INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 02/19/19 for the Period Ending 02/19/19

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): February 19, 2019

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4 Menorat Hamaor St. Tel Aviv, Israel	6744832
(Address of principal executive offices)	(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))

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 February 19, 2019, InspireMD, Inc. issued a press release announcing its financial and operating results for the fourth quarter and year ended December 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

Exhibit Number	Description
99.1	Press release dated February 19, 2019 (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: February 19, 2019

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Fourth Quarter 2018 Financial Results

2018 CGuard ™ EPS annual sales increased 55% compared to 2017

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

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

Tel Aviv, Israel— February 19, 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 fourth quarter ending December 31, 2018.

Fourth Quarter 2018 and recent highlights:

- CGuard™ EPS featured in the transmission of two successful live cases at Leipzig Interventional Course (LINC) 2019
- Also, at LINC 2019, interim data from the first 50 patients in the investigator-initiated SIBERIA trial were presented. Patients treated with CGuard™ EPS had a significantly lower incidence of multiple lesions in the brain (16% vs 44%), large cerebral lesions (24% vs 40%) and major adverse clinical events after 30 days (0% vs 12%) as compared to patients treated with a conventional open-cell carotid stent
- Also, at LINC 2019, Prof. Christian Wissgott presented his findings using CGuard™ EPS with SmartFit™ technology to treat a range of carotid artery diameters with a single diameter size device. SmartFit™ readily adapts to different artery diameters even over a range of diameters in the same patients with a single diameter sized device
- Announced the publication of a meta-analysis involving dual layered and mesh-covered carotid devices in *JACC: Cardiovascular Interventions* concluding that carotid artery disease (CAD) patients treated with mesh-covered devices experienced a lower 30-day minor stroke rate than rates reported in other widely cited studies, such as CREST and ACT 1, for patients treated with both carotid endarterectomy (CEA) and those treated with conventional carotid stents
- During the 45th Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons Symposium (VEITHsymposium), updated positive efficacy and safety data from the ongoing PARADIGM-Extend and IRONGUARD 2 studies were presented
- Received regulatory and reimbursement approval of CGuard™ EPS in Australia and Mexico and regulatory approval in South Africa.
- Recently opened the third “Center of Excellence” for vascular surgeons in Rome Italy with Prof. Speziale that included participation by key physicians from Italy, Poland and Slovenia.

- Pre-clinical testing remains on track for U.S. IDE submission mid 2019

- Year-to-date CGuard™ EPS revenue through December 31 was $3.0 million compared to $1.9 million for the comparable period in 2017, an increase of 55%

- $9.4 million of cash as of December 31, 2018

“During the fourth quarter and subsequent period, we continued to build upon the mounting evidence demonstrating the numerous clinical advantages of CGuard™ EPS versus conventional carotid stents, with numerous presentations prominently featuring CGuard at two international vascular medicine conferences,” commented James Barry, PhD, Chief Executive Officer of InspireMD. “These presentations complement our internal sales efforts and help drive awareness among cardiologists and vascular surgeons as to the use of CGuard as a safer treatment of carotid artery disease. Receiving regulatory approval in South Africa came as a direct result of treating physicians learning of CGuard at a medical conference and working proactively with local regulators and distributors to get access to the product for use in their own practices. We are gratified by this ‘pull-through’ demand that we are seeing and believe it speaks to physicians’ desire to offer safer, more durable and less-invasive treatment alternatives to their patients. We are awaiting reimbursement approval in South Africa, which we expect to receive shortly, and look forward to receiving such approval.”

Financial Results

Overall revenue for the fourth quarter ended December 31, 2018 was $822,000 compared to $833,000 during the same period in 2017. CGuard EPS sales increased by 16% or $95,000 compared to the sales made in the fourth quarter ended December 31, 2017, primarily due to our continued focus on expanding in existing markets such as Russia and Germany, expanding into new geographies such as India and our transition from our prior exclusive distribution partner for most of Europe to local distributors. Total sales for the fourth quarter ended December 31, 2018 compared to the fourth quarter ended December 31, 2017 declined due to a decrease in MGuard Prime™ EPS sales, driven largely by doctors predominantly using drug-eluting coronary stents rather than bare metal stents such as MGuard Prime EPS in patients with coronary artery disease. The Company’s gross profit for the quarter ended December 31, 2018 was $227,000 compared to $210,000 for the same period in 2017. Gross margin increased to 27.6% in the three months ended December 31, 2018 from 25.2% in the same period in 2017.

Total operating expenses for the quarter ended December 31, 2018 were $2,433,000, an increase of 46.6%, compared to $1,660,000 for the same period in 2017. This increase was primarily due to an increase in salary expenses, primarily due to a salary related accrual adjustment which reduced our salary expenses in 2017, and an increase in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2018. Financial expenses for the quarter ended December 31, 2018 were $7,000 compared to $24,000 for the same period in 2017. Net loss for the quarter ended December 31, 2018 totaled $2,213,000, or $0.05 per basic and diluted share, compared to a net loss of $1,500,000, or $7.38 per basic and diluted share, for the same period in 2017.

Revenue for the twelve months ended December 31, 2018 was $3,601,000 compared to $2,761,000 for the same period in 2017. The increase was primarily due to an increase in sales of CGuard™ EPS as a result of our transition from our prior exclusive distribution partner for most of Europe to local distributors, continued focus on expanding existing markets such as Germany, Russia, Spain and Italy, and expansion into new geographies such as India. The Company’s gross profit for the twelve months ended December 31, 2018 was $995,000 compared to $585,000 for the same period in 2017. Gross margin increased to 27.6% in the twelve months ended December 31, 2018 from 21.2% in the same period in 2017, driven mainly by higher volume of sales and more efficient utilization of fixed manufacturing resources.

Total operating expenses for the twelve months ended December 31, 2018 were $8,606,000, a decrease of 2.4% compared to $8,817,000 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. These decreases were partially offset by an increase in in quality assurance and regulatory expenses related to annual audit activities which included validation reviews required every two years and an increase in clinical expenses associated with CGuard™ EPS that we cited earlier. Financial income for the twelve months ended December 31, 2018 was $371,000 compared to $179,000 of financial expenses for the same period in 2017, largely due to non-cash income associated with preferred stock. Net loss for the twelve months ended December 31, 2018 totaled $7,240,000, or $0.33 per basic and diluted share, compared to a net loss of $8,438,000, or $34.98 per basic and diluted share, for the same period in 2017.

As of December 31, 2018, cash and cash equivalents were $9,384,000, compared to $3,710,000 as of December 31, 2017.

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.

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CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues	$ 822	$ 833	$ 3,601	$ 2,761
Cost of revenues	595	623	2,606	2,176
Gross Profit	227	210	995	585
Operating Expenses:				
Research and development	637	235	1,535	1,276
Selling and marketing	564	522	2,241	2,357
General and administrative	1,232	903	4,830	5,184
Total operating expenses	2,433	1,660	8,606	8,817
Loss from operations	(2,206)	(1,450)	(7,611)	(8,232)
Financial expenses (income)	7	24	(371)	179
Loss before tax expenses	(2,213)	(1,474)	(7,240)	(8,411)
Tax expenses	-	26	-	27
Net Loss	$ (2,213)	$ (1,500)	$ (7,240)	$ (8,438)
Basic and Diluted Loss Per Share:				
Beneficial conversion feature of series C preferred shares	-	-	-	(633)
Extinguishment and accretion of preferred shares	-	(3,957)	(456)	(3,957)
Net Loss Applicable to Ordinary Shares	$ (2,213)	$ (5,457)	$ (7,696)	$ (13,028)
Net loss per share – basic and diluted	$ (0.05)	$ (7.38)	$ (0.33)	$ (34.98)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	41,913,368	739,088	23,076,944	372,460

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

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 9,384	$ 3,710
Accounts receivable:		
Trade, net	716	643
Other	104	207
Prepaid expenses	81	62
Inventory	1,134	533
Total current assets	11,419	5,155
Non-current assets:		
Property, plant and equipment, net	421	476
Funds in respect of employee rights upon retirement	448	476
Total non-current assets	869	952
Total assets	$ 12,288	$ 6,107

	December 31, 2018	December 31, 2017
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 929	$ 328
Other	1,966	2,134
Contract liability	25	20
Total current liabilities	2,920	2,482
Long-term liabilities:		
Liability for employees rights upon retirement	605	624
Total long-term liabilities	605	624
Total liabilities	3,525	3,106
Redeemable preferred shares	-	274
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2018 and 2017; 38,408,953 and 1,483,808 shares issued and outstanding at December 31, 2018 and 2017, respectively	4	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2018 and 2017; 17,303 and 27,075 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2018; 61,423 and 741,651 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Preferred D shares, par value $0.0001 per share; 0 shares authorized at December 31, 2018; 0 and 750 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Additional paid-in capital	156,351	143,079
Accumulated deficit	(147,592)	(140,352)
Total equity	8,763	2,727
Total liabilities, redeemable preferred shares and equity	$ 12,288	$ 6,107