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 30, 2023**

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 30, 2023, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the fourth quarter and year ended December 31, 2022. 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 30, 2023
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 30, 2023

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

Exhibit 99.1

InspireMD Reports Fourth Quarter and Year-End 2022 Financial Results and Provides Business Update

- 2022 CGuard EPS revenue of $5.1 million increased 18.9% over 2021 –
- Resumed shipments of CGuard EPS to CE Mark territories under the pre-existing Medical Device Directive (MDD) regulatory framework; Company anticipates re-certification under new Medical Device Regulation (MRD) framework in coming weeks –
- Continued enrollment in the C-Guardian US IDE trial, with 20 sites currently enrolling patients; on track to complete enrollment by approximately end of Q2 2023 -

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

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Tel Aviv, Israel— March 30, 2023 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for treatment of carotid artery disease (CAD) and prevention of stroke today announced financial and operating results for the fourth quarter ended December 31, 2022.

Fourth Quarter 2022 and Recent Developments:

- Generated CGuard revenues for the fourth quarter 2022 of $1,026,000, a 20.6% decrease from $1,291,000 for the fourth quarter of 2021. The decrease was caused by reduced shipments due to the temporary expiration of the Company's CE Mark for the second half of the fourth quarter, due to delays in the European regulatory bodies in the Medical Device Regulation (MDR) recertification process.
- In mid-March 2023, resumed shipments of CGuard EPS to CE Mark territories on a temporary basis under the pre-existing Medical Device Directive (MDD) regulatory framework while awaiting final re-certification under MDR.
- Hired medical device commercial veteran Shane Gleason as General Manager of North America and Vice President of Global Marketing to position InspireMD to capitalize on the US market upon expected FDA approval.
- Promoted the Company's Vice President of Global Sales and Marketing, Andrea Tommasoli, to Chief Operating Officer to meet the Company's increasing demand for CGuard.
- Delivered multiple presentations highlighting the superior safety of CGuard, and resulting positive patient outcomes, at the 2022 VEITH Symposium in November.
- Continued enrollment in the C-Guardian Investigational Device Exemption (IDE) Clinical Trial. The Company currently has 20 trial sites enrolling patients. The Company anticipates completing enrollment by approximately the end of Q2 2023.

Marvin Slosman, CEO of InspireMD, commented: "We are very pleased to have resumed shipments of CGuard to our major European markets under the existing MDD framework as we await final approval and CE Mark recertification under MDR. While revenues in Q4 of 2022 and Q1 of 2023 were impacted by the temporary lapse of our CE Mark, our team did an outstanding job converting backlog to revenue, and we anticipate that the remaining backlog will be shipped over the next two quarters."

“Our U.S. IDE trial continues to progress, and now has 20 sites enrolling patients. We anticipate having the trial fully enrolled by approximately the end of the second quarter, a critical step forward in our goal to gain eventual marketing approval of CGuard EPS in the U.S.”

“With the expectation of potentially obtaining CE Mark recertification under MDR in the next few weeks, we plan to work tirelessly to continue to gain share in our key European territories, further driven by conversion of existing endovascular carotid procedures to CGuard from other stent systems, and the potential introduction of two new delivery systems, our SwitchGuard Trans Carotid (TCAR) and CGuard Prime Transfemoral (TFEM) platforms, later this year, subject to regulatory approval. I believe we are well positioned for continued success as we progress through 2023,” Mr. Slosman concluded.

Financial Results for the Fourth Quarter ended December 31, 2022

For the fourth quarter of 2022, total revenue decreased 25.7%, to $1,026,000, from $1,380,000 during the fourth quarter of 2021. This decrease was predominantly driven by a 20.6% decrease in sales of CGuard EPS, to $1,026,000 in the fourth quarter of 2022 from $1,291,000 in the same period one year ago. This sales decrease was due to the temporary expiration of the CE Mark and resulting inability to ship to EU countries for the second half of the quarter, due to delays in the European regulatory bodies in the MDR recertification process, offset by an increase in US sales related to stents used in the C-Guardian U.S. Food and Drug Administration (FDA) clinical trial.

Gross profit for the fourth quarter of 2022 decreased by $96,000, or 32.7%, to $198,000, compared to a gross profit of $294,000 for the fourth quarter of 2021. This decrease resulted from lower revenue offset by a decrease in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased to 19.3% during the three months ended December 31, 2022, from 21.3% during the three months ended December 31, 2021.

Total operating expenses for the fourth quarter of 2022, were $5,134,000, an increase of $909,000, or 21.5% compared to $4,225,000 for the fourth quarter of 2021. This increase was primarily due to increases in expenses related to the commencement of the C-Guardians FDA study, sales and marketing expenses, and regulatory expenses.

Net loss for the fourth quarter of 2022 totaled $4,845,000, or $0.60 per basic and diluted share, compared to a net loss of $4,097,000, or $0.53 per basic and diluted share, for the same period in 2021.

As of December 31, 2022, cash, cash equivalents and short-term bank deposits were $17.8 million compared to $34.0 million as of December 31, 2021.

Financial Results for the full year ended Dec 31, 2022

For the twelve months ended December 31, 2022, total revenue increased by $676,000, or 15.0%, to $5,171,000, from $4,495,000 during the twelve months ended December 31, 2021. This increase was predominantly driven by a 18.9% increase in sales of CGuard EPS, to $5,123,000 during the twelve months ended December 31, 2022 from $4,309,000 during the twelve months ended December 31, 2021. This sales increase was mainly due to growth in existing and new markets and sales in the United States related to stents used in our C-Guardians FDA study as enrollment accelerated.

Gross profit for the twelve months ended December 31, 2022 increased by $363,000, or 48.1%, to $1,117,000, compared to a gross profit of $754,000 for the twelve months ended December 31, 2021. This increase in gross profit resulted from higher revenue, and a decrease of $177,000 in miscellaneous expenses. Gross margin increased to 21.6% during the twelve months ended December 31, 2022 from 16.8% during the twelve months ended December 31, 2021.

Total operating expenses for the twelve months ended December 31, 2022, were $19,830,000, an increase of $4,360,000, or 28.2% compared to $15,470 for the twelve months ended December 31, 2021. This increase was primarily due to increases in expenses related to the commencement of the C-Guardians FDA study, share-based compensation, resumed activities in tradeshows and travel, regulatory expenses, and miscellaneous expenses.

Net loss for the twelve months ended December 31, 2022 totaled $18,491,000, or $2.35 per basic and diluted share, compared to a net loss of $14,918,000, or $2.03 per basic and diluted share, for the twelve months ended December 31, 2021.

Conference Call and Webcast Details

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

Thursday, March 30th at 8:30 a.m. ET

Domestic:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13735869
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, and substantial doubt regarding our ability to continue as a going concern; 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 December 31,		Twelve months ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues	$ 1,026	$ 1,380	$ 5,171	$ 4,495
Cost of revenues	828	1,086	4,054	3,741
Gross Profit	198	294	1,117	754
Operating Expenses:				
Research and development	2,013	1,534	7,810	5,158
Selling and marketing	1,087	761	3,664	2,907
General and administrative	2,034	1,930	8,356	7,405
Total operating expenses	5,134	4,225	19,830	15,470
Loss from operations	(4,936)	(3,931)	(18,713)	(14,716)
Financial expenses (income)	(119)	121	(250)	157
Loss before tax expenses	(4,817)	(4,052)	(18,463)	(14,873)
Tax expenses	28	45	28	45
Net Loss	$ (4,845)	$ (4,097)	$ (18,491)	$ (14,918)
Net loss per share – basic and diluted	$ (0.60)	$ (0.53)	$ (2.35)	$ (2.03)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	8,034,547	7,796,027	7,871,814	7,346,022

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

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,632	$ 12,004
Short-term bank deposits	13,171	22,036
Accounts receivable:		
Trade, net	1,034	1,224
Other	213	165
Prepaid expenses	655	522
Inventory	1,621	1,143
Total current assets	21,326	37,094
Non-current assets:		
Property, plant and equipment, net	917	632
Operating lease right of use assets	1,554	1,081
Funds in respect of employee rights upon retirement	856	905
Total non-current assets	3,327	2,618
Total assets	$ 24,653	$ 39,712

	December 31, 2022	December 31, 2021
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 659	$ 893
Other	4,411	3,454
Total current liabilities	5,070	4,347
Long-term liabilities:		
Operating lease liabilities	1,195	781
Liability for employee rights upon retirement	995	1,052
Total long-term liabilities	2,190	1,833
Total liabilities	7,260	6,180
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2022 and 2021; 8,330,918 and 8,296,256 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2022 and 2021; 1,718 shares issued and outstanding at December 31, 2022 and 2021, respectively	*	*
Additional paid-in capital	218,977	216,625
Accumulated deficit	(201,585)	(183,094)
Total equity	17,393	33,532
Total liabilities and equity	$ 24,653	$ 39,712

(1) All financial information for the twelve months ended December 31, 2022 is derived from the Company's 2022 audited financial statements and all financial information for the twelve months ended December 31, 2021 is derived from the Company's 2021 audited financial statements, included in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2022 filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2022 and 2021 is derived from the Company's unaudited, financial statements.

(2) All December 31, 2022 financial information is derived from the Company's 2022 audited financial statements and all December 31, 2021 financial information is derived from the Company's 2021 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2022 filed with the Securities and Exchange Commission.