

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
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): November 6, 2018

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35731

(Commission
File Number)

26-2123838

(IRS Employer
Identification No.)

4 Menorat Hamaor St.
Tel Aviv, Israel

(Address of principal executive offices)

6744832

(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 6, 2018, InspireMD, Inc. issued a press release announcing its financial and operating results for the fiscal quarter ended September 30, 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 November 6, 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: November 6, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



InspireMD Announces Third Quarter 2018 Financial Results and Provides Corporate Update

*Presented Three-Year Data Highlighting Long-Term Safety and Efficacy of
CGuard™ Embolic Prevention System*

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

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

Tel Aviv, Israel — November 6, 2018 – 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 third quarter ending September 30, 2018.

Third Quarter 2018 highlights:

- Announced preliminary cumulative three-year CGuard™ Embolic Prevention System (EPS) safety and efficacy data at the Transcatheter Cardiovascular Therapeutics (TCT) 2018 Conference that showed no stroke or stroke-related deaths between 24 and 36 months and the absence of any device related issues in the first 93 patients who had reached the three year follow up in the ongoing PARADIGM-Extend trial
- Received CGuard™ EPS regulatory approval and initiated commercial launch in Mexico
- Strengthened Intellectual Property portfolio with the issuance of two key United States patents covering the Company’s proprietary MicroNet™ stent jacket and related drug eluting technology across stent-based products
- Announced the opening of the first two Centers of Excellence at the Augusta Hospital Clinic for Vascular Surgery in Düsseldorf, Germany, and the Maria Cecilia Hospital in Cotignola, Italy
- Year-to-date CGuard™ EPS revenue through September 30 was \$2.3 million compared to \$1.3 million for the comparable period in 2017, an increase of 72%
- Closed an equity financing for gross proceeds of approximately \$10 million and completed the recapitalization of the company
- \$11.2 million of cash as of September 30, 2018

“We had an eventful and productive third quarter during which we believe we made significant progress in expanding the global commercial availability of CGuard™ EPS and bringing it one step closer to becoming the standard of care in stroke prevention following treatment for carotid artery disease,” commented James Barry, PhD, Chief Executive Officer of InspireMD. “The 36-month data that was presented at the TCT conference adds to the growing and compelling body of clinical evidence that has been compiled regarding CGuard’s long-term sustained benefits to patients relative to conventional carotid stent procedures and, together with ever increasing Key Opinion Leader support, are driving increased traction across our multi-faceted growth strategy.”

“In addition to continued growth in key existing commercial territories, we remain on-track to file a U.S. IDE expected in mid-2019, and our new program to educate vascular surgeons about the advantages of CGuard EPS through our Centers of Excellence are having a positive impact on awareness,” Dr. Barry continued. “With our strong balance sheet we believe we have set the stage for a truly transformational 2019.”

Financial Results

Revenue for the third quarter ended September 30, 2018 was \$769,000 compared to \$718,000 during 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, and expanding into new geographies such as India, Mexico and Vietnam. The Company's gross profit for the quarter ended September 30, 2018 was \$198,000 compared to \$153,000 for the same period in 2017. Gross margin increased to 25.7% in the three months ended September 30, 2018 from 21.3% in the same period in 2017, driven mainly by a higher average sales price of MGuard™ Prime EPS and a reduction in costs of one of the main components of CGuard™ EPS. .

Total operating expenses for the quarter ended September 30, 2018 were \$2,177,000, a decrease of 2.7% compared to \$2,238,000 for the same period in 2017. This decrease was primarily due to a decrease in salary expenses, primarily due to a salary related accrual in 2017 and a decrease in share-based compensation expenses, partially offset by an increase in quality assurance and regulatory expenses related to annual routine audit activities which included validation reviews required every two years. Financial expenses for the quarter ended September 30, 2018 were \$32,000 compared to \$1,000 for the same period in 2017. Net loss for the quarter ended September 30, 2018 totaled \$2,011,000, or \$0.05 per basic and diluted share, compared to a net loss of \$2,086,000, or \$6.56 per basic and diluted share, for the same period in 2017.

Revenue for the nine months ended September 30, 2018 was \$2,779,000 compared to \$1,927,000 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, and expanding into new geographies such as India and continued focus on expanding existing markets such as Germany and Italy. The Company's gross profit for the nine months ended September 30, 2018 was \$768,000 compared to \$374,000 for the same period in 2017. Gross margin increased to 27.6% in the nine months ended September 30, 2018 from 19.4% in the same period in 2017, driven mainly by more efficient utilization of fixed manufacturing resources.

Total operating expenses for the nine months ended September 30, 2018 were \$6,173,000, a decrease of 13.7% compared to \$7,157,000 for the same period in 2017. This decrease was primarily due to a decrease in salary expenses, primarily due to a salary related accrual in 2017 and a decrease in share-based compensation expenses. These decreases were partially offset by an increase in legal expenses, as well as costs related to the routine annual audit that we cited earlier. Financial income for the nine months ended September 30, 2018 was \$378,000 compared to \$155,000 of financial expenses for the same period in 2017, largely due to non-cash income associated with preferred stock. Net loss for the nine months ended September 30, 2018 totaled \$5,027,000, or \$0.32 per basic and diluted share, compared to a net loss of \$6,939,000, or \$30.42 per basic and diluted share, for the same period in 2017.

As of September 30, 2018, cash and cash equivalents were \$11,247,000, 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=131700>

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 November 20, 2018, 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: 13683949.

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.

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 ⁽¹⁾

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Revenues	\$ 769	\$ 718	\$ 2,779	\$ 1,927
Cost of revenues	571	565	2,011	1,553
Gross Profit	198	153	768	374
Operating Expenses:				
Research and development	416	288	898	1,041
Selling and marketing	605	671	1,677	1,835
General and administrative	1,156	1,279	3,598	4,281
Total operating expenses	2,177	2,238	6,173	7,157
Loss from operations	(1,979)	(2,085)	(5,405)	(6,783)
Financial expenses (income)	32	1	(378)	155
Loss before tax expenses	(2,011)	(2,086)	(5,027)	(6,938)
Tax expenses (Income)	-	-	-	1
Net Loss	\$ (2,011)	\$ (2,086)	\$ (5,027)	\$ (6,939)
Net loss per share – basic and diluted	\$ (0.05)	\$ (6.56)	\$ (0.32)	\$ (30.42)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	40,764,158	317,896	16,729,052	248,907

CONSOLIDATED BALANCE SHEETS ⁽¹⁾
(U.S. dollars in thousands)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 11,247	\$ 3,710
Accounts receivable:		
Trade, net	710	643
Other	169	207
Prepaid expenses	145	62
Inventory	816	533
	<u>13,087</u>	<u>5,155</u>
Total current assets	<u>13,087</u>	<u>5,155</u>
Non-current assets:		
Property, plant and equipment, net	400	476
Funds in respect of employee rights upon retirement	446	476
	<u>846</u>	<u>952</u>
Total non-current assets	<u>846</u>	<u>952</u>
Total assets	<u>\$ 13,933</u>	<u>\$ 6,107</u>

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	\$ 456	\$ 328
Other	1,891	2,134
Contract liability	26	20
Total current liabilities	<u>2,373</u>	<u>2,482</u>
Long-term liabilities:		
Liability for employees rights upon retirement	608	624
Total long-term liabilities	<u>608</u>	<u>624</u>
Total liabilities	<u>2,981</u>	<u>3,106</u>
Redeemable preferred shares	-	274
Equity:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at September 30, 2018 and December 31, 2017; 36,694,035 and 1,483,556 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at September 30, 2018 and December 31, 2017; 17,303 and 27,075 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at September 30, 2018 and December 31, 2017; 61,423 and 741,651 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Preferred D shares, par value \$0.0001 per share; 750 shares authorized at September 30, 2018 and December 31, 2017; 0 and 750 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Additional paid-in capital	156,327	143,079
Accumulated deficit	(145,379)	(140,352)
Total equity	<u>10,952</u>	<u>2,727</u>
Total liabilities, redeemable preferred shares and equity	<u>\$ 13,933</u>	<u>\$ 6,107</u>

(1) All 2018 financial information is derived from the Company's 2018 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; 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.

