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): **November 6, 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 November 6, 2023, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the three and nine months ended September 30, 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 November 6, 2023 (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: November 6, 2023

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

Exhibit 99.1

InspireMD Reports Third Quarter 2023 Financial Results and Provides Business Update

- Presented positive 30-day follow-up results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial demonstrating an overall major adverse events rate (DSMI) of 0.95% from procedure through 30 days at the Vascular InterVentional Advances Annual Meeting (VIVA23) –

- Announced support for CMS' final decision expanding coverage of CAS to include both asymptomatic and standard risk patients, significantly expanding the U.S. CAS addressable market –

- Generated Q3 2023 CGuard EPS revenue of $1.56 million, an increase of nearly 9% over Q3 2022 –

—

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

—

Tel Aviv, Israel, and Miami, FL — November 6, 2023 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for treatment of carotid artery disease and prevention of stroke today announced financial results and business updates for the third quarter ended September 30, 2023.

Third Quarter 2023 and Recent Developments:

- Announced presentation of positive 30-day results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial of CGuard EPS at the Vascular InterVentional Advances Annual Meeting (VIVA23). The results demonstrated that patients with obstructive carotid artery disease and at high risk for carotid endarterectomy (CEA) had an overall major adverse events rate (including cumulative death, stroke and myocardial infarction) of 0.95% from procedure through 30 days follow up when treated with carotid artery stenting (CAS) using the CGuard EPS.

- Implemented senior leadership additions and changes designed to support the Company's commercial growth initiatives, including the hiring of Patrick Verta, MD, as Executive Vice President of Clinical and Medical Affairs and Cheryl Tal as Vice President of Quality Assurance and Regulatory Affairs. In addition, Shane Gleason, former General Manager of North America and Vice President of Global Marketing, has been promoted to Chief Commercial Officer.

- 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.

- Generated CGuard revenue for the third quarter 2023 of $1,556,072, an 8.8 % increase over the same period in 2022.

- Sold 2,734 CGuard EPS stent systems in the third quarter of 2023, as compared to 2,624 in the third quarter of 2022, an increase of 4.2 %.

Marvin Slosman, CEO of InspireMD, commented: "During the third quarter, we continued to grow revenue in our served markets outside the U.S., generating nearly 9% year-over-year revenue growth, while continuing our post-enrollment work toward a potential approval and launch of CGuard EPS in the U.S. in the first half of 2025.

"As previously announced, we were pleased to have presented very compelling 30-day safety data from C-GUARDIANS at VIVA23, one of the most important gatherings of endovascular specialists in the world. The results are consistent with eight previously completed clinical studies demonstrating extremely low rates of complications – death, stroke or myocardial infarction – as compared to historical data on competing first generation stents as well as conventional surgery (carotid endarterectomy, or CEA). The data emerging from C-GUARDIANS adds to the vast and growing body of evidence demonstrating the outstanding short- and long-term patient outcomes facilitated by CGuard EPS, which remains the cornerstone of our business.

"Subsequent to the end of the quarter, CMS issued its final National Coverage Determination (NCD), expanding coverage of CAS to include both asymptomatic and standard risk patients, significantly expanding the U.S. CAS addressable market. As we are focused on developing products for both CAS and TCAR approaches, we view this as very positive for our company, and a change that we believe will accelerate the ongoing shift toward an endovascular 'stent first' approach for all carotid interventions from the current more invasive surgery standard of care.

"I am extremely pleased by our continued execution against our 2023 objectives and the transformational tailwind provided by the CMS coverage determination that will catalyze a stent-first approach to the treatment of carotid disease, a market we have invested to transform."

Financial Results for the Third Quarter ended September 30, 2023

For the three months ended September 30, 2023, revenue increased by $125,000, or 8.7%, to $1,556,000, from $1,431,000 during the three months ended September 30, 2022. This increase was predominantly primarily driven by an increase in commercial sales of $166,000 of CGuard EPS to existing geographies, offset by a $41,000 decrease in the United States as the enrollment of all patients in the C-Guardians IDE clinical trial was completed in June 2023 and accordingly there were no further enrollments in the three months ended September 30, 2023.

For the three months ended September 30, 2023, gross profit (revenue less cost of revenues) increased by $72,000, or 19.7%, to $438,000, from $366,000 during the three months ended September 30, 2022. This increase in gross profit resulted from a $85,000 increase in revenues less the associated related material and labor offset by $13,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 28.1% during the three months ended September 30, 2023, from 25.6% during the three months ended September 30, 2022, driven by the factors mentioned above.

Total operating expenses for the third quarter of 2023 were $6,077,000, an increase of $1,101,000 or 22.1% compared to $4,976,000 for the third quarter of 2022. This increase was primarily due to an increase in compensation expenses.

Total financial income for the third quarter of 2023 was $461,000, an increase of $380,000 or 469% compared to $81,000 for the third quarter of 2022. This increase was primarily due to a $412,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Net loss for the third quarter of 2023 totaled $5,178,000 or $0.15 per basic and diluted share, compared to a net loss of $4,529,000, or $0.58 per basic and diluted share, for the same period in 2022.

As of September 30, 2023, cash, cash equivalents and short-term investments and bank deposits were $43.0 million compared to $17.8 million as of December 31, 2022.

Financial Results for the Nine Months ended September 30, 2023

For the nine months ended September 30, 2023, revenue increased by $299,000, or 7.2%, to $4,444,000, from $4,145,000 during the nine months ended September 30, 2022. This increase was predominantly driven by a $347,000 increase in sales volume of CGuard EPS from $4,097,000 during the nine months ended September 30, 2022, to $4,444,000 during the nine months ended September 30, 2023.

For the nine months ended September 30, 2023, gross profit (revenue less cost of revenues) increased by 41.7%, or $383,000, to $1,302,000, compared to a $919,000 for the same period in 2022. This increase in gross profit resulted from a $246,000 increase in revenues less the associated related material and labor costs and a decrease in write-offs of $199,000. This increase was partially offset by an increase of $62,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 29.3% during the nine months ended September 30, 2023, from 22.2% during the nine months ended September 30, 2022, driven by the reasons mentioned above.

Total operating expenses for the nine months ended September 30, 2023, were $16,637,000, an increase of $1,941,000, or 13.2% compared to $14,696,000 for the nine months ended September 30, 2022. This increase was primarily due to an increase in compensation and other general and administrative expenses.

Total financial income for the nine months ended September 2023, was $824,000, an increase of $693,000 or 529% compared to $131,000 for the nine months ended September 30, 2022. This increase was primarily due to a $689,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Net loss for the nine months ended September 30, 2023 totaled $14,511,000, or $0.69 per basic and diluted share, compared to a net loss of $13,646,000, or $1.75 per basic and diluted share, for the nine months ended September 30, 2022.

Conference Call and Webcast Details

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

Monday, November 6th, at 8:30 a.m. ET

Domestic:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13741842
Call me™	Link here
Webcast:	Link 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 September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues	$ 1,556	$ 1,431	$ 4,444	$ 4,145
Cost of revenues	1,118	1,065	3,142	3,226
Gross Profit	438	366	1,302	919
Operating Expenses:				
Research and development	2,110	2,061	5,946	5,797
Selling and marketing	876	845	2,556	2,577
General and administrative	3,091	2,070	8,135	6,322
Total operating expenses	6,077	4,976	16,637	14,696
Loss from operations	(5,639)	(4,610)	(15,335)	(13,777)
Financial income	461	81	824	131
Net Loss	$ (5,178)	$ (4,529)	$ (14,511)	$ (13,646)
Net loss per share – basic and diluted	$ (0.15)	$ (0.58)	$ (0.69)	$ (1.75)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	33,984,953	7,838,506	21,148,538	7,816,974

(1) 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; all 2022 financial information is derived from the Company's 2022 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

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

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,869	$ 4,632
Short-term bank deposits	-	13,171
Marketable securities	29,159	-
Accounts receivable:		
Trade, net	1,045	1,034
Other	363	213
Prepaid expenses	476	655
Inventory	1,846	1,621
Total current assets	46,728	21,326
Non-current assets:		
Property, plant and equipment, net	907	917
Operating lease right of use assets	1,538	1,554
Funds in respect of employee rights upon retirement	847	856
Total non-current assets	3,292	3,327
Total assets	$ 50,020	$ 24,653

(2) All September 30, 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. 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, 2022 filed with the Securities

	September 30, 2023	December 31, 2022
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 600	$ 659
Other	4,090	4,411
Total current liabilities	4,690	5,070
Long-term liabilities:		
Operating lease liabilities	1,062	1,195
Liability for employees rights upon retirement	1,011	995
Total long-term liabilities	2,073	2,190
Total liabilities	$ 6,763	$ 7,260
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2023 and December 31, 2022; 21,400,163 and 8,330,918 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2023 and December 31, 2022; 1,718 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	*	*
Additional paid-in capital	259,351	218,977
Accumulated deficit	(216,096)	(201,585)
Total equity	43,527	17,393
Total liabilities and equity	$ 50,020	$ 24,653