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 15, 2017

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

321 Columbus Avenue
Boston, MA 02116
(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))

Item 2.02 Results of Operations and Financial Condition.

On February 16, 2017, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results for the fourth quarter and year ended December 31, 2016, 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 8.01 Other Events.

Termination Notice

As initially reported by the Company in a Current Report on Form 8-K filed with the Securities and Exchange Commission on August 5, 2015, InspireMD, Ltd. ("InspireMD"), a wholly owned subsidiary of the Company, entered into a distribution agreement (the "Distribution Agreement") with Penumbra, Inc. ("Penumbra"), pursuant to which Penumbra would act as the exclusive distributor of the Company's CGuard carotid embolic prevention system products (the "Products") in Austria, France, Sweden, Denmark, Norway, Finland, Estonia, Lithuania, Portugal, Switzerland and the United Kingdom and Ireland.

On February 15, 2017, the Company received a notice of termination (the "Termination Notice") of the Distribution Agreement from Penumbra notifying the Company that the Distribution Agreement will be terminated effective April 16, 2017. InspireMD and Penumbra have agreed to use commercially reasonable efforts to transition distribution of the Products at the time, in the manner, and to the persons or entities designated by InspireMD.

Change in Address of Principal Executive Offices

Effective as of February 16, 2017, the Company changed its principal executive office address to 4 Menorat Hamaor St., Tel Aviv, Israel, 6744832. The new telephone number for the Company is (888) 776-6804.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Earnings release dated February 16, 2017

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 21, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Provides Year End Business Update and Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2016

Transition from Exclusive Distribution Partner to Local Distributors and Internal Sales Strategy Validated by Strong Revenue Growth in Select Markets

BOSTON, MA—February 16, 2017 - InspireMD, Inc. (NYSE MKT:NSPR) (NYSE MKT:NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS) / thrombus management technologies and neurovascular devices, today provided a year-end business update including an update on its new commercialization strategy. The Company also reported financial and operating results for the fourth quarter and year ended December 31, 2016.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "Over the past six months we have rebuilt the InspireMD management team, bringing greater focus to our sales and marketing efforts. However, revenue has yet to mirror the clinical success and physician interest we have witnessed. In 2015, we announced an exclusive distribution agreement with Penumbra, Inc., covering 18 European countries. Through Penumbra, our CGuard was largely sold to interventional neuroradiologists. In an effort to broaden our sales efforts to vascular surgeons, interventional cardiologists and interventional radiologists as well, we have decided to shift our commercial strategy to focus sales on these specialties through local distribution partners and our own internal sales initiatives. As such, we and Penumbra have agreed to transition our European efforts to an InspireMD managed direct distribution model, which focuses on regional distributors that have access to all of the aforementioned clinical specialties. Given the positive growth we saw in 2016, with an annual increase in sales of 67% in select markets where this model has been in place and managed by InspireMD, we are very optimistic about this approach."

"As an example of our recent success, in Italy, one of the largest markets, we experienced 59% year-over-year growth in 2016 and were able to access all four clinical specialties. The next market we are targeting is Germany, the largest market in Europe for carotid artery stenting. We plan to launch CGuard™ EPS in several leading German medical centers in the first half of 2017. Once we have firmly established our presence in Germany, we believe the other European markets will rapidly follow. We are now in advanced discussions with distributors in multiple markets including Germany, Poland, Belgium, Netherlands and Portugal. As a result, we are excited about the outlook of the business as we transition to a regional model, which we will now manage directly and expect to see similar results to our own direct distribution efforts over the last year."

"Looking ahead, we are engaging new distribution partners in countries with current or near-term regulatory approval. We recently received approval in Russia where we plan to commence sales in the first half of this year. We also anticipate regulatory approvals in India and Mexico where we plan to launch our sales initiatives in the second half of this year. We are also pursuing partnership strategies in the Asia Pacific region."

“As these initiatives begin to take hold, we continue to maintain strict financial discipline. We believe InspireMD is well positioned for growth in the coming years. We appreciate the continued support of all our stakeholders and remain laser focused on driving value for shareholders.”

Financial Results

Revenue for the fourth quarter ended December 31, 2016 was $322,000 compared to $516,000 during the same period in 2015. The decrease was primarily the result of a decline in sales of MGuard™ Prime EPS associated with the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients. This decrease was partially offset by a slight increase in sales of CGuard™ EPS. Total operating expenses for the quarter ended December 31, 2016 were $2,038,000, a decrease of 17.7% compared to $2,475,000 for the same period in 2015. This decrease was primarily due to a reduction of compensation related expenses, clinical and development expenses and other savings associated with our ongoing cost reduction plan. Net loss for the quarter ended December 31, 2016 totaled $2,268,000, or $0.88 per basic and diluted share, compared to a net loss of $2,854,000, or $9.34 per basic and diluted share, in the same period in 2015.

Revenue for the twelve months ended December 31, 2016 was $1,894,000, compared to $2,310,000 during the same period in 2015. The decrease was predominantly driven by the aforementioned decline in sales of MGuard™ Prime EPS. This decrease was partially offset by an increase in sales of $444,000 of CGuard™ EPS. Total operating expenses for the twelve months ended December 31, 2016 were $7,750,000, a decrease of 45.4% compared to $14,189,000 for the same period in 2015. This decrease was primarily due to a reduction of compensation related expenses, clinical and development expenses, restructuring and impairment costs, consulting fees and other savings associated with our ongoing cost reduction plan. Net loss for the twelve months ended December 31, 2016 totaled $8,461,000, or $5.93 per basic and diluted share, compared to a net loss of $15,585,000, or $55.85 per basic and diluted share, in the same period in 2015.

As of December 31, 2016, cash and cash equivalents were $7,516,000, compared to $3,257,000 as of December 31, 2015. The Company also disclosed in its Annual Report on Form 10-K for the year ended December 31, 2016, which was filed on February 16, 2017 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 MKT Company Guide Section 610(b), which requires public announcement of the receipt of an audit opinion containing a going concern paragraph. This announcement does not represent any change or amendment to the Company’s consolidated financial statements or to its Annual Report on Form 10-K for the year ended December 31, 2016.

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 MKT under the ticker symbol NSPR and certain warrants are quoted on the NYSE MKT 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.

CONSOLIDATED STATEMENTS OF OPERATIONS [1]

(U.S. dollars in thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenues	$ 322	$ 516	$ 1,894	$ 2,310
Cost of revenues	378	652	1,792	2,606
Gross Profit (Loss)	(56)	(136)	102	(296)
Operating Expenses:				
Research and development	345	762	1,291	3,642
Selling and marketing	382	578	1,459	3,178
General and administrative	1,311	1,117	5,000	6,387
Restructuring and impairment	-	18	-	982
Total operating expenses	2,038	2,475	7,750	14,189
Loss from operations	(2,094)	(2,611)	(7,648)	(14,485)
Financial expenses	174	240	812	1,096
Loss before tax expenses	(2,268)	(2,851)	(8,460)	(15,581)
Tax expenses (Income)	-	3	1	4
Net Loss	$ (2,268)	$ (2,854)	$ (8,461)	$ (15,585)
Net loss per share – basic and diluted	$ (0.88)	$ (9.34)	$ (5.93)	$ (55.85)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	2,591,200	305,560	1,425,617	279,055

CONSOLIDATED BALANCE SHEETS [2]

(U.S. dollars in thousands)

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,516	$ 3,257
Accounts receivable:		
Trade, net	356	405
Other	157	142
Prepaid expenses	65	75
Inventory	500	753
Total current assets	8,594	4,632
Non-current assets:		
Property, plant and equipment, net	379	472
Funds in respect of employee rights upon retirement	399	502
Royalties buyout	38	87
Total non-current assets	816	1,061
Total assets	$ 9,410	$ 5,693

	December 31, 2016	December 31, 2015
LIABILITIES AND EQUITY (NET OF CAPITAL DEFICIENCY)		
Current liabilities:		
Current maturity of long-term loan	$ 2,680	$ 4,149
Accounts payable and accruals:		
Trade	618	512
Other	1,447	2,006
Advanced payment from customers	33	167
Total current liabilities	4,778	6,834
Long-term liabilities:		
Liability for employees rights upon retirement	587	706
Long-term loan	-	1,099
Total long-term liabilities	587	1,805
Total liabilities	5,365	8,639
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 and 50,000,000 shares authorized at December 31, 2016 and 2015, respectively; 1,475,318 and 314,065 shares issued and outstanding at December 31, 2016 and 2015, respectively	-	-
Preferred shares, par value $0.0001 per share; 5,000,000 shares authorized at December 31, 2016 and 2015, respectively; 311,521 and 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	-	-
Additional paid-in capital	135,959	120,050
Accumulated deficit	(131,914)	(122,996)
Total equity (capital deficiency)	4,045	(2,946)
Total liabilities and equity (net of capital deficiency)	$ 9,410	$ 5,693

(1) All financial information for the twelve months ended December 31, 2016 is derived from the Company's 2016 audited financial statements and all financial information for the twelve months ended December 31, 2015 is derived from the Company's 2015 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2016 filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2016 and 2015 is derived from the Company's unaudited, internal financial statements.

(2) All December 31, 2016 financial information is derived from the Company's 2016 audited financial statements and all December 31, 2015 financial information is derived from the Company's 2015 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2016 filed with the Securities and Exchange Commission.