INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/06/19 for the Period Ending 08/06/19

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 6, 2019

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** (Address of principal executive offices)	**6744832** (Zip Code)

(888) 776-6804
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, par value $0.0001 per share	NSPR	NYSE American

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 6, 2019, InspireMD, Inc. issued a press release announcing its financial and operating results for the second fiscal quarter ended June 30, 2019. 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 No.	Description
99.1	Press Release dated August 6, 2019 (furnished herewith pursuant to Item 2.02).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

InspireMD Inc.

Date: August 6, 2019

By: */s/ Craig Shore*

Name: Craig Shore
Title: Chief Financial Officer

InspireMD Announces Second Quarter 2019 Financial Results

U.S. Investigational Device Exemption (IDE) application submitted to FDA

Company to host investor conference call today, August 6, at 8:00am ET

Tel Aviv, Israel— August 6, 2019 – 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 second quarter ended June 30, 2019.

Second Quarter 2019 and recent highlights:

- Submitted U.S. IDE application which, if approved, will allow the company to commence U.S. clinical trials of CGuard™
- Successfully transitioned to a new sterilization partner and cleared all of the $592,000 sales backlog that existed entering the second quarter
- Cash and equivalents expected to fund operations until the end of 2019

"Despite the headwinds that we faced in the first quarter of the year with the company's prior sterilization partner that limited us to selling products that were predominantly in stock in our warehouse from 2018, we were pleased to see the entire $592,000 of product backlog shipped in the second quarter, as key accounts were once again able to obtain the products, and we returned to normalizing product availability in all of our markets," said James Barry, PhD, Chief Executive Officer of InspireMD. "Importantly, we submitted our IDE application as planned, and if approved, we would have the ability to begin U.S. clinical trials. We believe CGuard™ represents a true paradigm shift in the treatment of carotid artery disease, and we continue to execute on our multi-faceted growth plan with the goal of making this cutting-edge device technology platform available to patients worldwide."

Financial Results

For the three months ended June 30, 2019, revenue was $1,354,000, representing an increase of 35.0% from the comparable period in 2018. This increase was predominantly driven by a 34.0% increase in sales of CGuard EPS from $833,000 in the three months ended June 30, 2018, to $1,116,000 in the three months ended June 30, 2019, and a 39.9% increase in sales of MGuard EPS from $170,000 in the three months ended June 30, 2018, to $238,000 in the three months ended June 30, 2019. Both increases were due to the shipments during the three months ended June 30, 2019 of approximately $592,000 of backlog that accumulated in the three months ended March 31, 2019 that we were unable to previously ship. These increases, however, were partially offset by sales decreases in certain markets during the three months ended June 30, 2019, resulting from new orders being delayed while the product backlog was being cleared.

The Company's gross profit for the quarter ended June 30, 2019 was $442,000 compared to a gross profit of $277,000 for the same period in 2018. Gross margin increased to 32.6% in the three months ended June 30, 2019 from 27.6% in the same period in 2018. This increase in gross profit resulted from a $180,000 increase in revenues, less the related material and labor costs, as discussed above, and a receipt of $135,000 compensation from the company's former third-party sterilizer for the delays related to the product sterilization interruption during the first quarter of 2019. These increases were offset by $69,000 of expenses related to upgrades made to the company's production facilities, $40,000 of expenses pertaining to annual and new employee training of the production workers and an increase of $41,000 in miscellaneous expenses.

Total operating expenses for the quarter ended June 30, 2019 were $2,625,000, an increase of 50.0% compared to $1,750,000 for the same period in 2018. This increase was primarily due to an increase in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2019 and due to a salary related accrual reversal in the second quarter of 2018 that did not repeat itself in the same period this year.

Financial expenses for the quarter ended June 30, 2019 were $23,000 compared to financial income of $846,000 for the same period in 2018. This decrease in financial income of $869,000 was predominately due to a non-cash income associated with the company's preferred stock in the quarter ended June 30, 2018, which did not occur during this quarter. Net loss for the quarter ended June 30, 2019 totaled $2,206,000, or $1.59 per basic and diluted share, compared to a net loss of $627,000, or $7.66 per basic and diluted share, for the same period in 2018.

For the six months ended June 30, 2019, revenue was $1,769,000, representing a decrease of 12.0% from the comparable period in 2018. This decrease was predominantly driven by a 10.3% decrease in sales of CGuard EPS from $1,664,000 in the six months ended June 30, 2018, to $1,492,000 in the six months ended June 30, 2019, and a 19.9% decrease in sales of MGuard EPS from $346,000 in the six months ended June 30, 2018, to $277,000 in the six months ended June 30, 2019. Both decreases were primarily due to shipment delays in the three months ended March 31, 2019 associated with us changing sterilization companies and sales decreases in certain of the company's markets. The transition to the company's new sterilization is now complete and we do not currently anticipate any future disruptions in fulfilling new orders.

The Company's gross profit for the six months ended June 30, 2019 was $369,000 compared to a gross profit of $570,000 for the same period in 2018. Gross margin decreased to 20.9 % in the six months ended June 30, 2019 from 28.4% in the same period in 2018. This decrease in gross profit resulted from a $69,000 decrease in revenues (as mentioned above), less the related material and labor costs, $69,000 of expenses related to upgrades made to the company's production facilities, $38,000 of expenses pertaining to annual and new employee training of the production workers, and an increase of $25,000 in miscellaneous expenses.

Total operating expenses for the six months ended June 30, 2019 were $5,682,000, an increase of 42.2% compared to $3,996,000 for the same period in 2018. This increase was primarily due to an increase in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2019 and due to a settlement payment made to a former service provider pursuant to a settlement agreement.

Financial expenses for the six months ended June 30, 2019 were $100,000 compared to financial income of 410,000 for the same period in 2018. This decrease in financial income of $510,000 was predominately due to a non-cash income associated with the company's preferred stock in the six months ended June 30, 2018, which did not occur during the six months ended June 30, 2019. Net loss for the six months ended June 30, 2019 totaled $5,413,000, or $4.86 per basic and diluted share, compared to a net loss of $3,016,000, or $38.48 per basic and diluted share, for the same period in 2018.

As of June 30, 2019, cash and cash equivalents were $4,823,000, compared to $9,384,000 at December 31, 2018.

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=135364. The webcast will be archived on the Company's website.

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 and NSPR.WSB.

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:

Craig Shore
Chief Financial Officer
InspireMD, Inc.
888-776-6804
craigs@inspiremd.com

Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.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,	
	2019	**2018**	**2019**	**2018**
Revenues	$ 1,354	$ 1,003	$ 1,769	$ 2,010
Cost of revenues	912	726	1,400	1,440
Gross Profit	442	277	369	570
Operating Expenses:				
Research and development	865	230	1,990	482
Selling and marketing	620	580	1,254	1,072
General and administrative	1,140	940	2,438	2,442
Total operating expenses	2,625	1,750	5,682	3,996
Loss from operations	(2,183)	(1,473)	(5,313)	(3,426)
Financial expenses (income)	(23)	846	(100)	410
Loss before tax expenses	(2,206)	(627)	(5,413)	(3,016)
Tax expenses (Income)	-	-	-	-
Net Loss	$ (2,206)	$ (627)	$ (5,413)	$ (3,016)
Net loss per share – basic and diluted	$ (1.59)	$ (7.66)	$ (4.86)	$ (38.48)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	1,383,238	134,907	1,112,888	90,234

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

	June 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 4,823	$ 9,384
Accounts receivable:		
Trade, net	861	716
Other	276	104
Prepaid expenses	44	81
Inventory	1,218	1,134
Total current assets	7,222	11,419
Non-current assets:		
Property, plant and equipment, net	513	421
Right of use	1,042	-
Funds in respect of employee rights upon retirement	507	448
Total non-current assets	2,062	869
Total assets	$ 9,284	$ 12,288

	June 30, 2019	December 31, 2018
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 618	$ 929
Other	1,307	1,966
Contract liability	20	25
Total current liabilities	1,945	2920
Long-term liabilities:		
Leasing liability	1,095	-
Liability for employees rights upon retirement	670	605
Total long-term liabilities	1,765	605
Total liabilities	3,710	3,525
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2019 and December 31, 2018; 1,397,133 and 768,615 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	-	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at June 30, 2019 and December 31, 2018; 17,303 shares issued and outstanding at June 30, 2019 and December 31, 2018.	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2019 and December 31, 2018; 38,806 and 61,423 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	-	-
Additional paid-in capital	158,579	156,355
Accumulated deficit	(153,005)	(147,592)
Total equity	5,574	8,763
Total liabilities, redeemable preferred shares and equity	$ 9,284	$ 12,288

(1) All 2019 financial information is derived from the Company's 2019 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; 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.

(2) All June 30, 2019 financial information is derived from the Company's 2019 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, 2018 financial information is derived from the Company's 2018 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2018 filed with the Securities and Exchange Commission.