

# INSPIREMD, INC.

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

Filed 05/07/18 for the Period Ending 05/07/18

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

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): May 7, 2018

**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

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

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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))

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 7, 2018, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended March 31, 2018. 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 7, 2018 (furnished herewith pursuant to Item 2.02).</a>

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**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 7, 2018, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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## InspireMD Reports 132% Increase in CGuard™ EPS Sales for the First Quarter of 2018

Tel Aviv, Israel— May 7, 2018 - InspireMD, Inc. (NYSE American:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced results for the first quarter ending March 31, 2018.

### First Quarter 2018 highlights:

- Achieves revenue of \$1.0 million for Q1 2018 versus \$569,000 in Q1 2017, an increase of 77%
- Total CGuard™ EPS sales increase 132% to \$831,000 for Q1 2018
- 5th consecutive quarter of sequential double-digit growth
- Continues global expansion setting up distribution in South Korea, Greece and the Carribean.
- Achieves regulatory approvals and launches CGuard™ in India and Peru
- Ends Q1 with \$4.6 million of cash plus an additional \$4.1 million in net proceeds from capital raise that closed in Q2

James Barry, PhD, Chief Executive Officer of InspireMD, commented, “We are pleased to report sales in excess of \$1 million for the first quarter of 2018. This marks a major milestone since full implementation of our new commercial strategy in Q3 of 2017. Achieving this level of sales in such a short time is a tribute to our operational and commercial teams, as well as the growing physician enthusiasm and appreciation for CGuard™ EPS. Specifically, sales of CGuard™ EPS increased by 132% versus the same period last year. We believe this sets the foundation for continued growth in 2018. At the same time, we are building strong support among key opinion leaders, illustrated by the featured presentations at top industry conferences and publication of clinical results in leading journals.”

“Given the enthusiasm by leading physicians, including their conducting investigator initiated clinical trials, we remain confident in the potential for CGuard™ EPS to become the preferred option for patients that are candidates for carotid artery stenting (CAS). In addition, clinical data suggests that CGuard™ EPS may offer a safer alternative to the surgical gold standard carotid endarterectomy (CEA). This could significantly expand the addressable market for CGuard™ given the safety advantages of our device, as we believe more physicians, including surgeons, would choose a minimally invasive procedure over surgery for their patients.”

“Having met previously with the FDA regarding our investigational device exemption (IDE) submission for CGuard™ EPS, we are now evaluating plans to restart the regulatory approval process in the United States. Concurrently, we are exploring other synergistic opportunities and product extensions that may allow us to leverage our distribution network and growing sales channels in Europe, Asia and Latin America.”

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## Financial Results

Revenue for the first quarter ended March 31, 2018 was \$1,007,000 compared to \$569,000 during the same period in 2017. The increase was primarily due to an increase in sales of CGuard™ EPS as we transitioned from our prior exclusive distribution partner for most of Europe to local distributors, continued focus on expanding existing markets such as Germany and Italy and expanding into new geographies such as India. Total operating expenses for the quarter ended March 31, 2018 were \$2,246,000, a decrease of 9.4% compared to \$2,478,000 for the same period in 2017. This decrease was primarily due to a decrease in share-based compensation expenses and a decrease in salary expenses, primarily due to a salary related accrual in 2017, partially offset by an increase in legal expenses. Financial expenses for the quarter ended March 31, 2018 were \$436,000 compared to \$154,000 for the same period in 2017, largely due to a non-cash expense associated with our preferred stock.

Net loss for the quarter ended March 31, 2018 totaled \$2,389,000, or \$1.08 per basic and diluted share, compared to a net loss of \$2,559,000, or \$28.31 per basic and diluted share, in the same period in 2017.

As of March 31, 2018, cash and cash equivalents were \$4,637,000, compared to \$3,710,000 as of December 31, 2017. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of March 31, 2018, will be sufficient to meet its operating requirements for approximately 12 months from the date of the balance sheet.

## About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard™), neurovascular, and peripheral artery procedures. 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.

## 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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(tables follow)

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	Three months ended March 31,	
	2018	2017
<b>Revenues</b>	\$ 1,007	\$ 569
Cost of revenues	714	495
<b>Gross Profit (Loss)</b>	<u>293</u>	<u>74</u>
Operating Expenses:		
Research and development	252	350
Selling and marketing	492	532
General and administrative	1,502	1,596
Total operating expenses	<u>2,246</u>	<u>2,478</u>
Loss from operations	(1,953)	(2,404)
Financial expenses	436	154
Loss before tax expenses	(2,389)	(2,558)
Tax expenses (Income)	<u>-</u>	<u>1</u>
<b>Net Loss</b>	<u>\$ (2,389)</u>	<u>\$ (2,559)</u>
Net loss per share – basic and diluted	<u>\$ (1.08)</u>	<u>\$ (28.31)</u>
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	<u>2,253,945</u>	<u>112,756</u>



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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 4,637	\$ 3,710
Accounts receivable:		
Trade, net	754	643
Other	238	207
Prepaid expenses	53	62
Inventory	517	533
<b>Total current assets</b>	<u>6,199</u>	<u>5,155</u>
Non-current assets:		
Property, plant and equipment, net	444	476
	155	-
Funds in respect of employee rights upon retirement	487	476
<b>Total non-current assets</b>	<u>1,086</u>	<u>952</u>
<b>Total assets</b>	<u>\$ 7,285</u>	<u>\$ 6,107</u>

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	<u>March 31, 2018</u>	<u>December 31, 2017</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 512	\$ 328
Other	2,417	2,134
Contract liability	26	20
<b>Total current liabilities</b>	<u>2,955</u>	<u>2,482</u>
Long-term liabilities:		
Liability for employees rights upon retirement	635	624
Derivative liability	872	-
<b>Total long-term liabilities</b>	<u>1,507</u>	<u>624</u>
<b>Total liabilities</b>	<u>4,462</u>	<u>3,106</u>
<b>Redeemable preferred shares</b>	1,779	274
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2018 and December 31, 2017, respectively; 3,501,331 and 1,483,556 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at March 31, 2018 and December 31, 2017, respectively; 17,303 and 27,075 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2018 and December 31, 2017, respectively; 451,695 and 741,651 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Preferred D shares, par value \$0.0001 per share; 750 shares authorized at March 31, 2018 and December 31, 2017, respectively; 300 and 750 issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Additional paid-in capital	143,785	143,079
Accumulated deficit	(142,741)	(140,352)
<b>Total equity</b>	<u>1,044</u>	<u>2,727</u>
<b>Total liabilities, redeemable preferred shares and equity</b>	<u>\$ 7,285</u>	<u>\$ 6,107</u>

(1) 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; all 2017 financial information is derived from the Company's 2017 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, 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. All December 31, 2017 financial information is derived from the Company's 2017 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2017 filed with the Securities and Exchange Commission.

