INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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, 2021

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 9, 2021, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the fourth quarter and year ended December 31, 2020. 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 9, 2021 (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, 2021

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Fourth Quarter and Year-End 2020 Financial Results

Management to host investor conference call today, March 9, at 8:30am ET

Tel Aviv, Israel— March 9, 2021 – 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, 2020.

Fourth Quarter 2020 and recent highlights:

- Announced the closing of an upsized underwritten public offering of $20.7 million.
- Announced the addition of renowned interventional cardiologist Gary Roubin, M.D., Ph.D., to the Board of Directors.
- Announced the appointment of leading interventional cardiologist Chris Metzger, M.D., system chair of clinical research at Ballad Health System in Eastern Tennessee as the principal investigator for its planned FDA registration trial for CGuard EPS.
- Secured China-based investment partner for process of seeking regulatory approval and distribution of CGuard EPS in mainland China.
- Announced the engagement of Hart Clinical Consultants (HCC), a leading Contract Research Organization (CRO) to conduct the clinical trial of CGuard Carotid Stent System in the United States.
- Conducted multiple presentations regarding CGuard EPS, including a live demonstration, during the Leipzig Interventional Congress.
- Shipments for the quarter were $738,000

“It was a very remarkable, albeit challenging year for us – and the global community — and we achieved many important milestones toward our goal of changing the standard of care for the prevention of stroke caused by carotid artery disease,” said Marvin Slosman, CEO of InspireMD. “Our team’s performance during the COVID-19 pandemic has remained steadfast, focused on execution, financial stability and commercial growth. This included maintaining our global presence with CGuard during this most challenging time when elective procedures were impacted. While the market curtailed our ability to grow revenue, and we took an accounting adjustment to Q4 revenue for a one time historical event from 2014, we remained focus on building our business by investing heavily in our strategic plans, human capital, infrastructure, new market and product development opportunities, all to create more rapid growth potential as the impact from COVID normalizes. We view 2020 revenue as an unanticipated exception to what otherwise could have been a promising year of growth. As we enter 2021 with more optimism, we reflect on the many foundational achievements 2020 brought to our business.

“Most significantly, in 2020 we received approval of our Investigational Device Exemption (IDE) application to initiate a pivotal study of CGuard™ EPS (C-Guardian) in the United States by the FDA. This triggered a number of critical additions to our team, including renowned interventional cardiologist Gary Roubin, M.D., Ph.D. to our Board of Directors, Dr. Chris Metzger to lead the investigators, a world-class contract research organization (HCC), as well as Christina Brennan, M.D., to assist with trial execution. The culmination of this good work resulted in an oversubscribed public offering which raised proceeds of $20.7M, providing the financial support needed to complete the effort. We are diligently preparing for initiation of the trial.

“In terms of our global strategy, in 2020 we continued to expand our market presence, including by obtaining registration and distribution for CGuard in Brazil, the largest market for medical devices in Latin America. The Brazilian clearance supports our goals to expand in other Latin and South American markets. We also completed an investment and distribution agreement as part of our strategy to enter mainland China, believed to be the second fastest growing market for peripheral stent procedures, as stroke is the leading cause of death in China. We are currently applying for and planning regulatory and reimbursement approvals in important new markets such as France, Taiwan and Korea and are working on distributor options for Japan to bolster our global footprint.

“Finally, our cash position has improved significantly, after completing a $11.5 million public offering in mid-2020, and a $20.7 million public offering last month as well as other successful equity offerings. We believe that we are now well-positioned financially with the resources needed to execute our global expansion strategy. Our company focus is built on the foundational value of our CGuard stent system, supportive of all delivery systems and available to all vascular specialists, resulting in the highest patient care with unmatched clinical outcomes,” concluded Mr. Slosman.

Financial Results for the Fourth Quarter and Twelve Months ended December 31, 2020

For the three months ended December 31, 2020, revenue decreased by $855,000, or 84.4%, to $158,000, from $1,013,000 during the three months ended December 31, 2019. Revenues were negatively impacted by our settlement of litigation with a former distributor relating to a 2014 transaction. Under the settlement, we agreed to pay them $580,000. Under US GAAP we were required to charge that amount against sales. Excluding such impact, revenue decreased by $275,000, or 27.1%, to $738,000, from $1,013,000 during the three months ended December 31, 2019. This decrease was driven mainly by a 25.2% decrease in sales volume of CGuard EPS from $921,000 during the three months ended December 31, 2019, to $689,000 during the three months ended December 31, 2020, mainly due to the postponement of procedures with CGuard EPS, which are generally scheduled or nonemergency procedures, as hospitals shifted resources to patients affected by COVID-19. The 46.7% decrease in sales volume of MGuard Prime EPS from $92,000 during the three months ended December 31, 2019, to $49,000 during the three months ended December 31, 2020, was also mainly due to the impact of COVID-19, as mentioned above.

For the three months ended December 31, 2020, gross profit decreased by 250.6%, or $649,000, to a negative $390,000, from $259,000 during the three months ended December 31, 2019. This decrease in gross profit resulted from the impact of the $580,000 settlement with our former distributor in 2014 as well as $79,000 decrease in revenues less the related material and labor costs (as mentioned above). This decrease was partially offset by a decrease of $10,000 in miscellaneous expenses during the three months ended December 31, 2020. Gross margin (gross profits as a percentage of revenue) decreased to a negative 246.8% during the three months ended December 31, 2020 from 25.6% during the three months ended December 31, 2019, driven mainly by a negative effect on gross margin of 272.5% due to the settlement with our former distributor.

Total operating expenses for the quarter ended December 31, 2020 were $3,328,000, an increase of 20.4% compared to $2,765,000 for the same period in 2019. This increase was primarily due to increases of $363,000 in compensation expenses as we added resources to our clinical, product development and sales infrastructure, $134,000 of Directors' and Officers' Liability Insurance expense due to recent economic changes in the insurance industry, $96,000 in development expenses associated with CGuard EPS, mainly related to the new advanced delivery system and accessories, and $75,000 of miscellaneous expense. These increases were partially offset by a decrease in travel expenses of $105,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19.

For the three months ended December 31, 2020, financial expenses increased by 385.2%, or $104,000, to $131,000, from $27,000 during the three months ended December 31, 2019. The increase in financial expenses primarily resulted from changes in exchange rates.

Net loss for the fourth quarter of 2020 totaled $3,853,000, or $0.10 per basic and diluted share, compared to a net loss of $2,557,000, or $0.57 per basic and diluted share, for the same period in 2019.

For the twelve months ended December 31, 2020, revenue decreased by $1,236,000, or 33.2%, to $2,485,000, from $3,721,000 during the twelve months ended December 31, 2019. Revenues were negatively impacted by 15.6% due to settlement of our litigation with a former distributor relating to a 2014 transaction under which we agreed to pay them $580,000. Under US GAAP we were required to charge that amount against sales. Excluding such impact, revenue decreased by $656,000, or 17.6%, to $3,065,000, from $3,721,000 during the 12 months ended December 31, 2019.This decrease was driven mainly by a 15.3% decrease in sales volume of CGuard EPS from $3,265,000 during the twelve months ended December 31, 2019, to $2,764,000 during the twelve months ended December 31, 2020, mainly due to the postponement of procedures with CGuard EPS, which are generally scheduled or nonemergency procedures, as hospitals shifted resources to patients affected by COVID-19. There was also a 34.0% decrease in sales volume of MGuard Prime EPS from $456,000 during the twelve months ended December 31, 2019, to $301,000 during the twelve months ended December 31, 2020, mainly due to the impact of COVID-19, as mentioned above.

For the twelve months ended December 31, 2020, gross profit (revenue less cost of revenues) decreased by 89.0%, or $673,000, to $83,000, compared to a $756,000 for the same period in 2019. This decrease in gross profit resulted from the impact of the $580,000 settlement with our former distributor in 2014 as well as $198,000 decrease in revenues less the related material and labor costs (as mentioned above). This decrease was partially offset by a decrease of $69,000 in expenses related to upgrades made to our production facilities during the year ended December 31, 2019, which did not reoccur during the year ended December 31, 2020 and a decrease of $36,000 in miscellaneous expenses during the year ended December 31, 2020. Gross margin (gross profits as a percentage of revenue) decreased to 3.3% during the year ended December 31, 2020 from 20.3% during the year ended December 31, 2019, driven mainly by a negative effect on gross margin of 18.3% due to the settlement with our former distributor offset by a 1.3% gross margin increase due to the upgrades made to our production facilities and miscellaneous expenses as mentioned above.

Total operating expenses for the twelve months ended December 31, 2020 were $10,463,000, a decrease of 1.0% compared to $10,572,000 for the same period in 2019. This decrease was primarily due to a decrease of $861,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, for which an approval from the FDA was received on September 8, 2020, $421,000 in travel expenses in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19, $354,000 due to settlement expenses that were paid to a former service provider pursuant to a settlement agreement during the twelve months ended December 31, 2019, $136,000 in quality assurance and regulatory expenses related to the development of various projects and $129,000 in promotional expenses, primarily related to having already built our social media infrastructure in 2019. These decreases were partially offset by an increase in expenses of $531,000 in development expenses related to CGuard EPS new advanced delivery system and accessories, $400,000 due to the settlement agreement with the underwriter of our prior offerings paid during the twelve months ended December 31, 2020, $386,000 in compensation expenses as we added resources to our clinical, product development and sales infrastructure, $249,000 in our Directors' and Officers' Liability Insurance expenses, partially due to recent changes in the insurance industry, and $177,000 in regulatory expenses required for new regulatory standards set by the European Union, and $49,000 of miscellaneous expenses.

Financial expenses for the twelve months ended December 31, 2020 was $160,000 compared to $200,000 for the same period in 2019. The decrease in financial expenses primarily resulted from changes in exchange rates.

Net loss for the twelve months ended December 31, 2020 totaled $10,544,000, or $0.46 per basic and diluted share, compared to a net loss of $10,040,000, or $4.80 per basic and diluted share, for the same period in 2019.

As of December 31, 2020, cash and cash equivalents were $12,645,000 compared to $5,514,000 as of December 31, 2019. During the first quarter of 2021, the Company raised $35.1 million net through various equity transactions.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, March 9, 2021, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Please note that registered participants will receive their dial in number upon registration and will dial directly into the call without delay. Those without internet access or unable to pre-register may dial in by calling: 1-844-854-4417 (domestic), 1-412-317-5739 (international) or 1-80-9212373 (Israel). All callers should dial in approximately 10 minutes prior to the scheduled start time and ask to be joined into the InspireMD call.

The conference call will also be available through a live webcast found here: https://services.choruscall.com/links/nspr210309.html.

Additionally, it will be broadcast live through the Company's website via the following link: https://www.inspiremd.com/en/investors/investor-relations/.

A webcast replay of the call will be available approximately one hour after the end of the call through June 9, 2021 at the above links. A telephonic replay of the call will be available through March 23, 2021 and may be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10152728.

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:

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CONSOLIDATED STATEMENTS OF OPERATIONS [1]

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

	Three months ended December 31,		Twelve months ended December 31,	
	2020	**2019**	**2020**	**2019**
Revenues	$ 158	$ 1,013	$ 2,485	$ 3,721
Cost of revenues	548	754	2,402	2,965
Gross Profit	(390)	259	83	756
Operating Expenses:				
Research and development	720	522	2,233	2,954
Selling and marketing	617	605	2,103	2,396
General and administrative	1,991	1,638	6,127	5,222
Total operating expenses	3,328	2,765	10,463	10,572
Loss from operations	(3,718)	(2,506)	(10,380)	(9,816)
Financial expenses (income)	131	27	160	200
Loss before tax expenses	(3,849)	(2,533)	(10,540)	(10,016)
Tax expenses	4	24	4	24
Net Loss	$ (3,853)	$ (2,557)	$ (10,544)	$ (10,040)
Net loss per share – basic and diluted	$ (0.10)	$ (0.57)	$ (0.46)	$ (4.80)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	38,009,045	4,449,020	22,686,590	2,089,964

CONSOLIDATED BALANCE SHEETS [2]

(U.S. dollars in thousands)

	December 31, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,645	$ 5,514
Accounts receivable:		
Trade, net	476	823
Other	146	150
Prepaid expenses	334	87
Inventory	1,415	1,236
Receivable for sale of Shares	323	-
Total current assets	15,339	7,810
Non-current assets:		
Property, plant and equipment, net	448	547
Operating lease right of use assets	1,265	937
Funds in respect of employee rights upon retirement	725	586
Total non-current assets	2,438	2,070
Total assets	$ 17,777	$ 9,880

	December 31, 2020	December 31, 2019
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 236	$ 646
Other	3,469	2,469
Total current liabilities	3,705	3,115
Long-term liabilities:		
Operating lease liabilities	999	653
Liability for employee rights upon retirement	910	729
Total long-term liabilities	1,909	1,382
Total liabilities	5,614	4,497
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2020 and 2019; 49,264,830 and 3,916,134 shares issued and outstanding at December 31, 2020 and 2019, respectively	5	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2020 and 2019; 17,303 shares issued and outstanding at December 31, 2020 and 2019, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2020 and 2019; 2,343 and 34,370 shares issued and outstanding at December 31, 2020 and 2019, respectively	-	-
Additional paid-in capital	180,334	163,015
Accumulated deficit	(168,176)	(157,632)
Total equity	12,163	5,383
Total liabilities and equity	$ 17,777	$ 9,880

(1) All financial information for the twelve months ended December 31, 2020 is derived from the Company's 2020 audited financial statements and all financial information for the twelve months ended December 31, 2019 is derived from the Company's 2019 audited financial statements, included in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2020 filed with the Securities and Exchange Commission. All financial information for the three months ended December 31, 2020 and 2019 is derived from the Company's unaudited, financial statements.

(2) All December 31, 2020 financial information is derived from the Company's 2020 audited financial statements and all December 31, 2019 financial information is derived from the Company's 2019 audited financial statements, as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2020 filed with the Securities and Exchange Commission.