,171
Cost of revenues	1,256	828	4,398	4,054
Gross Profit	505	198	1,807	1,117
Operating Expenses:				
Research and development	2,035	2,013	7,981	7,810
Selling and marketing	1,309	1,087	3,865	3,664
General and administrative	2,969	2,034	11,104	8,356
Total operating expenses	6,313	5,134	22,950	19,830
Loss from operations	(5,808)	(4,936)	(21,143)	(18,713)
Financial expenses (income)	(468)	(119)	(1,292)	(250)
Loss before tax expenses	(5,340)	(4,817)	(19,851)	(18,463)
Tax expenses	65	28	65	28
Net Loss	$ (5,405)	$ (4,845)	$ (19,916)	$ (18,491)
Net loss per share – basic and diluted	$ (0.16)	$ (0.60)	$ (0.82)	$ (2.35)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	33,937,425	8,034,547	24,268,181	7,871,814

(1) All financial information for the twelve months ended December 31, 2023 is derived from the Company's 2023 audited financial statements and all financial information for the twelve months ended December 31, 2022 is derived from the Company's 2022 audited financial statements, included 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. All financial information for the three months ended December 31, 2023 and 2022 is derived from the Company's unaudited, financial statements.

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

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,640	$ 4,632
Short-term bank deposits	-	13,171
Marketable securities	29,383	-
Accounts receivable:		
Trade, net	1,804	1,034
Other	648	213
Prepaid expenses	578	655
Inventory	2,106	1,621
Total current assets	44,159	21,326
Non-current assets:		
Property, plant and equipment, net	1,060	917
Operating lease right of use assets	1,473	1,554
Funds in respect of employee rights upon retirement	951	856
Total non-current assets	3,484	3,327
Total assets	$ 47,643	$ 24,653
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 939	$ 659
Other	5,081	4,411
Total current liabilities	6,020	5,070
Long-term liabilities:		
Operating lease liabilities	1,038	1,195
Liability for employee rights upon retirement	1,084	995
Total long-term liabilities	2,122	2,190
Total liabilities	8,142	7,260
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2023 and 2022; 21,841,215 and 8,330,918 shares issued and outstanding at December 31, 2023 and 2022, respectively	2	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2023 and 2022; 1,718 shares issued and outstanding at December 31, 2023 and 2022, respectively	*	*
Additional paid-in capital	261,000	218,977
Accumulated deficit	(221,501)	(201,585)
Total equity	39,501	17,393
Total liabilities and equity	$ 47,643	$ 24,653

(2) All December 31, 2023 financial information is derived from the Company's 2023 audited financial statements and all December 31, 2022 financial information is derived from the Company's 2022 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.

PLACEHOLDER FOR FINANCIALS