

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): **May 10, 2022**

InspireMD, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-35731
(Commission
File Number)

26-2123838
(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 10, 2022, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 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 May 10, 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: May 10, 2022

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

InspireMD Reports First Quarter 2022 Financial Results and Business Update

- 20% growth in CGuard™ revenue Year-over-Year -

- C-Guardian FDA IDE Trial Completes First European Enrollment -

- Held Key Opinion Leader (KOL) Webinar on Carotid Artery Disease Management and Stroke Prevention, highlighting CGuard™ clinical advantages -

- European logistics hub established with BOMI Group –for direct market access as well as establishing the commercial footprint for a growing portfolio of new systems across different channels –

- Upcoming Clinical Evidence and Live Case to be presented at LINNC 2022-

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Management to Host Investor Conference Call Today, May 10, at 8:30am ET

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Tel Aviv, Israel— May 10, 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 first quarter ended March 31, 2022.

First Quarter 2022 and Recent Highlights:

- CGuard revenues for the first quarter 2022 were \$1,161,000 a 20% increase over the same period in 2021 on 1,910 stent systems sold.
 - Enrollment in the C-Guardian Investigational Device Exemption (IDE) Clinical Trial accelerated and continues to progress on track across both the United States and Europe. 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 which is now one of the 14 trial sites actively enrolling or recruiting patients worldwide.
 - On March 22, internationally recognized Key Opinion Leaders and members of the Company’s Scientific Advisory Board, Chris Metzger, MD, PhD, from Ballad Health System, Adnan Siddiqui, MD, PhD, FACS, FAHA, FAANS, from State University of New York at Buffalo’s Jacobs School of Medicine and Biomedical Sciences, and Sean Lyden, MD, from Cleveland Clinic, chaired an interactive discussion around the current endovascular trends in the carotid and neurovascular market, and presented their perspective of how InspireMD’s CGuard stent system and expanding pipeline have the potential to offer better clinical outcomes.
 - Executed a logistics agreement with BOMI Group which is designed to support a growing commercial infrastructure dedicated to the expansion of InspireMD’s direct sales program. The BOMI agreement provides a logistics hub to allow greater flexibility as the Company expands its portfolio across direct channels.
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Marvin Slosman, CEO of InspireMD, commented: “The first quarter marked important progress, as we continued to execute our commercial strategies, increase our market share, and grow revenue across most of our served markets in particular in Europe. The CGuard, with the unique MicroNet mesh for sustained cerebral protection, continues to demonstrate steady physician adoption by improving the endovascular standard of care for the prevention of stroke caused by carotid artery disease. Our focus on superior stent performance translates directly to best patient outcomes serving all vascular specialties. As we expand our delivery systems around CGuard, we expect to continue to grow our market share and drive conversion of surgeries to stenting.

Our pipeline of innovative delivery solutions such as CGuard Prime and SwitchGuard are anticipated to launch early 2023, to facilitate greater utilization of our devices as first line solution for carotid artery disease management.

Ongoing enrollment in the C-Guardians IDE pivotal study in the United States has now expanded to include European participation, which we believe will continue to accelerate enrollment with experienced CGuard investigators,” said Marvin Slosman, CEO of InspireMD.

“We remain committed to our core mission to establish a new standard of care for addressing carotid artery disease and stroke prevention, delivering best patient outcomes both short and long term through stent performance, which delivers unmatched clinical results to this ever-expanding endovascular focused market. We believe our CGuard EPS stent with MicroNet mesh combined with the broadest range of new delivery options, will establish a new standard of care,” Marvin Slosman added.

Financial Results for the First Quarter ended March 31, 2022

For the first quarter of 2022, revenue increased 17.6%, to \$1,183,000, from \$1,006,000 during the first quarter of 2021. This increase was predominantly driven by a 19.8% increase in sales volume of CGuard EPS from \$969,000 in the same period one year ago, to \$1,161,000 for the first quarter 2022. This sales increase was mainly due to growth in existing and new markets as well as the returning demand from hospitals in a post COVID 19 environment. In addition, US sales increased related to stents used in the C-Guardian U.S. Food and Drug Administration (FDA) clinical trial. The increase in sales of CGuard EPS was slightly offset by a lack of sales to Russia, Belarus and the Ukraine in quarter due to the regional conflict and related currency restrictions.

Gross profit for the first quarter of 2022 increased by \$16,000, to \$122,000, compared to a gross profit of \$106,000 for the first quarter of 2021. This increase in gross profit resulted from a \$30,000 decrease in write-offs which were driven mainly by components supply issues. Gross margin decreased to 10.3% during the three months ended March 31, 2022 from 10.5% during the three months ended March 31, 2021, driven by the factors mentioned above.

Total operating expenses for the first quarter of 2022, were \$4,608,000, an increase of \$1,188,000, or 34.7% compared to \$3,420,000 for the first quarter of 2021. This increase was primarily due to increases in expenses related to the commencement of the C-Guardians FDA study and share based compensation.

Net loss for the first quarter of 2022 totaled \$4,481,000, or \$0.57 per basic and diluted share, compared to a net loss of \$3,243,000, or \$0.53 per basic and diluted share, for the same period in 2021.

As of March 31, 2022, cash, cash equivalents and short-term bank deposits were \$29.9 million compared to \$34.0 million as of December 31, 2021.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, May 10, 2022, 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 10, 2022 at 8:30 a.m. ET

Domestic:	877-407-4018
International:	201-689-8471
Conference ID:	13729033
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, (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	
	March 31,	
	2022	2021
Revenues	\$ 1,183	\$ 1,006
Cost of revenues	1,061	900
Gross Profit	122	106
Operating Expenses:		
Research and development	1,680	839
Selling and marketing	746	708
General and administrative	2,182	1,873
Total operating expenses	4,608	3,420
Loss from operations	(4,486)	(3,314)
Financial Income, net	5	71
Net Loss	\$ (4,481)	\$ (3,243)
Net loss per share – basic and diluted	\$ (0.57)	\$ (0.53)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,804,245	6,122,690

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

	March 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 7,798	\$ 12,004
Short-term bank deposits	22,053	22,036
Accounts receivable:		
Trade, net	1,113	1,224
Other	91	165
Prepaid expenses	291	522
Inventory	1,286	1,143
Total current assets	32,632	37,094
Non-current assets:		
Property, plant and equipment, net	628	632
Operating lease right of use assets	996	1,081
Funds in respect of employee rights upon retirement	915	905
Total non-current assets	2,539	2,618
Total assets	\$ 35,171	\$ 39,712

	March 31, 2022	December 31, 2021
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 900	\$ 893
Other	2,791	3,454
Total current liabilities	3,691	4,347
Long-term liabilities:		
Operating lease liabilities	678	781
Liability for employees rights upon retirement	1,098	1,052
Total long-term liabilities	1,776	1,833
Total liabilities	\$ 5,467	\$ 6,180
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2022 and December 31, 2021; 8,317,876 and 8,296,256 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	1	1
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2021 and December 31, 2020; 1,718 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	*	*
Additional paid-in capital	217,278	216,625
Accumulated deficit	(187,575)	(183,094)
Total equity	29,704	33,532
Total liabilities and equity	\$ 35,171	\$ 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 March 31, 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.