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 16, 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 May 16, 2023, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 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 May 16, 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: May 16, 2023

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

Exhibit 99.1

InspireMD Reports First Quarter 2023 Financial Results and Provides Business Update

- Completed transformational private placement for up to $113.6 million, including $42.2 million upfront -

- Generated Q1 2023 CGuard EPS revenue of $1.2 million, an increase of 6.7% over Q1 2022 despite the temporary expiration of the Company's CE Mark certification until mid-March –

- Resumed shipments of CGuard EPS to CE Mark territories under the pre-existing Medical Device Directive (MDD) regulatory framework; Anticipates re-certification under new Medical Device Regulation (MRD) framework in coming weeks –

- Continued enrollment in the C-Guardian US IDE trial; on track to complete enrollment by end of Q2 2023 -

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Management to host investor conference call today, May 16th, at 8:30am ET

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Tel Aviv, Israel, and MIAMI — May 16, 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 first quarter ended March 31, 2023.

First Quarter 2023 and Recent Developments:

- Successfully completed a transformational private placement of common shares, prepaid warrants and warrants for up to $113.6 million in gross proceeds, including $42.2 million upfront and additional proceeds of up to $71.4 million if milestone-driven warrants are exercised. Proceeds are intended to be used to advance the company's business towards achieving several notable milestones, including obtaining potential regulatory approval and launch of CGuard in the U.S., initiating new regulatory pathways for advanced applications of its CGuard stent platform, and developing new products, while at the same time continuing to grow its business outside of the United States.

- Generated CGuard revenue for the first quarter 2023 of $1,239,064, a 6.7% increase over the same period in 2022. Shipments for the first half of the quarter were negatively impacted by the temporary expiration of the Company's CE Mark. During the second half of the quarter, the CE Mark was reinstated under the MDD allowing the Company to resume shipments to EU countries. The Company continues to work through the backlog of orders resulting from the temporary CE Mark lapse.

- Sold 2,033 CGuard EPS stent systems in the first quarter of 2023, as compared to 1,910 in the first quarter of 2022, an increase of 6.4%.

- Announced that the U.S. Food and Drug Administration (FDA) approved the Company's next generation stent delivery system, CGuard Prime, for use in its ongoing U.S. IDE trial.

- 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 increasing demand for CGuard globally.

- 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, consistent with prior guidance.

Marvin Slosman, CEO of InspireMD, commented: "The clear highlight since our last quarterly update was the truly transformational financing that we successfully completed, with participation from leading fundamental healthcare investors. This significant transaction allows us to advance our business towards several very meaningful milestones, including potential FDA approval and launch of CGuard EPS in the U.S., initiation of new regulatory pathways for advanced applications of our CGuard stent platform, and development of new products, while at the same time continuing to grow our business outside of the United States. It also provides invaluable validation of our Company's strategy to lead the carotid revascularization market globally with a stent-focused, clinical outcomes-based approach.

"Regarding the first quarter, we were able to generate year-over-year growth in CGuard EPS revenue and units shipped even as the temporary lapse of our CE Mark certification prevented us from selling into our key markets until approximately the second half of the quarter, when we were permitted to resume sales under the pre-existing MDD framework as we await final recertification under MDR. We believe this speaks to growing awareness of CGuard's superior short- and long-term clinical outcomes, demonstrated across numerous clinical studies, that differentiate it from competing stent systems and make it a compelling alternative to far more invasive surgery.

"In parallel, our critical U.S. IDE trial continues to progress, with the recent completion of the first-in-human stenting procedure using the CGuard Prime CAS delivery system. We anticipate completing enrollment by approximately the end of this quarter. Obtaining U.S. marketing approval of CGuard EPS remains a top priority and would represent a watershed opportunity in the direction for our company.

"With the planned introduction of a new stent delivery system in CGuard Prime, along with our SwitchGuard TCAR neuro protection system, we believe we are well positioned to accelerate the ongoing conversion of carotid surgical procedures to endovascular stent-based interventions, where carotid artery disease significantly lags other endovascular procedure categories. At the same time, with the likely recertification of our CE Mark under MDR occurring imminently, we plan to continue to grow market share in our approved served markets. We are incredibly encouraged by the potential of these transformational milestones for our company and look forward to our focus on growth and market leadership," Mr. Slosman concluded.

Financial Results for the First Quarter ended March 31, 2023

For the three months ended March 31, 2023, revenue increased by $56,000, or 4.7%, to $1,239,000, from $1,183,000 during the three months ended March 31, 2022. This increase was predominantly driven by a 6.7% increase in sales of CGuard EPS from $1,161,000 during the three months ended March 31, 2022, to $1,239,000 during the three months ended March 31, 2023.

During the second half of the quarter, the company's CE mark was reinstated under the MDD directive allowing the company to resume sales and shipments to the EU countries. The Company worked through the remainder of the quarter shipping product to reduce the backlog of orders that accumulated over the past few months. InspireMD believes the quarter-over-quarter increase in revenue during the first quarter of 2023 is not representative of the real underlying market demand for CGuard EPS, due to the Company's inability to ship product for the first half of the quarter. The Company continues to work to expedite the review process for recertification under the MDR.

For the three months ended March 31, 2023, gross profit (revenue less cost of revenues) increased by $251,000, or 205.6%, to $373,000, from $122,000 during the three months ended March 31, 2022. This increase in gross profit resulted from a decrease in write-offs of $184,000 and a $71,000 increase in revenues (as mentioned above), less the associated related material and labor. Gross margin (gross profits as a percentage of revenue) increased to 30.1% during the three months ended March 31, 2023, from 10.3% during the three months ended March 31, 2022, driven by the factors mentioned above.

Total operating expenses for the first quarter of 2023, were $4,754,000, an increase of $146,000 or 3.2% compared to $4,608,000 for the first quarter of 2022. This increase was primarily due to increases in expenses related to C-Guardians FDA study, sales and marketing expenses, and regulatory expenses.

Net loss for the first quarter of 2023 totaled $4,256,000 or $0.53 per basic and diluted share, compared to a net loss of $4,481,000, or $0.57 per basic and diluted share, for the same period in 2022.

As of March 31, 2023, cash, cash equivalents and short-term bank deposits were $12.9 million compared to $17.8 million as of December 31, 2022. As noted, subsequent to the end of the first quarter 2023, the Company completed a private placement that resulted in upfront gross proceeds of $42.2 million.

Conference Call and Webcast Details

Management will host a conference call today, Tuesday, May 16th, 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.

Tuesday, May 16th, at 8:30 a.m. ET

Domestic:	1-844-826-3035
International:	1-412-317-5195
Conference ID:	10178031
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, 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:

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

	Three months ended March 31,	
	2022	**2022**
Revenues	$ 1,239	$ 1,183
Cost of revenues	866	1,061
Gross Profit	373	122
Operating Expenses:		
Research and development	1,843	1,680
Selling and marketing	788	746
General and administrative	2,123	2,182
Total operating expenses	4,754	4,608
Loss from operations	(4,381)	(4,486)
Financial Income, net	125	5
Net Loss	$ (4,256)	$ (4,481)
Net loss per share – basic and diluted	$ (0.53)	$ (0.57)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	8,093,340	7,804,245

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

	March 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,228	$ 4,632
Short-term bank deposits	8,657	13,171
Accounts receivable:		
Trade, net	1,417	1,034
Other	310	213
Prepaid expenses	394	655
Inventory	1,697	1,621
Total current assets	16,703	21,326
Non-current assets:		
Property, plant and equipment, net	887	917
Operating lease right of use assets	1,472	1,554
Funds in respect of employee rights upon retirement	859	856
Total non-current assets	3,218	3,327
Total assets	$ 19,921	$ 24,653

	March 31, 2022	December 31, 2021
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 607	$ 659
Other	3,776	4,411
Total current liabilities	4,383	5,070
Long-term liabilities:		
Operating lease liabilities	1,081	1,195
Liability for employees rights upon retirement	1,031	995
Total long-term liabilities	2,112	2,190
Total liabilities	$ 6,495	$ 7,260
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2023 and December 31, 2022; 8,326,648 and 8,330,918 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2023 and December 31, 2022; 1,718 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	*	*
Additional paid-in capital	219,266	218,977
Accumulated deficit	(205,841)	(201,585)
Total equity	13,426	17,393
Total liabilities and equity	$ 19,921	$ 24,653

(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.

(2) All March 31, 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 and Exchange Commission.