INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

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): August 8, 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 August 8, 2017, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended June 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 August 8, 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: August 8, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Reports Double Digit Sequential and Year-Over-Year Revenue Growth for the Second Quarter of 2017

Completes Transition to Local Distribution Network Across Europe

CGuard Sales in European Countries Transitioned Back from Former Distributor Increase 122% Versus Q1 2017

Tel Aviv—August 8, 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 business update, including the successful transition of all territories previously covered by the Company's former European distributor to a local network of regional distributors. The Company also reported financial and operating results for the second quarter ended June 30, 2017.

James Barry, PhD, Chief Executive Officer of InspireMD, commented, "I am pleased to report we successfully completed our transition from a single distributor covering 18 European countries, to now having a direct distribution model with local distributors that have much greater reach into all the relevant clinical specialties and each of their respective markets. Our new distributors share our belief that CGuard™ can achieve market leadership in all countries where it is available. Moreover, we completed the rollout on schedule and there has been tremendous support from the top key opinion leaders (KOL) in each of these markets. In fact, CGuard sales in these specific European countries increased 122% sequentially versus the first quarter of 2017."

"With our European distribution network in place, we are now focusing our efforts on expansion into other markets around the world. Most recently, we signed an agreement with a leading distributor in Taiwan. This follows a similar agreement in Hong Kong earlier this year, and we are in talks with a number of distributors across Asia to further expand our footprint. We expect to make additional announcements on this subject in the coming months. We also announced recent agreements in Peru and Ecuador, and our plan is to continue to expand our presence in Central and South America. CGuard™ is a platform technology that can be transferred to a number of other products, and building this global distributor network should allow us to launch new products quickly and efficiently as our pipeline develops over the coming years."

"We also continue to report new data and are gaining significant attention from top KOLs around the world. In May, we reported publication of the investigator initiated IRON-GUARD Italian clinical registry in the peer reviewed journal EuroIntervention. IRON-GUARD was an independent, multicenter, multi-disciplinary clinical study treating patients with carotid artery disease using the CGuard™ EPS in 12 Italian centers. The IRON-GUARD registry enrolled 200 patients, and showed results of 100% technical success placing the device, and zero incidence of major adverse cardiovascular events (MACE), comprised of death, major stroke or myocardial infarction, in all patients at 30 days. Also in May, we were honored to have the team of Professor Alberto Cremonesi, Chief of the Cardiovascular Department and Director of the Interventional Cardiovascular Unit of Maria Cecilia Hospital – GVM Care & Research, Cotignola (Italy), perform a live endovascular interventional procedure featuring the CGuard™ EPS Carotid Stent at EuroPCR 2017. The case was transmitted real time to the entire congress. EuroPCR is the world's leading course in interventional cardiovascular medicine bringing together over 12,000 clinicians and industry executives each year."

Dr. Barry concluded, “We remain extremely encouraged by the favorable response from leading medical practitioners around the world. Now that we have a robust distribution network in place across Europe, we believe we have a highly scalable and cost-effective platform to grow sales. We plan to replicate this model around the world. Overall, we achieved solid double-digit year-over-year and sequential revenue growth, which we expect to continue in the second half of the year. We also remain focused on carefully managing expenses and driving shareholder value. We appreciate the patience and support of our shareholders, and look forward to announcing additional significant milestones in the months ahead.”

Financial Results

Revenue for the second quarter ended June 30, 2017 was $640,000 compared to $540,000 during the same period in 2016. The increase was primarily due to an increase in sales of CGuard™ EPS as we entered new regional markets during the transition from our prior exclusive distribution partner for most of Europe. The transition to local distributors reflects an effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well. In addition to the increase in sales of CGuard™ EPS, sales of MGuard™ Prime EPS slightly increased, as well. Total operating expenses for the quarter ended June 30, 2017 were $2,441,000, an increase of 33.5% compared to $1,828,000 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 non-cash accrual adjustment. Net loss for the quarter ended June 30, 2017 totaled $2,294,000, or $0.21 per basic and diluted share, compared to a net loss of $1,946,000, or $4.56 per basic and diluted share, in the same period in 2016.

Revenue for the six months ended June 30, 2017 was $1,209,000 compared to $1,103,000 during the same period in 2016. The increase was predominantly driven by the increase in sales of CGuard™ EPS offset by a decrease in sales of MGuard™ Prime EPS associated with the trend of doctors increasingly using drug eluting stents (DES) rather than bare metal stents in STEMI patients. Total operating expenses for the six months ended June 30, 2017 were $4,919,000, an increase of 25.4% compared to $3,924,000 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 non-cash accrual. Net loss for the six months ended June 30, 2017 totaled $4,853,000, or $0.73 per basic and diluted share, compared to a net loss of $4,198,000, or $11.21 per basic and diluted share, in the same period in 2016.

As of June 30, 2017, cash and cash equivalents were $6,879,000, compared to $7,516,000 as of December 31, 2016.

Conference Call

The Company will host a conference call on Wednesday, August 9 at 8:00 a.m. Eastern Time. The conference call will be available via telephone by dialing toll free 866-682-6100 for U.S. callers or +1 862-255-5401 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 August 23, 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: 15963.

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.

Investor Contacts:

InspireMD, Inc.
Craig Shore
Chief Financial Officer
Phone: 1-888-776-6804 FREE
Email: craigs@inspiremd.com

Crescendo Communications, LLC
David Waldman
Phone: (212) 671-1021
Email: NSPR@crescendo-ir.com

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

	Three months ended June 30,		Six months ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenues	$ 640	$ 540	$ 1,209	$ 1,103
Cost of revenues	493	478	988	975
Gross Profit	147	62	221	128
Operating Expenses:				
Research and development	403	278	753	657
Selling and marketing	632	403	1,164	768
General and administrative	1,406	1,147	3,002	2,499
Total operating expenses	2,441	1,828	4,919	3,924
Loss from operations	(2,294)	(1,766)	(4,698)	(3,796)
Financial expenses	-	180	154	401
Loss before tax expenses	(2,294)	(1,946)	(4,852)	(4,197)
Tax expenses (Income)	-	-	1	1
Net Loss	$ (2,294)	$ (1,946)	$ (4,853)	$ (4,198)
Net loss per share – basic and diluted	$ (0.21)	$ (4.56)	$ (0.73)	$ (11.21)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	10,983,402	426,976	7,484,399	374,330

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

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,879	$ 7,516
Accounts receivable:		
Trade, net	451	356
Other	161	157
Prepaid expenses	73	65
Inventory	429	500
Total current assets	7,993	8,594
Non-current assets:		
Property, plant and equipment, net	459	379
Funds in respect of employee rights upon retirement	430	399
Royalties buyout	25	38
Total non-current assets	914	816
Total assets	$ 8,907	$ 9,410

	June 30, 2017	December 31, 2016
LIABILITIES AND EQUITY		
Current liabilities:		
Current maturity of long-term loan	$ -	$ 2,680
Accounts payable and accruals:		
Trade	473	618
Other	2,066	1,447
Advanced payment from customers	54	33
Total current liabilities	2,593	4,778
Long-term liabilities		
Liability for employees rights upon retirement	572	587
Total long-term liabilities	572	587
Total liabilities	3,165	5,365
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2017 and December 31, 2016; 7,467,646 and 1,475,318 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	1	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at June 30, 2017 and December 31, 2016; 181,295 and 311,521 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2017 ; 745,775 shares issued and outstanding at June 30, 2017	-	-
Additional paid-in capital	142,508	135,959
Accumulated deficit	(136,767)	(131,914)
Total equity	5,742	4,045
Total liabilities and equity	$ 8,907	$ 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 June 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.