INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 03/10/20 for the Period Ending 03/10/20

Telephone	(888) 776-6804
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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): March 10, 2020

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)

(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
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	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 March 10, 2020, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the fourth quarter and year ended December 31, 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 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 March 10, 2020 (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: March 10, 2020

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Fourth Quarter and Year-End 2019 Financial Results

Robust CGuard™ EPS year-over-year revenue growth of 31%

Management to host investor conference call today, March 10, at 8:30am ET

Tel Aviv, Israel— March 10, 2020 – 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 (CAD), today announced financial and operating results for the fourth quarter and year ended December 31, 2019.

Fourth Quarter 2019 and recent highlights:

- Announced the appointment of leading medical devices executive Marvin Slosman as Chief Executive Officer
- Generated revenue of $1,013,000, representing growth of 23% over the fourth quarter 2018, driven by continued strong growth in sales of CGuard™ EPS
- Generated CGuard™ EPS revenue of $921,000, up 31% over the fourth quarter 2018
- Chosen for the third consecutive year to demonstrate a successful live clinical case transmission featuring CGuard™ EPS at the Leipzig Interventional Course (LINC) 2020 that showcased CGuard's ease-of-use and exceptional patient safety features
- Presented updated data at the 2019 VEITH Symposium and LINC 2020 from the IRONGUARD 2 study, a physician initiated prospective multi-center and multi-specialty registry that enrolled more than 700 patients, which suggested that the use of the CGuard EPS in routine clinical practice is associated with no major periprocedural and 30-day neurologic complications
- Began exploring the potential broadening of the company's product portfolio with procedural protection devices based on its reverse flow technology
- Beginning to engage with French health authorities to gain reimbursement in France
- Advanced productive discussions with FDA and addressed requests related to the company's pending IDE application

“I assumed the role of Chief Executive Officer of InspireMD because I believe the combination of the substantial amount of published data confirming the safety and efficacy of CGuard, along with real world performance demonstrating the unique patient safety features of the device and a growing appreciation of CAS, or carotid artery stenting, as a first line treatment for CAD, position CGuard EPS and MicroNet to change the standard of care in this disease,” said Marvin Slosman, Chief Executive Officer. “The strong revenue growth that we reported in the fourth quarter was again driven by growing demand for CGuard in our key European markets, and my discussions with our physician and distribution partners in the field confirm that we are realizing this success by educating practitioners and creating awareness for the value of our platform.”

“We are also executing on another of the pillars of our commercial focus which is compilation of multiple clinical registries designed to capture relevant data to support additional indications for the CGuard EPS platform, which we believe are numerous and significant.”

“Presentations at key industry conferences such as VEITH and LINC, along with our strong relationships with key opinion leaders in the field, are absolutely crucial to our long-term growth, and we are pleased to continue to play a significant role at these events, which attract leading vascular surgeons and interventionalists from around the world. We believe these presentations serve as the foundation of a multifaceted commercial growth strategy that we continue to drive in CE mark territories and Asia.”

“In parallel with these efforts, we continue to work vigorously to address FDA’s information and testing requests in support of our pending IDE application, and the initiation of clinical testing in the all-important US market which is among our highest corporate priorities.”

Financial Results

For the three months ended December 31, 2019, revenue increased by 23.2%, to $1,013,000, from $822,000 during the three months ended December 31, 2018. This increase was predominantly driven by a 31.4% increase in sales volume of CGuard EPS from $701,000 during the three months ended December 31, 2018, to $921,000 during the three months ended December 31, 2019, mainly due to our continued focus on expanding existing markets. This increase in sales of CGuard EPS was partially offset by a 24.0% decrease in sales of MGuard Prime EPS, largely driven by the general shift in preference to drug-eluting stents rather than bare metal stents, such as MGuard Prime EPS, in ST-Elevation Myocardial Infarction (“STEMI”) patients. The company’s gross profit for the quarter ended December 31, 2019 was $259,000, compared to a gross profit of $227,000 for the same period in 2018. This increase in gross profit was primarily driven by a higher volume of sales of CGuard EPS less the related material and labor costs, offset by an increase in write-offs predominantly driven by a non-recurring component supply issue of CGuard EPS. Gross margin decreased to 25.6% in the fourth quarter of 2019 from 27.6% for the same period in 2018.

Total operating expenses for the quarter ended December 31, 2019 were $2,765,000, an increase of 13.6% compared to $2,433,000 for the same period in 2018. This increase was primarily due to payments related to the separation agreement of $684,000 the company entered into with its former chief executive officer, offset by a reduction of miscellaneous expenses of approximately $352,000 throughout the organization.

Financial expenses for the quarter ended December 31, 2019 were $27,000 compared to financial expenses of $7,000 for the same period in 2018. This increase in financial expenses of $20,000 was predominately due to changes in exchange rates. Net loss for the fourth quarter of 2019 totaled $2,557,000, or $0.57 per basic and diluted share, compared to a net loss of $2,213,000, or $2.64 per basic and diluted share, for the same period in 2018.

For the twelve months ended December 31, 2019, revenue increased by $120,000, or 3.3%, to $3,721,000, from $3,601,000 during the twelve months ended December 31, 2018. This increase was predominantly driven by a 10.0% increase in sales volume of CGuard EPS from $2,970,000 during the twelve months ended December 31, 2018, to $3,265,000 during the twelve months ended December 31, 2019, as a result of our continued focus on expanding existing markets such as Poland, Switzerland, Italy, and Spain and expansion into new geographies such as Australia and South Africa. This increase was offset by a 27.7% decrease in sales volume of MGuard Prime EPS from $631,000 during the twelve months ended December 31, 2018, to $456,000 during the twelve months ended December 31, 2019. In addition, the overall increase mentioned above was offset across the board by shipment delays in the three months ended March 31, 2019 associated with the company's decision to switch its third-party sterilizer. The transition to the new sterilization company was completed in early April 2019, and the company does not currently anticipate any future disruptions in fulfilling new orders.

The Company's gross profit for the twelve months ended December 31, 2019 was $756,000 compared to a gross profit of $995,000 for the same period in 2018. This decrease in gross profit resulted from a $142,000 increase in write-offs predominantly driven by a non-recurring component supply issue of CGuard EPS and slow moving MGuard Prime EPS, $69,000 of expenses related to upgrades made to our production facilities and $48,000 of expenses pertaining to annual and new employee training of production workers, and offset by a reduction of $20,000 in miscellaneous expenses. Gross margin decreased to 20.3% in the twelve months ended December 31, 2019 from 27.6% in the same period in 2018.

Total operating expenses for the twelve months ended December 31, 2019 were $10,572,000, an increase of 22.8% compared to $8,606,000 for the same period in 2018. This increase was primarily due to an increase of $804,000 in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2019, payments related to the separation agreement of $684,000 the company entered into with its former chief executive officer and a settlement payment of $354,000 made to a former service provider.

Financial expenses for the twelve months ended December 31, 2019, were $200,000 as compared to financial income of $371,000 for the twelve months ended December 31, 2018. The increase in financial expenses primarily resulted from the $438,000 of financial income related to the revaluation of the embedded derivative of the Series C Convertible Preferred Stock recorded during the twelve months ended December 31, 2018, which did not occur during the twelve months ended in December 31, 2019, and an increase of $144,000 in financial expenses related to changes in exchange rates. These increases in financial expenses were partially offset by a decrease of $11,000 in miscellaneous expenses during the twelve months ended December 31, 2019. Net loss for the twelve months ended December 31, 2019 totaled $10,040,000, or $4.80 per basic and diluted share, compared to a net loss of $7,240,000, or $16.67 per basic and diluted share, for the same period in 2018.

As of December 31, 2019, cash and cash equivalents were $5,514,000, compared to $9,384,000 at December 31, 2018. Based on the Company's current business plan, the Company believes its cash and cash equivalents as of December 31, 2019, will be sufficient to meet its operating requirements until the end of May 2020. As disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, which was filed on March 9, 2020, 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 1b 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 American Company Guide Section 610(b), which requires public announcement of the receipt of an audit opinion containing a going concern paragraph.

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 13699019. To access the webcast, please go to the following link: http://public.viavid.com/index.php?id=138070. 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, including the transition to the new European Medical Devices Regulation, (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 and public health crisis 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
(U.S. dollars in thousands, except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues	$ 1,013	$ 822	$ 3,721	$ 3,601
Cost of revenues	754	595	2,965	2,606
Gross Profit	259	227	756	995
Operating Expenses:				
Research and development	522	637	2,954	1,535
Selling and marketing	605	564	2,396	2,241
General and administrative	1,638	1,232	5,222	4,830
Total operating expenses	2,765	2,433	10,572	8,606
Loss from operations	(2,506)	(2,206)	(9,816)	(7,611)
Financial expenses (income)	27	7	200	(371)
Loss before tax expenses	(2,533)	(2,213)	(10,016)	(7,240)
Tax expenses	24	-	24	-
Net Loss	$ (2,557)	$ (2,213)	$ (10,040)	$ (7,240)
Basic and Diluted Loss Per Share:				
Extinguishment and accretion of preferred shares	-	-	-	(456)
Net Loss Applicable to Ordinary Shares	$ (2,557)	$ (2,213)	$ (10,040)	$ (7,696)
Net loss per share – basic and diluted	$ (0.57)	$ (2.64)	$ (4.80)	$ (16.67)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	4,449,020	838,268	2,089,964	461,539

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

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,514	$ 9,384
Accounts receivable:		
Trade, net	823	716
Other	150	104
Prepaid expenses	87	81
Inventory	1,236	1,134
Total current assets	7,810	11,419
Non-current assets:		
Property, plant and equipment, net	547	421
Operating lease right of use assets	937	-
Funds in respect of employee rights upon retirement	586	448
Total non-current assets	2,070	869
Total assets	$ 9,880	$ 12,288

	December 31, 2019	December 31, 2018
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 646	$ 929
Other	2,449	1,966
Contract liability	20	25
Total current liabilities	3,115	2,920
Long-term liabilities:		
Operating lease liabilities	653	-
Liability for employees rights upon retirement	729	605
Total long-term liabilities	1,382	605
Total liabilities	4,497	3,525
Redeemable preferred shares	-	-
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2019 and 2018; 3,916,134 and 768,615 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2019 and 2018; 17,303 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2019 and 2018; 34,370 and 61,423 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Additional paid-in capital	163,015	156,355
Accumulated deficit	(157,632)	(147,592)
Total equity	5,383	8,763
Total liabilities and equity	$ 9,880	$ 12,288

(1) All financial information for the twelve months ended December 31, 2019 is derived from the Company's 2019 audited financial statements and all financial information for the twelve months ended December 31, 2018 is derived from the Company's 2018 audited financial statements, included in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2019 filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2019 and 2018 is derived from the Company's unaudited, financial statements.

(2) All December 31, 2019 financial information is derived from the Company's 2019 audited financial statements and 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, 2019 filed with the Securities and Exchange Commission.