INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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 9, 2022**

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 9, 2022, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the three and six months ended June 30, 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 August 9, 2022 (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 11, 2022

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

Exhibit 99.1

InspireMD Reports Second Quarter 2022 Financial Results and Provides Business Update

- Generated 47.8% growth in CGuard™ revenue year-over-year -

- Delivered several presentations at LINC 2022 featuring CGuard™ EPS, including a successful live case transmission -

- Announced that endovascular pioneer Dr. Juan Parodi has agreed to act as strategic advisor to the company -

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Management to Host Investor Conference Call Today, August 9th, at 8:30am ET

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Tel Aviv, Israel— August 9, 2022 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention 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, 2022.

Second Quarter 2022 and Recent Highlights:

- CGuard revenues for the second quarter 2022 were $1,505,000, a 47.8% increase over the same period in 2021, on 2,602 stent systems sold, as compared to 1,623 stents sold in the same period in 2021.

- Continued enrollment in the C-Guardian Investigational Device Exemption (IDE) Clinical Trial. The Company completed its first European enrollment in April, led by co-principal investigator Professor Piotr Musialek, at John Paul II Hospital, in Krakow, Poland. The company currently has 20 trial sites enrolling patients and anticipates adding seven more by the end of the year. The company anticipates completing enrollment in Q1 2023.

- Delivered several presentations at LINC 2022 featuring CGuard™ EPS, including a live case transmission on a 62-year-old asymptomatic male with progressive and calcified internal carotid critical stenosis. The procedure was successfully performed with the 10mm x 30mm CGuard™ EPS and produced an excellent angiographic result.

- Announced that endovascular pioneer Dr. Juan Parodi has agreed to act as strategic advisor to the company. Dr. Parodi is credited with performing the first endovascular repair procedure in 1990 and the first TCAR procedure in 1994.

Marvin Slosman, CEO of InspireMD, commented: "Our second quarter revenue results again demonstrated our ability to gain share in our key European markets. With 48% growth in revenue in the quarter, respectively, over the same quarterly period last year, we believe we are well on our way to establishing CGuard™ EPS as a 'new' standard of care for the management of carotid artery disease and stroke prevention."

"Regarding our U.S. IDE trial, we now have 22 sites enrolling patients, and plan to bring an additional seven online by the end of the year. Enrollment is accelerating and tracking nicely, and we continue to anticipate having the trial fully enrolled by approximately Q1 of next year."

"We expect future growth to be driven by continued market share gains, additional geographic expansion, and the introduction of our new stent delivery systems, CGuard Prime and Switchguard. I look forward to continued momentum and I am beyond excited for what the future holds, not only for our company, but for CAD patients and their treating physicians as well," Mr. Slosman concluded.

Financial Results for the Second Quarter ended June 30, 2022

For the second quarter of 2022, total revenue increased 47.6%, to $1,531,000, from $1,038,000 during the second quarter of 2021. This increase was predominantly driven by a 47.8% increase in sales volume of CGuard EPS, to $1,505,000 in the second quarter of 2022 from $1,019,000 in the same period one year ago. This sales increase was mainly due to growth in existing and new markets as well as US sales related to stents used in the C-Guardian U.S. Food and Drug Administration (FDA) clinical trial.

Gross profit for the second quarter of 2022 increased by $169,000, or 64.4%, to $431,000, compared to a gross profit of $262,000 for the second quarter of 2021. This increase resulted from higher revenue and a reduction in miscellaneous expenses of $55,000, partially offset by a $83,000 reduction in costs of goods sold due to an inventory adjustment that occurred during the three months ended June 30, 2021 which did not occur during the three months ended June 30, 2022. Gross margin (gross profits as a percentage of revenue) increased to 28.1% during the three months ended June 30, 2022 from 25.2% during the three months ended June 30, 2021.

Total operating expenses for the second quarter of 2022, were $5,112,000, an increase of $1,410,000, or 38.1% compared to $3,702,000 for the second quarter of 2021. This increase was primarily due to increases in expenses related to the commencement of the C-Guardians FDA study, resumed activities in tradeshows, travel and share-based compensation.

Net loss for the second quarter of 2022 totaled $4,636,000, or $0.59 per basic and diluted share, compared to a net loss of $3,507,000, or $0.46 per basic and diluted share, for the same period in 2021.

As of June 30, 2022, cash, cash equivalents and short-term bank deposits were $26.5 million compared to $34.0 million as of December 31, 2021.

Financial Results for the Six Months ended June 30, 2022

For the six months ended June 30, 2022, total revenue increased by $670,000, or 32.8%, to $2,714,000, from $2,044,000 during the six months ended June 30, 2021. This increase was predominantly driven by a 34.2% increase in sales volume of CGuard EPS, to $2,666,000 during the six months ended June 30, 2022 from $1,987,000 during the six months ended June 30, 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 which occurred in the six months ended June 30, 2022, but not in the corresponding period in 2021.

Gross profit for the six months ended June 30, 2022 increased by $185,000, or 50.2%, to $553,000, compared to a gross profit of $368,000 for the six months ended June 30, 2021. This increase in gross profit resulted from higher revenue, partially offset by an increase of $38,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 20.4% during the six months ended June 30, 2022 from 18% during the six months ended June 30, 2021.

Total operating expenses for the six months ended June 30, 2022, were $9,720,000, an increase of $2,598,000, or 36.5% compared to $7,122,000 for the six months ended June 30, 2021. This increase was primarily due to increases in expenses related to the commencement of the C-Guardians FDA study, share-based compensation and resumed activities in tradeshows and travel.

Net loss for the six months ended June 30, 2022 totaled $9,117,000, or $1.17 per basic and diluted share, compared to a net loss of $6,750,000, or $0.98 per basic and diluted share, for the six months ended June 30, 2021.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, August 9, 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 9th at 8:30 a.m. ET

Domestic:	855-327-6837
International:	631-891-4304
Conference ID:	10019719
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.

For more information, please visit www.inspiremd.com.

Forward-looking Statements

This press release contains "forward-looking statements." 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 (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, including the changing regulatory environment in Europe and the timing of the renewal of certificate to continue to sell CGuard under the new MDR rule structure, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) 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. 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 June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues	$ 1,531	$ 1,038	$ 2,714	$ 2,044
Cost of revenues	1,100	776	2,161	1,676
Gross Profit	431	262	553	368
Operating Expenses:				
Research and development	2,056	1,290	3,736	2,129
Selling and marketing	986	636	1,732	1,344
General and administrative	2,070	1,776	4,252	3,649
Total operating expenses	5,112	3,702	9,720	7,122
Loss from operations	(4,681)	(3,440)	(9,167)	(6,754)
Financial income (expenses)	45	(67)	50	4
Net Loss	$ (4,636)	$ (3,507)	$ (9,117)	$ (6,750)
Net loss per share – basic and diluted	$ (0.59)	$ (0.46)	$ (1.17)	$ (0.98)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,807,795	7,704,707	7,806,030	6,918,090

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

	June 30, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,393	$ 12,004
Short-term bank deposits	20,078	22,036
Accounts receivable:		
Trade, net	1,183	1,224
Other	171	165
Prepaid expenses	221	522
Inventory	1,454	1,143
Total current assets	29,500	37,094
Non-current assets:		
Property, plant and equipment, net	700	632
Operating lease right of use assets	1,717	1,081
Funds in respect of employee rights upon retirement	849	905
Total non-current assets	3,266	2,618
Total assets	$ 32,766	$ 39,712

	June 30, 2022	December 31, 2021
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,127	$ 893
Other	3,585	3,454
Total current liabilities	4,712	4,347
Long-term liabilities:		
Operating lease liabilities	1,350	781
Liability for employees rights upon retirement	962	1,052
Total long-term liabilities	2,312	1,833
Total liabilities	$ 7,024	$ 6,180
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2022 and December 31, 2021; 8,323,200 and 8,296,256 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2022 and December 31, 2021; 1,718 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	*	*
Additional paid-in capital	217,952	216,625
Accumulated deficit	(192,211)	(183,094)
Total equity	25,742	33,532
Total liabilities and equity	$ 32,766	$ 39,712

(1) 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; all 2021 financial information is derived from the Company's 2021 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, 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. 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, 2021 filed with the Securities and Exchange Commission.