

# INSPIREMD, INC.

## **FORM 8-K** (Current report filing)

Filed 05/14/19 for the Period Ending 05/14/19

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 14, 2019

**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)

Registrant's telephone number, including area code: (888) 776-6804

(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 each exchange on which registered
Common Stock, par value \$0.0001 per share	NSPR	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 14, 2019, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended March 31, 2019. 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, including Exhibit 99.1, 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

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press release dated May 14, 2019 (furnished herewith pursuant to Item 2.02).</a>

**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 14, 2019

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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## InspireMD Announces First Quarter 2019 Financial Results

*On-Track to Submit U.S. IDE expected in Mid-2019*

*Company to Host Investor Conference Call at 8:00am ET*

**Tel Aviv, Israel— May 14, 2019** – 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, today announced results for the first quarter ending March 31, 2019.

First Quarter 2019 and recent highlights:

- Pre-clinical testing remains on track for U.S. IDE submission expected in mid 2019
- \$5.8 million of cash as of March 31, 2019
- Subsequent to the end of the quarter, completed a follow-on offering of common stock that raised gross proceeds of approximately \$2.5 million
- Pro-forma cash and equivalents expected to be sufficient to achieve key milestones through year-end

Other developments:

- During the first quarter 2019, the Company's third party sterilizer experienced equipment failures that resulted in significant interruption in product processing for the majority of the quarter. As a result, InspireMD primarily sold CGuard™ units already in inventory. The Company estimates that this issue negatively impacted the reported first quarter revenue by approximately \$600,000 and created a \$600,000 backlog. The Company immediately validated an alternate sterilization partner, conducted all required testing, submitted all materials and received approval from the European Notified Body for the new supplier on April 1st. As such, the issue has been completely resolved and InspireMD has cleared the majority of the back orders as of the date of this press release.

“Notwithstanding the issue that we encountered with our primary sterilization partner during the first quarter which led to a shortfall of product available to ship to our distributors, we continued to execute on our multi-faceted growth plan,” said James Barry, PhD, Chief Executive Officer of InspireMD. “In addition to our more focused sales strategy opening more hospital centers in our key European territories, our Centers of Excellence that we have established continue to yield very positive results by providing interventional cardiologists and vascular surgeons with hands-on, real-world experience with the CGuard™ device and continues to help us expand our user base across clinical specialties. We believe these efforts are creating a solid foundation from which to drive future growth. Finally, our IDE submission remains on-track for submission expected in the coming months. The continuing and growing body of evidence confirming the superiority of the CGuard™ procedure versus conventional open strut stents and carotid endarterectomy surgery, continued through the first quarter as we reported earlier in the year from the data presented at the LINCC meeting in January. We continue to believe CGuard™ is well positioned to become the new standard of care in the treatment of carotid artery disease.”

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## Financial Results

For the three months ended March 31, 2019, revenue was \$415,000, representing a decrease of 59% from the comparable period in 2018. This decrease was predominantly driven by a 55% decrease in sales of CGuard EPS from \$831,000 in the three months ended March 31, 2018, to \$376,000 in the three months ended March 31, 2019, and a 78% decrease in sales of MGuard EPS from \$176,000 in the three months ended March 31, 2018, to \$39,000 in the three months ended March 31, 2019. Both decreases were due to the Company's third-party sterilizer's equipment failures that resulted in significant interruption in sterilized product supply for the majority of the quarter. As a result, the Company was unable to fulfill a significant portion of the orders received during the quarter resulting in a backlog of approximately \$600,000. As of today, the third-party sterilizer issue has been resolved and the majority of the \$600,000 of the backlog recorded has been shipped.

The Company's gross loss for the quarter ended March 31, 2019 was \$73,000 compared to a gross profit of \$293,000 for the same period in 2018. Gross margin decreased to (17.6) % in the three months ended March 31, 2019 from 29.1% in the same period in 2018. This decrease in gross margin resulted from a \$249,000 decrease in revenues, less the related material and labor costs, resulting from delays related to product sterilization interruption as discussed above and an increase of \$118,000 in write-offs of inventory due to the same issue.

Total operating expenses for the quarter ended March 31, 2019 were \$3,057,000, an increase of 36 % compared to \$2,246,000 for the same period in 2018. This increase was primarily due to an increase in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2019 and due to a settlement payment made to a former service provider pursuant to a settlement agreement.

Financial expenses for the quarter ended March 31, 2019 were \$77,000 compared to \$436,000 for the same period in 2018. This decrease of \$359,000 was predominately due to a non-cash expense associated with our preferred stock in the quarter ended March 31, 2018 that we did not incur this quarter. Net loss for the quarter ended March 31, 2019 totaled \$3,207,000, or \$3.82 per basic and diluted share, compared to a net loss of \$2,389,000, or \$54.00 per basic and diluted share, for the same period in 2018.

As of March 31, 2019, cash and cash equivalents were \$5,807,000, compared to \$9,384,000 at December 31, 2018. Subsequent to the end of the first quarter, the Company completed an offering of common stock that yielded gross proceeds of approximately \$2.5 million.

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## 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 13683949. To access the webcast, please go to the following link: <http://public.viavid.com/index.php?id=133118>

A webcast will also be archived on the Company's website and a telephone replay of the call will be available approximately one hour following the call for approximately two weeks and can be accessed by dialing 844-512-2921 for U.S. callers or +1 412-317-6671 for international callers and entering conference ID: 13687159.

## 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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	Three months ended	
	March 31,	
	<u>2019</u>	<u>2018</u>
<b>Revenues</b>	\$ 415	\$ 1,007
Cost of revenues	488	714
<b>Gross Profit (Loss)</b>	<u>(73)</u>	<u>293</u>
Operating Expenses:		
Research and development	1,125	252
Selling and marketing	634	492
General and administrative	1,298	1,502
<b>Total operating expenses</b>	<u>3,057</u>	<u>2,246</u>
<b>Loss from operations</b>	(3,130)	(1,953)
Financial expenses	<u>77</u>	<u>436</u>
<b>Loss before tax expenses</b>	(3,207)	(2,389)
Tax expenses (Income)	<u>-</u>	<u>-</u>
<b>Net Loss</b>	<u>\$ (3,207)</u>	<u>\$ (2,389)</u>
Net loss per share – basic and diluted	<u>\$ (3.82)</u>	<u>\$ (54.00)</u>
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	<u>839,533</u>	<u>45,079</u>

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

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 5,807	\$ 9,384
Accounts receivable:		
Trade, net	464	716
Other	186	104
Prepaid expenses	66	81
Inventory	1,447	1,134
<b>Total current assets</b>	<b>7,970</b>	<b>11,419</b>
Non-current assets:		
Property, plant and equipment, net	452	421
Right of use	1,104	-
Deferred issuance costs	49	-
Funds in respect of employee rights upon retirement	482	448
<b>Total non-current assets</b>	<b>2,087</b>	<b>869</b>
<b>Total assets</b>	<b>\$ 10,057</b>	<b>\$ 12,288</b>

	March 31, 2019	December 31, 2018
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 872	\$ 929
Other	1,740	1,966
Contract liability	25	25
<b>Total current liabilities</b>	<b>2,637</b>	<b>2,920</b>
Long-term liabilities:		
Leasing liability	1,138	-
Liability for employees rights upon retirement	642	605
<b>Total long-term liabilities</b>	<b>1,780</b>	<b>605</b>
<b>Total liabilities</b>	<b>4,417</b>	<b>3,525</b>
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2019 and December 31, 2018; 871,872 and 768,615 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	-	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at March 31, 2019 and December 31, 2018; 17,303 shares issued and outstanding at March 31, 2019 and December 31, 2018.	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2019 and December 31, 2018; 59,423 and 61,423 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	-	-
Additional paid-in capital	156,439	156,355
Accumulated deficit	(150,799)	(147,592)
<b>Total equity</b>	<b>5,640</b>	<b>8,763</b>
<b>Total liabilities and equity</b>	<b>\$ 10,057</b>	<b>\$ 12,288</b>

(1) 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; all 2018 financial information is derived from the Company's 2018 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, 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. All December 31, 2018 financial information is derived from the Company's 2018 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2018 filed with the Securities and Exchange Commission.

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