

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 05/12/20 for the Period Ending 05/12/20

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 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 12, 2020

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)

N/A

(Former Name or former address, if changed since last report)

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 exchange on which registered
Common Stock, par value \$0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company 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 12, 2020, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 31, 2020. 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 12, 2020 (furnished herewith pursuant to Item 2.02)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

InspireMD, Inc.

Date: May 12, 2020

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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InspireMD Announces First Quarter 2020 Financial Results

First quarter revenue growth driven by continued strong uptake of the CGuard™ Embolic Prevention System (EPS) in the company's major markets

Management to host investor conference call today, May 12, at 8:30am ET

Tel Aviv, Israel— May 12, 2020 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of Carotid Artery Disease (CAD), today announced financial and operating results for the first quarter ended March 31, 2020.

First Quarter 2020 and recent highlights:

- Generated CGuard™ EPS revenue of \$971,000, an increase of 158.2% compared to \$376,000 in the first quarter of 2019, when the company's previous third-party sterilizer equipment failures caused a significant interruption in sterilized product supply for the majority of the first quarter.
- For the third consecutive year, company was chosen to demonstrate a successful live clinical case transmission featuring CGuard™ EPS at the Leipzig Interventional Course (LINC) 2020 that showcased CGuard's ease-of-use and exceptional patient safety features
- Completed all additional bench testing requested by FDA in support of the company's pending IDE application, which the company expects to re-file in May 2020
- Continued to advance plans to broaden the company's product portfolio with procedural protection devices based on its reverse flow technology as well as develop new indications for the CGuard EPS with MicroNet.

“The ongoing COVID-19 pandemic has placed unprecedented pressure on healthcare systems around the world, and we are seeing this impact on elective procedure volumes, including carotid artery disease treatments,” stated Marvin Slosman, Chief Executive Officer of InspireMD. “However, these procedures must ultimately occur to save lives, and we stand ready with our support and supply infrastructure to quickly fulfill the needs of physicians and their patients as a more normalized healthcare environment reemerges.”

“I am more enthusiastic than ever about the potential of CGuard EPS – and its novel MicroNet® technology - to fundamentally disrupt the current standard of care in carotid stenosis. During the quarter, we continued to see consistent growth across all our current markets while we simultaneously worked to open new opportunities in Brazil, France, the Asia/Pacific region and, of course, the United States. Longer-term, I believe we can establish another pillar of growth by further exploiting our reverse flow technology in a procedural protection device and to expand our product pipeline with CGuard with MicroNet into new high-value indications.

“During these highly challenging and uncertain times, I am buoyed by our team’s ability to maintain these essential growth drivers in light of the changes we have made in order to operate safely and effectively. This is a reflection of our team’s ongoing quest for high achievement, high accountability and laser focus,” concluded Mr. Slosman.

Financial Results

For the three months ended March 31, 2020, revenue increased by \$619,000, or 149.2%, to \$1,034,000, from \$415,000 during the three months ended March 31, 2019. This increase was predominantly driven by a 158.2% increase in sales volume of CGuard EPS from \$376,000 during the three months ended March 31, 2019, to \$971,000 during the three months ended March 31, 2020, mainly due to the company’s previous third-party sterilizer equipment failures which caused a significant interruption in sterilized product supply for the majority of the first quarter 2019 as well as the company’s continued focus in expanding revenue base in the company’s major markets. In addition, MGuard Prime EPS sales increased from \$39,000 during the three months ended March 31, 2019, to \$63,000 during the three months ended March 31, 2020, due to the delayed shipments of sterilized products during the three months ended March 31, 2019, as mentioned above. The company’s gross profit for the quarter ended March 31, 2020 was \$295,000, compared to a gross loss of \$73,000 for the same period in 2019. This increase in gross profit was primarily driven by a higher volume of sales of CGuard EPS less the related material and labor costs and a decrease in write-offs of inventory during the three months ended March 31, 2020 due to the same sterilization issue mentioned above. Gross margin increased to 28.5% in the first quarter of 2020 from (17.6%) for the same period in 2019.

Total operating expenses for the quarter ended March 31, 2020 were \$2,316,000, a decrease of 24.2% compared to \$3,057,000 for the same period in 2019. This decrease was primarily due to a reduction of \$328,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, a decrease of \$354,000 due to settlement expenses made to a former service provider pursuant to a settlement agreement during the three months ended March 31, 2019, which did not occur during the three months ended on March 31, 2020 as well as \$59,000 of miscellaneous expense reductions.

Financial income for the quarter ended March 31, 2020 was \$43,000 compared to financial expenses of \$77,000 for the same period in 2019. This increase in income of \$120,000 was predominately due to changes in exchange rates. Net loss for the fourth quarter of 2020 totaled \$1,978,000, or \$0.43 per basic and diluted share, compared to a net loss of \$3,207,000, or \$3.82 per basic and diluted share, for the same period in 2019.

As of March 31, 2020, cash and cash equivalents were \$3,141,000, compared to \$5,514,000 at December 31, 2019.

Conference Call and Webcast Details

The conference call will be available via telephone by dialing toll free 877-451-6152 for U.S. callers, or +1 201-389-0879 for international callers, and referencing conference ID 13703268. To access the webcast, please go to the following link: <http://public.viavid.com/index.php?id=139696>. The webcast will be archived on the Company's website.

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 NYSE American under the ticker symbol NSPR and certain warrants are quoted on the NYSE American under the ticker symbol NSPR.WS and NSPR.WSB.

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" 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 transition to the new European Medical Devices Regulation, (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 and public health crisis 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,	
	2020	2019
Revenues	\$ 1,034	\$ 415
Cost of revenues	739	488
Gross Profit (Loss)	295	(73)
Operating Expenses:		
Research and development	523	1,125
Selling and marketing	624	634
General and administrative	1,169	1,298
Total operating expenses	2,316	3,057
Loss from operations	(2,021)	(3,130)
Financial expenses (Income)	(43)	77
Net Loss	\$ (1,978)	\$ (3,207)
Net loss per share – basic and diluted	\$ (0.43)	\$ (3.82)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	4,623,034	839,533

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

	March 31, 2020	December 31, 2019
	<u> </u>	<u> </u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 3,141	\$ 5,514
Accounts receivable:		
Trade, net	856	823
Other	174	150
Prepaid expenses	63	87
Inventory	<u>1,202</u>	<u>1,236</u>
Total current assets	<u>5,436</u>	<u>7,810</u>
Non-current assets:		
Property, plant and equipment, net	496	547
Operating lease right of use assets	864	937
Funds in respect of employee rights upon retirement	<u>589</u>	<u>586</u>
Total non-current assets	<u>1,949</u>	<u>2,070</u>
Total assets	<u>\$ 7,385</u>	<u>\$ 9,880</u>

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 562	\$ 646
Other	2,024	2,449
Contract liability	17	20
Total current liabilities	<u>2,603</u>	<u>3,115</u>
Long-term liabilities:		
Operating lease liabilities	544	653
Liability for employees rights upon retirement	761	729
Total long-term liabilities	<u>1,305</u>	<u>1,382</u>
Total liabilities	<u>3,908</u>	<u>4,497</u>
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2020 and December 31, 2019; 4,338,910 and 3,916,134 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	-	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at March 31, 2020 and December 31, 2019; 17,303 shares issued and outstanding at March 31, 2020 and December 31, 2019.	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2020 and December 31, 2019; 26,558 and 34,370 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	-	-
Additional paid-in capital	163,087	163,015
Accumulated deficit	(159,610)	(157,632)
Total equity	<u>3,477</u>	<u>5,383</u>
Total liabilities and equity	<u>\$ 7,385</u>	<u>\$ 9,880</u>

(1) All 2020 financial information is derived from the Company's 2020 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; all 2019 financial information is derived from the Company's 2019 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, 2020 financial information is derived from the Company's 2020 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, 2019 financial information is derived from the Company's 2019 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2019 filed with the Securities and Exchange Commission.

