INSPIREMD, INC.

FORM 8-K
(Current report filing)

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Telephone	(888) 776-6804
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Industry	Medical Equipment, Supplies & Distribution
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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): November 7, 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

(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 November 7, 2017, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended September 30, 2017. 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 November 7, 2017 (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: November 7, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Third Quarter 2017 Results;
CGuard™ Revenue Increases 90% Versus Same Period Last year

Tel Aviv, Israel—November 7, 2017 - InspireMD, Inc. (NYSE AMER:NSPR), a leader in Embolic Prevention Systems (EPS) / thrombus management technologies and neurovascular devices, today announced preliminary results for the third quarter ending September 30, 2017.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "Not only did we achieve a 90% year-over-year increase in sales of CGuard™ EPS for the third quarter of 2017, but we also achieved a 22% sequential increase versus the second quarter of 2017. We achieved these strong results, even though the third quarter tends to be seasonally weak. We believe this growth is evidence that our new distribution and key opinion leader strategy is working. We are hopeful that this growth will continue as the broader community of mainstream vascular surgeons, interventional cardiologists, interventional neuroradiologists, and interventional radiologists begin to adopt our technology. Given the safety advantages of the CGuard™ EPS, we believe that CGuard™ has the potential to become the standard of care and to be regarded by physicians as a safer alternative to vascular surgery for patients with carotid artery disease, thereby expanding the addressable market opportunity."

Dr. Barry continued, "We had several other notable accomplishments during the quarter. Most recently a live endovascular interventional procedure featuring the CGuard™ EPS was transmitted real time at the Cracow Vascular Summit (CVS) 2017. The case was extremely challenging, and CGuard™ EPS Carotid System performance was excellent. Additionally, patient enrollment began in an investigator initiated trial in Russia, to assess the neuro protection and clinical superiority of the CGuard™ EPS versus Abbott's RX ACCULINK® Carotid Stent in subjects at high risk for Carotid Endarterectomy (CEA), a surgical procedure. Earlier in the second quarter, we announced publication of an independent clinical review, authored by leading U.S. and European physicians supporting the safety advantages of treating carotid artery disease with next generation carotid devices, specifically highlighting the CGuard ^{TM} EPS clinical data compared to its competitors. We also announced that an endovascular interventional procedure featuring the CGuard™ EPS was performed by two of the top key opinion leaders in Latin America and was broadcast at the SOLACI CACI Congress of Cardiology 2017 in Buenos Aires. We believe these premier presentations, publications, and live clinical cases at major clinical meetings further illustrate the growing interest and support for CGuard™ across Europe and around the world."

Dr. Barry concluded, "Operationally, we believe that the business looks very good as we continue to implement the strategy we set out at the end of last year. We continue to grow our sales with our European distributors and are expanding our distribution network globally. Several top key opinion leaders in Europe are embracing and advocating the CGuard™ EPS to their colleagues. This is evident not only through their use of the product, but further illustrated by the testimonials we recently posted on our website featuring leading clinicians from the fields of vascular surgery, interventional cardiology and interventional neuroradiology. As a result, we remain hopeful CGuard™ EPS will in time become standard-of-care."

Financial Results

Revenue for the third quarter ended September 30, 2017 was $718,000 compared to $469,000 during the same period in 2016. The increase was primarily due to an increase in sales of CGuard™ EPS as we continued focus on expanding existing markets such as Italy, expansion into new geographies such as Russia as well as the transition from our prior exclusive distribution partner for most of Europe to local distributors. Total operating expenses for the quarter ended September 30, 2017 were $2,238,000, an increase of 25.2% compared to $1,788,000 for the same period in 2016. This increase was primarily due to an increase in sales and marketing expenses to support the commercialization of CGuard™ EPS. Net loss for the quarter ended September 30, 2017 totaled $2,086,000, or $0.19 per basic and diluted share, compared to a net loss of $1,995,000, or $0.85 per basic and diluted share, in the same period in 2016.

Revenue for the nine months ended September 30, 2017 was $1,927,000 compared to $1,572,000 during the same period in 2016. The increase was primarily due to an increase in sales of CGuard™ EPS as we expanded into new geographies such as Russia, continued focus on expanding existing markets such as Italy as well as the transition from our prior exclusive distribution partner for most of Europe to local distributors. Total operating expenses for the nine months ended September 30, 2017 were $7,157,000, an increase of 25.3% compared to $5,712,000 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), as well as an increase in salary expenses primarily due to a salary related accrual. Net loss for the nine months ended September 30, 2017 totaled $6,939,000, or $0.87 per basic and diluted share, compared to a net loss of $6,193,000, or $5.98 per basic and diluted share, in the same period in 2016.

As of September 30, 2017, cash and cash equivalents were $4,765,000, 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 September 30, 2017, will be sufficient to meet its operating requirements up to 4 months from the date of issuing these interim consolidated financial statements.

Conference Call

The Company will host a conference call on Wednesday, November 8 at 8:00 a.m. Eastern Time. The conference call will be available via telephone by dialing toll free 888-567-1602 for U.S. callers or +1 404-267-0373 for international callers, or on the Company's Investor Relations section of the website: http://www.inspiremd.com/en/investors/investor-relations/.

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, through midnight November 22, 2017 , and can be accessed by dialing 877-481-4010 for U.S. callers or +1 919-882-2331 for international callers and entering conference ID: 22280 .

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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CONSOLIDATED STATEMENTS OF OPERATIONS [1]
(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues	$ 718	$ 469	$ 1,927	$ 1,572
Cost of revenues	565	439	1,553	1,414
Gross Profit	153	30	374	158
Operating Expenses:				
Research and development	288	289	1,041	946
Selling and marketing	671	309	1,835	1,077
General and administrative	1,279	1,190	4,281	3,689
Total operating expenses	2,238	1,788	7,157	5,712
Loss from operations	(2,085)	(1,758)	(6,783)	(5,554)
Financial expenses	1	237	155	638
Loss before tax expenses	(2,086)	(1,995)	(6,938)	(6,192)
Tax expenses (Income)	-	-	1	1
Net Loss	$ (2,086)	$ (1,995)	$ (6,939)	$ (6,193)
Net loss per share – basic and diluted	$ (0.19)	$ (0.85)	$ (0.87)	$ (5.98)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	11,126,366	2,341,807	8,711,755	1,034,943

CONSOLIDATED BALANCE SHEETS [2]
(U.S. dollars in thousands)

	September 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,765	$ 7,516
Accounts receivable:		
Trade, net	538	356
Other	167	157
Prepaid expenses	109	65
Inventory	576	500
Total current assets	6,155	8,594
Non-current assets:		
Property, plant and equipment, net	495	379
Funds in respect of employee rights upon retirement	444	399
Royalties buyout	19	38
Total non-current assets	958	816
Total assets	$ 7,113	$ 9,410

	September 30, 2017	December 31, 2016
LIABILITIES AND EQUITY		
Current liabilities:		
Current maturity of long-term loan	$ -	$ 2,680
Accounts payable and accruals:		
Trade	402	618
Other	2,293	1,447
Advanced payment from customers	28	33
Total current liabilities	2,723	4,778
Long-term liabilities:		
Liability for employees rights upon retirement	610	587
Total long-term liabilities	610	587
Total liabilities	3,333	5,365
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2017 and December 31, 2016; 7,465,889 and 1,475,318 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	1	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at September 30, 2017 and December 31, 2016; 180,992 and 311,521 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2017; 743,213 shares issued and outstanding at September 30, 2017	-	-
Additional paid-in capital	142,632	135,959
Accumulated deficit	(138,853)	(131,914)
Total equity	3,780	4,045
Total liabilities and equity	$ 7,113	$ 9,410

(1) 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, all 2016 financial information is derived from the Company's 2016 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All September 30, 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. All December 31, 2016 financial information is derived from the Company's 2016 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.