

INSPIREMD, INC.

FORM 8-K (Current report filing)

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Telephone	(888) 776-6804
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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 11, 2021

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 11, 2021, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the first quarter ended March 31, 2021. A copy of that 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 11, 2021 (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 11, 2021

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces First Quarter 2021 Financial Results

Company Completes Up-List to Nasdaq Capital Market, with Trading Becoming Effective May 21, 2021

Management to host investor conference call today, May 11, 2021, at 8:30am ET

Tel Aviv, Israel— May 11, 2021 – 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, 2021.

First Quarter 2021 and recent highlights:

- Announced the up-list to the Nasdaq Capital Market, on which the company's stock will be traded beginning May 21, 2021
- Announced reverse stock split of 1:15 with subsequent successful up-listing of shares on the Nasdaq Capital Market.
- Announced the closing of an upsized underwritten public offering combined with other capital raising transactions in Q1 2021, which netted the Company a total of \$35.1 million.
- Announced the appointment of leading interventional cardiologist Chris Metzger, M.D., as the principal investigator for planned the C-Guardian FDA trial for CGuard EPS.
- Secured China distribution agreement including investment and partnership for seeking regulatory approval for CGuard EPS in mainland China.
- Announced the engagement of Hart Clinical Consultants (HCC), a leading Contract Research Organization (CRO) to conduct the clinical trial of CGuard Carotid Stent System in the United States.
- Selected for multiple presentations for CGuard EPS, including a live demonstration during the Leipzig Interventional Congress (LINC).

“Our persistent and tireless focus on execution continues as we build on our quest to change the standard of care in the treatment of carotid artery disease and stroke prevention, with CGuard EPS and our novel Micronet mesh. Our Q1 achievements have set up 2021 to be a meaningful year of progress toward our goals of global expansion, commercial revenue growth, progress toward FDA approval, growing our unmatched body of clinical evidence, and differentiating CGuard as a truly unique and preferred stent solution for carotid artery disease,” said Marvin Slosman, CEO of InspireMD.



“Most recently, we announced a successful up-listing approval of our common stock on the Nasdaq Capital Market as a part of a reverse stock split approved by stockholders. We believe listing on Nasdaq will help broaden our stockholder base, increase interest by institutional and fundamental investors, and create stockholder value. The anticipated date for our shares to begin trading on NASDAQ is May 21, 2021.

“As we ramp up the start of the C-Guardian U.S. pivotal trial for CGuard EPS -- an important step in our goal to achieve commercial registration in the United States -- we announced that leading interventional cardiologist Chris Metzger, M.D., system chair of clinical research at Ballard Health System in eastern Tennessee, has accepted a role as principle investigator in the U.S., along with Piotr Musialek, who will serve as co-principal investigator focusing on the European enrollment in the trial. Hart Clinical Consultants (HCC), a leading Contract Research Organization (CRO), will spearhead the effort managing the trial execution.

“Executing on our global expansion strategy, we announced this quarter an agreement with three China-based investment partners who will be responsible for conducting all necessary registration and establish distribution for the CGuard EPS in mainland China. This is a foundational building block for our overall Asia growth plan. Stroke is the leading cause of death in China, and the country is believed to be the second largest market for peripheral stent procedures. We continue our push to expand into new the markets of France, Taiwan and Korea.

“Lastly, we have strengthened our balance sheet and cash reserves and believe that we are well positioned and have the resources needed to fund our trial, global expansion and build a pipeline of new products poised to transform the access and delivery of CGuard EPS.

“Advancing into 2021, we are optimistic and encouraged by the direction of our business and the potential for CGuard EPS to change the carotid disease treatment market with the most advanced stent system available,” concluded Mr. Slosman.



Financial Results for the First Quarter ended March 31, 2021

For the three months ended March 31, 2021, revenue decreased by \$28,000, or 2.7%, to \$1,006,000, from \$1,034,000 during the three months ended March 31, 2020. CGuard revenue remained essentially unchanged at \$969,000 during the three months ended March 31, 2021 as compared to \$971,000 during the three months ended March 31, 2020, in spite of the continued postponement of many elective procedures as a result of the residual COVID directed resources. However, MGuard Prime EPS revenue decreased by a 41.3% from \$63,000 during the three months ended March 31, 2020, to \$37,000 during the three months ended March 31, 2021, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in ST-Elevation Myocardial Infarction (“STEMI”) patients.

For the three months ended March 31, 2021, gross profit (revenue less cost of revenues) decreased by 64.1%, or \$189,000, to \$106,000, from \$295,000 during the three months ended March 31, 2020. This decrease in gross profit resulted from an increase in write-offs of \$156,000, which were driven mainly by a component supply issue during the three months ended March 31, 2021 and an increase of \$33,000 in miscellaneous expenses during the three months ended March 31, 2021. Gross margin (gross profits as a percentage of revenue) decreased to 10.5% during the three months ended March 31, 2021 from 28.5% during the three months ended March 31, 2020, driven by the factors mentioned above.

Total operating expenses for the quarter ended March 31, 2021 were \$3,420,000, an increase of 47.7% compared to \$2,316,000 for the same period in 2020. This increase was primarily due to increases of \$430,000 in salary expenses and related accrual expenses mainly driven by additional resources in our product development and sales infrastructure, \$248,000 in share-based compensation-related expenses due to the expense recognition of grants made in the second half of 2020, \$136,000 in development expenses associated with CGuard EPS, mainly related to the new advanced delivery system and accessories, \$118,000 of Directors’ and Officers’ Liability Insurance expense due to increased premiums caused by recent trends in the overall insurance industry, an increase of \$108,000 in stockholder related expenses due to the special stockholder meeting and \$64,000 of miscellaneous expense.

For the three months ended March 31, 2021, financial income increased by 65.1%, or \$28,000, to \$71,000, from \$43,000 during the three months ended March 31, 2020. The increase in financial income primarily resulted from changes in exchange rates.



Net loss for the first quarter of 2021 totaled \$3,243,000, or \$0.53 per basic and diluted share, compared to a net loss of \$1,978,000, or \$6.42 per basic and diluted share, for the same period in 2020. The average amount of shares outstanding used for the earnings per share calculation were 6,122,690 in Q1 2021 and 308,202 in Q1 2020, both adjusted to reflect the 1:15 reverse split.

As of March 31, 2021, cash and cash equivalents were \$44.0 million compared to \$12.6 million as of December 31, 2020. During the first quarter of 2021, the Company raised \$35.1 million net through various equity transactions.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, May 11, 2021, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Please note that registered participants will receive their dial in number upon registration and will dial directly into the call without delay. Those without internet access or unable to pre-register may dial in by calling 1-844-854-4417 (domestic), 1-412-317-5739 (international) or 1-80-9212373 (Israel). All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the InspireMD call.

The conference call will also be available through a live webcast found here: <https://services.choruscall.com/mediaframe/webcast.html?webcastid=yieueRnJ>.

Additionally, it will be broadcast live through the Company's website via the following link: <https://www.inspiremd.com/en/investors/investor-relations/>.

A webcast replay of the call will be available approximately one hour after the end of the call through August 11, 2021 at the above links. A telephonic replay of the call will be available through May 25, 2021 and may be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10155884.

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, (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,	
	2021	2020
Revenues	\$ 1,006	\$ 1,034
Cost of revenues	900	739
Gross Profit	106	295
Operating Expenses:		
Research and development	839	523
Selling and marketing	708	624
General and administrative	1,873	1,169
Total operating expenses	3,420	2,316
Loss from operations	(3,314)	(2,021)
Financial Income, net	71	43
Net Loss	\$ (3,243)	\$ (1,978)
Net loss per share – basic and diluted	\$ (0.53)	\$ (6.42)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	6,122,690	308,202



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

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 44,034	\$ 12,645
Accounts receivable:		
Trade, net	708	476
Other	117	146
Prepaid expenses	207	334
Inventory	1,184	1,415
Receivable for sale of Shares	-	323
Total current assets	<u>46,250</u>	<u>15,339</u>
Non-current assets:		
Property, plant and equipment, net	422	448
Operating lease right of use assets	1,240	1,265
Funds in respect of employee rights upon retirement	723	725
Total non-current assets	<u>2,385</u>	<u>2,438</u>
Total assets	<u>\$ 48,635</u>	<u>\$ 17,777</u>



	<u>March 31, 2021</u>	<u>December 31, 2020</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 401	\$ 236
Other	2,465	3,469
Total current liabilities	<u>2,866</u>	<u>3,705</u>
Long-term liabilities:		
Operating lease liabilities	894	999
Liability for employees rights upon retirement	921	910
Total long-term liabilities	<u>1,815</u>	<u>1,909</u>
Total liabilities	<u>\$ 4,681</u>	<u>\$ 5,614</u>
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2021 and December 31, 2020; 7,852,791 and 3,284,322 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	1	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at March 31, 2021 and December 31, 2020; 0 and 17,303 shares issued and outstanding at March 31, 2021 and December 31, 2020	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2021 and December 31, 2020; 1,718 and 2,343 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital	215,372	180,339
Accumulated deficit	(171,419)	(168,176)
Total equity	<u>43,954</u>	<u>12,163</u>
Total liabilities and equity	<u>\$ 48,635</u>	<u>\$ 17,777</u>



(1) 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; 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.

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