INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Telephone	(888) 776-6804
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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 14, 2018

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 14, 2018, InspireMD, Inc. issued a press release announcing its financial and operating results for the fourth quarter and year ended December 31, 2017, and reporting that it received an audit opinion with a going concern qualification paragraph from its independent registered public accounting firm. 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 14, 2018 (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 14, 2018

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Fourth Quarter and Year-End 2017 Results;
CGuard™ EPS Fourth Quarter Sales Increase 211%
Versus Same Period Last year

Tel Aviv, Israel— February 14, 2018 - InspireMD, Inc. (NYSE American:NSPR), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today announced results for the fourth quarter and year-ending December 31, 2017.

Fourth Quarter 2017 financial highlights:

- Sales increase 159% versus the same period last year
- CGuard™ EPS sales increase 211% versus Q4 2016

Recent operating highlights:

- CGuard™ EPS prominently featured in two successful live case transmissions at LINC 2018 in Germany, a live case transmission at ENDOGRAFT 2017 in Italy, and a live case transmission at Cracow Vascular Summit 2017 in Poland
- New distributors announced for CGuard™ EPS in India, Australia, New Zealand and Vietnam
- Regulatory approval of CGuard™ EPS granted in India
- Independent imaging study published highlighting the advantages of CGuard™ EPS in reducing stent plaque prolapse compared to another next generation carotid stent
- CGuard™ EPS demonstrated improved outcomes over carotid endarterectomy in a 50-patient comparative study; preliminary results featured at the 7th Munich Vascular Conference 2017
- Follow-up results from the PARADIGM clinical study presented at the 2017 VEITH Symposium in New York and ICI Meeting 2017 in Tel Aviv demonstrating the sustained benefits of CGuard™ out to two years
- Patient enrollment commenced in a randomized investigator-initiated trial of CGuard™ EPS vs the market leading Acculink™ carotid stent in Russia

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "2017 was a transformative year for InspireMD, culminating in a 211% increase in sales of CGuard™ EPS for the fourth quarter of 2017. We are rapidly building a global distribution network, but most importantly, we are growing our market share in countries where we have existing business. In addition, we continue to build strong support among key opinion leaders around the world. CGuard™ EPS has been featured at six major conferences, including live case transmissions at three of these conferences, since the fourth quarter of 2017 alone. CGuard™ EPS continues to be featured in a number of independent studies and third-party publications that further illustrate the enthusiasm for, and clinical benefits of, our technology. As a result, not only do we believe CGuard™ EPS has the potential to become a leading option for patients that undergo carotid artery stenting (CAS), but we also believe CGuard™ EPS may represent a safer alternative to the current gold standard, carotid endarterectomy (CEA), for patients with carotid artery disease, which, we believe, could significantly expand the addressable market for CGuard ^{TM}. Overall, we are extremely excited about the outlook for the business and are off to a very strong start to the first quarter of 2018."

Financial Results

Revenue for the fourth quarter ended December 31, 2017 was $833,000 compared to $322,000 during the same period in 2016. 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, expanded into new geographies such as Russia, and continued focus on expanding existing markets such as Italy. In addition to the increase in sales of CGuard™ EPS, sales of MGuard Prime EPS™ also increased primarily from increased geographical coverage in Latin America. Total operating expenses for the quarter ended December 31, 2017 were $1,660,000, a decrease of 18.4% compared to $2,035,000 for the same period in 2016. This decrease was primarily due to a decrease in salary expenses primarily due to a salary related accrual as well as a decrease in clinical and development costs related to CGuard™ EPS. Net loss for the quarter ended December 31, 2017 totaled $1,500,000, or $7.38 per basic and diluted share, compared to a net loss of $2,265,000, or $30.59 per basic and diluted share, in the same period in 2016.

Revenue for the twelve months ended December 31, 2017 was $2,761,000, representing an increase of 31.4% compared to $1,894,000 during the same period in 2016. 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, expanded into new geographies such as Russia, and continued focus on expanding existing markets such as Italy. Total operating expenses for the twelve months ended December 31, 2017 were $8,817,000, an increase of 13.8% compared to $7,750,000 for the same period in 2016. This increase was primarily due to an increase in sales and marketing expenses (primarily to support the commercialization of CGuard™ EPS). Net loss for the twelve months ended December 31, 2017 totaled $8,438,000, or $34.98 per basic and diluted share, compared to a net loss of $8,461,000, or $207.72 per basic and diluted share, in the same period in 2016.

As of December 31, 2017, cash and cash equivalents were $3,710,000, compared to $7,516,000 as of December 31, 2016. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of December 31, 2017, will be sufficient to meet its operating requirements up to 4 months from the date of issuing these consolidated financial statements. As disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, which was filed on February 13, 2018, with the Securities and Exchange Commission, the audited financial statements contained a going concern qualification paragraph in the audit opinion from its independent registered public accounting firm. See further discussion in Note 1 to the Company's consolidated financial statements included in the Company's Annual Report on Form 10-K. This announcement is made pursuant to NYSE American Company Guide Section 610(b), which requires public announcement of the receipt of an audit opinion containing a going concern paragraph.

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.

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(tables follow)

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

	Three months ended December 31,		Twelve months ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenues	$ 833	$ 322	$ 2,761	$ 1,894
Cost of revenues	623	378	2,176	1,792
Gross Profit (Loss)	210	(56)	585	102
Operating Expenses:				
Research and development	235	345	1,276	1,291
Selling and marketing	522	382	2,357	1,459
General and administrative	903	1,308	5,184	5,000
Total operating expenses	1,660	2,035	8,817	7,750
Loss from operations	(1,450)	(2,091)	(8,232)	(7,648)
Financial expenses	24	1747	179	812
Loss before tax expenses	(1,474)	(2,265)	(8,411)	(8,460)
Tax expenses (Income)	26	-	27	1
Net Loss	$ (1,500)	$ (2,265)	$ (8,438)	$ (8,461)
Basic and diluted loss per share:				
Beneficial conversion feature of series C preferred shares	$ -	$ -	$ (633)	$ -
Extinguishment of series B preferred shares	$ (3,957)	-	$ (3,957)	-
Net loss applicable to ordinary shares	$ (5,457)	$ (2,265)	$ (13,028)	$ (8,461)
Net loss per share – basic and diluted	$ (7.38)	$ (30.59)	$ (34.98)	$ (207.72)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	739,088	74,035	372,460	40,732

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

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 3,710	$ 7,516
Accounts receivable:		
Trade, net	643	356
Other	207	195
Prepaid expenses	62	65
Inventory	533	500
Total current assets	5,155	8,632
Non-current assets:		
Property, plant and equipment, net	476	379
Funds in respect of employee rights upon retirement	476	399
Total non-current assets	952	778
Total assets	$ 6,107	$ 9,410

	December 31, 2017	December 31, 2016
LIABILITIES AND EQUITY		
Current liabilities:		
Current maturity of long-term loan	$ -	$ 2,680
Accounts payable and accruals:		
Trade	328	618
Other	2,134	1,447
Advanced payment from customers	20	33
Total current liabilities	2,482	4,778
Long-term liabilities:		
Liability for employees rights upon retirement	624	587
Total long-term liabilities	624	587
Total liabilities	3,106	5,365
Redeemable preferred shares	274	-
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2017 and 2016; 1,483,808 and 42,653 shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2017 and 2016; 27,075 and 311,521 shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2017; 741,651 shares issued and outstanding at December 31, 2017	-	-
Preferred D shares, par value $0.0001 per share; 750 shares authorized at December 31, 2017; 750 shares issued and outstanding at December 31, 2017	-	-
Additional paid-in capital	143,079	135,959
Accumulated deficit	(140,352)	(131,914)
Total equity	2,727	4,045
Total liabilities, redeemable preferred shares and equity	$ 6,107	$ 9,410