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): **August 8, 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 August 8, 2023, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the three and six months ended June 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 August 8, 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: August 8, 2023

By: */s/ Amir Kohen*
Name: Amir Kohen
Title: Interim Chief Financial Officer

Exhibit 99.1

InspireMD Reports Second Quarter 2023 Financial Results and Provides Business Update

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

- Completed enrollment in the C-Guardians US IDE trial; on track to announce primary and secondary endpoints and, if successful, submit PMA application in H2 2024 –

- Generated Q2 2023 CGuard EPS revenue of $1.6 million, an increase of nearly 10% over Q2 2022 –

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

Tel Aviv, Israel, and Miami, FL — August 8, 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 and operating results for the second quarter ended June 30, 2023.

Second 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 upon exercise of milestone-driven warrants.
- Completed enrollment in the C-Guardians Investigational Device Exemption (IDE) Clinical Trial. The Company anticipates announcing primary and secondary endpoints and, if successful, submitting a Premarket Approval (PMA) application to FDA in the second half of 2024.
- Announced the first-in-human cases successfully performed with its CGuard Prime CAS stent delivery platform as part of C-Guardians trial enrollment.
- Generated record CGuard revenue for the second quarter 2023 of $1,649,000, a 9.6 % increase over the same period in 2022 and a 33% increase over the first quarter of 2023.
- Sold 2,804 CGuard EPS stent systems in the second quarter of 2023, as compared to 2,602 in the second quarter of 2022, an increase of 7.8%, and compared to 2,033 in the first quarter of 2023, an increase of 38%.

Marvin Slosman, CEO of InspireMD, commented: “Our second quarter was marked by several transformational milestones for our business, including the financing of up to $113.6 million that we announced in May. This capital allows us to advance our business towards multiple value-creating milestones, including obtaining potential regulatory approval of and launching our CGuard stent system in the U.S., initiating regulatory pathways for new advanced indications for CGuard, and developing new products, while at the same time continuing to grow our business in approved markets outside of the United States.

“We also announced completion of enrollment in our C-Guardians IDE trial, which includes the first ever cases performed with our CGuard Prime CAS stent delivery platform that we also plan to include in our regulatory submissions. Importantly, enrollment was completed efficiently in under 24 months and gives us line of sight to results and, if successful, a PMA submission in the second half of next year. In parallel, we continue to advance critical pre-commercial activities in the U.S. with the goal of launching CGuard Prime in the first half of 2025, if approved.

“The ongoing shift toward an endovascular standard of care with both CAS and TCAR, highlighted by the current CMS proposed decision memo to expand reimbursement for CAS, further validates our strategic direction. We are striving to serve all physician specialties that treat carotid disease, both CAS and TCAR, with our best-in-class CGuard EPS implant. We believe we are optimally positioned to make the CGuard EPS stent system the standard of care, not only in the U.S. but globally,” Mr. Slosman concluded.

Financial Results for the Second Quarter ended June 30, 2023

For the three months ended June 30, 2023, revenue increased by $118,000, or 7.7%, to $1,649,000, from $1,531,000 during the three months ended June 30, 2022. This increase was predominantly driven by a 9.6% increase in sales of CGuard EPS from $1,505,000 during the three months ended June 30, 2022, to $1,649,000 during the three months ended June 30, 2023.

For the three months ended June 30, 2023, gross profit (revenue less cost of revenues) increased by $60,000, or 14.0%, to $491,000, from $431,000 during the three months ended June 30, 2022. This increase in gross profit resulted from a $90,000 increase in revenues (as mentioned above), less the associated related material and labor offset by $30,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 29.8% during the three months ended June 30, 2023, from 28.1% during the three months ended June 30, 2022, driven by the factors mentioned above.

Total operating expenses for the second quarter of 2023, were $5,806,000, an increase of $694,000 or 13.6% compared to $5,122,000 for the second quarter of 2022. This increase was primarily due to an increase in compensation expenses.

Net loss for the second quarter of 2023 totaled $5,077,000 or $0.24 per basic and diluted share, compared to a net loss of $4,636,000, or $0.59 per basic and diluted share, for the same period in 2022.

As of June 30, 2023, cash, cash equivalents and short-term investments and bank deposits were $47.0 million compared to $17.8 million as of December 31, 2022. This includes the initial net funding of $37.5 million received upon closing of the transformational private placement that was announced in May, after deducting transaction expenses.

Financial Results for the Six Months ended June 30, 2023

For the six months ended June 30, 2023, revenue increased by $174,000, or 6.4%, to $2,888,000, from $2,714,000 during the six months ended June 30, 2022. This increase was predominantly driven by a 8.3% increase in sales volume of CGuard EPS from $2,666,000 during the six months ended June 30, 2022, to $2,888,000 during the six months ended June 30, 2023.

For the six months ended June 30, 2023, gross profit (revenue less cost of revenues) increased by 56.2%, or $311,000, to $864,000, compared to a $553,000 for the same period in 2022. This increase in gross profit resulted from a decrease in write-offs of $181,000 and a $161,000 increase in revenues (as mentioned above) less the associated related material and labor costs. This increase was partially offset by an increase of $31,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 29.9% during the six months ended June 30, 2023, from 20.4% during the six months ended June 30, 2022, driven by the reasons mentioned above.

Total operating expenses for the six months ended June 30, 2023, were $10,560,000, an increase of $840,000, or 8.6% compared to $9,720,000 for the six months ended June 30, 2022. This increase was primarily due to an increase in compensation and other general and administrative expenses.

Net loss for the six months ended June 30, 2023 totaled $9,333,000, or $0.64 per basic and diluted share, compared to a net loss of $9,117,000, or $1.17 per basic and diluted share, for the six months ended June 30, 2022.

Conference Call and Webcast Details

Management will host a conference call today, Tuesday, August 8, 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, August 8th, at 8:30 a.m. ET

Domestic:	1-844-826-3035
International:	1-412-317-5195
Conference ID:	10180798
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.

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

	Three months ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues	$ 1,649	$ 1,531	$ 2,888	$ 2,714
Cost of revenues	1,158	1,100	2,024	2,161
Gross Profit	491	431	864	553
Operating Expenses:				
Research and development	1,993	2,056	3,836	3,736
Selling and marketing	892	986	1,680	1,732
General and administrative	2,921	2,070	5,044	4,252
Total operating expenses	5,806	5,112	10,560	9,720
Loss from operations	(5,315)	(4,681)	(9,696)	(9,167)
Financial income	238	45	363	50
Net Loss	$ (5,077)	$ (4,636)	$ (9,333)	$ (9,117)
Net loss per share – basic and diluted	$ (0.24)	$ (0.59)	$ (0.64)	$ (1.17)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	21,074,187	7,807,795	14,619,622	7,806,030

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

	June 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,545	$ 4,632
Short-term bank deposits	6,631	13,171
Marketable securities	28,817	-
Accounts receivable:		
Trade, net	1,470	1,034
Other	312	213
Prepaid expenses	56	655
Inventory	1,689	1,621
Total current assets	50,520	21,326
Non-current assets:		
Property, plant and equipment, net	873	917
Operating lease right of use assets	1,388	1,554
Funds in respect of employee rights upon retirement	857	856
Total non-current assets	3,118	3,327
Total assets	$ 53,638	$ 24,653

	June 30, 2023	December 31, 2022
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 768	$ 659
Other	4,061	4,411
Total current liabilities	4,829	5,070
Long-term liabilities:		
Operating lease liabilities	970	1,195
Liability for employees rights upon retirement	1,026	995
Total long-term liabilities	1,996	2,190
Total liabilities	$ 6,825	$ 7,260
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2023 and December 31, 2022; 21,192,204 and 8,330,918 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 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	257,729	218,977
Accumulated deficit	(210,918)	(201,585)
Total equity	46,813	17,393
Total liabilities and equity	$ 53,638	$ 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 June 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