INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/09/20 for the Period Ending 11/09/20

Telephone	(888) 776-6804
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Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
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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 9, 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 November 9, 2020, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the third quarter and nine months ended September 30, 2020. A copy of that 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 November 9, 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: November 9, 2020

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

Exhibit 99.1

InspireMD Announces Third Quarter 2020 Financial Results

Third quarter 2020 revenue returns to pre-COVID-19 levels

Management to host investor conference call today, November 9, 2020 at 8:30 a.m. ET

Tel Aviv, Israel— November 9, 2020 – InspireMD, Inc. (NYSE American: NSPR)("Inspire" or the "Company"), 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 third quarter ended September 30, 2020.

Third Quarter 2020 and recent highlights:

- The U.S. Food and Drug Administration (FDA) granted InspireMD approval of its Investigational Device Exemption (IDE) application to initiate a pivotal study of CGuard™ EPS. The company has begun to plan its pivotal study and has retained Dr. Christine Brennan, recognized expert in carotid artery disease, as a consultant during the planning process.

- InspireMD added Dr. Gary Roubin to its Board of Directors. One of the most recognized interventional cardiologists in the world, Dr. Roubin's pioneering work in carotid stenting and embolic protection devices brings knowledge and experience that will be invaluable. During his tenure as Chief of Interventional Cardiology at The University of Alabama at Birmingham and later as Department Chairman and Chief of Service of the Lenox Hill Hospital Cardiac and Vascular program in New York, he helped bring both programs to international standing in peripheral, neurovascular, and cardiac interventions. Dr. Roubin's vast clinical experience has enabled him to recognize and advance technical innovations that improve patient outcomes. He played a pivotal role in the success of Mednova Inc., which was acquired by Abbott Vascular, resulting in the introduction and marketing in the U.S. of the top selling carotid embolic protection system (NAV6) and stent system (XACT).

- The Company appointed Andrea Tommasoli as senior vice president of global sales and marketing. Andrea's leadership of our global sales and marketing effort is an investment in our customer and commercial focus and provides the essential leadership needed to elevate our growth and acceleration to standard of care with CGuard EPS. Andrea's experience in leading commercial teams, in particular, indirect channel partners, globally adds immediate value to our geographic expansion and higher performance in served markets.

- InspireMD appointed Patrick Jamnik as vice president of business development and strategic initiatives. Patrick will oversee the Company's business development activities and play a key role in advancing our short and long-term strategic goals.

Marvin Slosman, InspireMD's Chief Executive Officer commented, "Our third quarter financial results return us to our pre-COVID revenue levels, and while we remain cautiously optimistic about the fourth quarter, new restrictions instituted to combat the spread of COVID-19 may provide additional uncertainly in our markets. Nevertheless, our strategic pathway to growth for CGuard EPS is robust, rooted in broadening market share in endovascular carotid artery stent procedures in our served markets, while encouraging practitioners to make the shift from carotid endarterectomy to carotid stenting and launching our products in new countries. We view carotid artery disease as the next significant vascular condition to shift toward an endovascular standard of care, much the same way cerebral aneurysms, coronary artery disease, thoracic/abdominal aortic aneurysms, and peripheral artery disease already have. Therefore, making the case for the value of expanded application of carotid stenting to the vascular surgeon and INR (interventional neuroradiology) communities remains a top priority.

"Another of our key goals is the initiation of our pivotal study in the United States, and we are buoyed by the addition of Dr. Gary Roubin to our Board of Directors and Dr. Christine Brennan as a strategic advisor, both of whom will be instrumental in the development and implementation of the trial. While it is important to continue to grow revenues in the markets we currently serve, we believe our investments in the world's largest markets, including the United States, China and Japan, will pave a pathway to global adoption of CGuard EPS.

"Finally, to meet the needs of each physician specialty, our strategy includes developing a new advanced tool set of adjunctive delivery system options including periprocedural embolic protection, specifically targeted for the vascular surgical community, all intended to drive adoption of CGuard EPS. These advances represent additional significant revenue pathways for InspireMD, and we are excited to broaden our portfolio and build on our growth and market adoption," concluded Mr. Slosman.

Financial Results for the Third Quarter and Nine Months ended September 30, 2020

For the three months ended September 30, 2020, revenue increased by $41,000, or 4.4%, to $980,000, from $939,000 during the three months ended September 30, 2019. This increase was predominantly driven by a 69.0% increase in sales volume of MGuard EPS from $87,000 during the three months ended September 30, 2019, to $147,000 during the three months ended September 30, 2020. This increase was mainly due to the timing of shipments to one of the distributors for a tender recently won. This increase was offset, in part, by a 2.2% decrease in sales volume of CGuard Prime EPS from $852,000 during the three months ended September 30, 2019, to $833,000 during the three months ended September 30, 2020, largely driven by procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, only beginning to return to normal levels towards the end of the quarter as hospitals began to re-shift resources to non-COVID-19 patients.

For the three months ended September 30, 2020, gross profit increased by 132.8%, or $170,000, to $298,000, from $128,000 during the three months ended September 30, 2019. This increase in gross profit resulted from a $94,000 increase in revenues (as described above), less the related material and labor costs, a $56,000 decrease in write-offs, which were driven by a component supply issue during the three months ended September 30, 2019 and which did not reoccur during the three months ended September 30, 2020, and a decrease of $20,000 in miscellaneous expenses during the three months ended September 30, 2020. Gross margin increased to 30.4% during the three months ended September 30, 2020 from 13.6% during the three months ended September 30, 2019, driven by the factors mentioned above.

Total operating expenses for the quarter ended September 30, 2020 were $2,493,000, an increase of 17.3% compared to $2,125,000 for the same period in 2019. This increase was primarily due to increases of $127,000 in compensation expenses, $116,000 in development expenses associated with CGuard EPS, mainly related to the new advanced delivery system, $92,000 of Directors' and Officers' Liability Insurance expense due to recent economic changes in the insurance industry, $71,000 in regulatory expenses associated with compliance to new European Union standards, $60,000 mainly due to the timing of our annual shareholders meeting, and $79,000 of miscellaneous expense. These increases were partially offset by a decrease in travel expenses of $177,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19.

For the three months ended September 30, 2020, financial expenses decreased by 47.9%, or $35,000, to $38,000, from $73,000 during the three months ended September 30, 2019. The decrease in financial expenses primarily resulted from changes in exchange rates.

Net loss for the third quarter of 2020 totaled $2,233,000, or $0.06 per basic and diluted share, compared to a net loss of $2,070,000, or $1.26 per basic and diluted share, for the same period in 2019.

For the nine months ended September 30, 2020, revenue decreased by $381,000, or 14.1%, to $2,327,000, from $2,708,000 during the nine months ended September 30, 2019. This decrease was predominantly driven by a 11.5% decrease in sales volume of CGuard EPS from $2,344,000 during the nine months ended September 30, 2019, to $2,075,000 during the nine months ended September 30, 2020, mainly due to the postponement of procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, as hospitals shifted resources to patients affected by COVID-19. In addition, there was a 30.8% decrease in sales volume of MGuard Prime EPS from $364,000 during the nine months ended September 30, 2019, to $252,000 during the nine months ended September 30, 2020, mainly due to the impact of COVID-19, as mentioned above.

For the nine months ended September 30, 2020, gross profit decreased by 4.8%, or $24,000, to $473,000, compared to a $497,000 for the same period in 2019. This decrease in gross profit resulted from a $119,000 decrease in revenues (as mentioned above), less the related material and labor costs. This decrease was partially offset by a decrease of $69,000 in expenses related to upgrades made to our production facilities during the nine months ended September 30, 2019 that did not reoccur during the nine months ended September 30, 2020 and a decrease of $26,000 in miscellaneous expenses during the nine months ended September 30, 2020. Gross margin increased to 20.3% during the nine months ended September 30, 2020 from 18.4% during the nine months ended September 30, 2019, driven by the factors mentioned above.

Total operating expenses for the nine months ended September 30, 2020 were $7,135,000, a decrease of 8.6% compared to $7,807,000 for the same period in 2019. This decrease was primarily due to a decrease of $708,000 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, $354,000 due to settlement expenses that were paid to a former service provider pursuant to a settlement agreement during the nine months ended September 30, 2019, $316,000 in travel expenses in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19, $150,000 in quality assurance and regulatory expenses related to the development of various projects and $91,000 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 $400,000 due to the settlement agreement with the underwriter of our prior offerings paid during the nine months ended September 30, 2020, $280,000 in development expenses related to CGuard EPS new advanced delivery system, $130,000 in regulatory expenses required for new regulatory standards set by the European Union, and $115,000 in our Directors' and Officers' Liability Insurance expenses, partially due to recent changes in the insurance industry, and $22,000 of miscellaneous expenses.

Financial expenses for the nine months ended September 30, 2020 was $29,000 compared to $173,000 for the same period in 2019. The decrease in financial expenses primarily resulted from changes in exchange rates.

Net loss for the nine months ended September 30, 2020 totaled $6,691,000, or $0.38 per basic and diluted share, compared to a net loss of $7,483,000, or $5.79 per basic and diluted share, for the same period in 2019.

As of September 30, 2020, cash and cash equivalents were $10,882,000 compared to $5,514,000 as of December 31, 2019.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, November 9, 2020, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question and answer session. Participants are asked to pre-register for the call through the following link: https://dpregister.com/sreg/10149730/dc9d128e76.

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: 1-866-777-2509 (domestic) or 1-412-317-5413 (international). 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/nspr201109.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 February 9, 2021 at the above links. A telephonic replay of the call will be available through November 23, 2020 and may be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10149730.

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) the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy; (v) intense competition in the medical device industry from much larger, multinational companies, (vi) product liability claims, (vii) product malfunctions, (viii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (ix) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (x) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (xi) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xii) our reliance on single suppliers for certain product components, (xiii) 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 (xiv) 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,	
	2020	**2019**	**2020**	**2019**
Revenues	$ 980	$ 939	$ 2,327	$ 2,708
Cost of revenues	682	811	1,854	2,211
Gross Profit	298	128	473	497
Operating Expenses:				
Research and development	546	442	1,513	2,432
Selling and marketing	485	537	1,486	1,791
General and administrative	1,462	1,146	4,136	3,584
Total operating expenses	2,493	2,125	7,135	7,807
Loss from operations	(2,195)	(1,997)	(6,662)	(7,310)
Financial expenses	(38)	(73)	(29)	(173)
Net Loss	(2,233)	(2,070)	(6,691)	(7,483)
Net loss per share – basic and diluted	$ (0.06)	$ (1.26)	$ (0.38)	$ (5.79)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	34,884,285	1,648,302	17,460,184	1,293,321

CONSOLIDATED BALANCE SHEETS [2]

(U.S. dollars in thousands)

	September 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,882	$ 5,514
Accounts receivable:		
Trade, net	565	823
Other	332	150
Prepaid expenses	169	87
Inventory	1,388	1,236
Total current assets	13,336	7,810
Non-current assets:		
Property, plant and equipment, net	415	547
Operating lease right of use assets	1,215	937
Funds in respect of employee rights upon retirement	643	586
Total non-current assets	2,273	2,070
Total assets	$ 15,609	$ 9,880

	September 30, 2020	December 31, 2019
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 427	$ 646
Other	2,123	2,449
Contract liability	19	20
Total current liabilities	2,569	3,115
Long-term liabilities:		
Operating lease liabilities	917	653
Liability for employees' rights upon retirement	843	729
Total long-term liabilities	1,760	1,382
Total liabilities	4,329	4,497
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2020 and December 31, 2019; 36,059,128 and 3,916,134 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at September 30, 2020 and December 31, 2019; 17,303 shares issued and outstanding at September 30, 2020 and December 31, 2019.	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2020 and December 31, 2019; 2,343 and 34,370 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	-	-
Additional paid-in capital	175,600	163,015
Accumulated deficit	(164,323)	(157,632)
Total equity	11,280	5,383
Total liabilities and equity	$ 15,609	$ 9,880

(1) All 2020 financial information is derived from the Company's 2020 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; 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.

(2) All September 30, 2020 financial information is derived from the Company's 2020 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, 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, 2019 filed with the Securities and Exchange Commission.