INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/05/20 for the Period Ending 08/05/20

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 5, 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 August 5, 2020, InspireMD, Inc. issued a press release announcing its financial and operating results and recent highlights for the second quarter and six months ended June 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 August 5, 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: August 5, 2020

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Second Quarter 2020 Financial Results

In the second quarter the Company was granted approval to market its CGuard™ MicroNet stent in Brazil and completed an $11.5 million capital raise; reported outstanding results in studies treating patients with the CGuard™ MicroNET stent

Management to host investor conference call today, August 5, 2020 at 8:30am ET

Tel Aviv, Israel— August 5, 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 second quarter ended June 30, 2020.

Second Quarter 2020 and recent highlights:

- Received approval from the Brazilian registration authority (ANVISA), to market the CGuard™ MicroNet®- covered stent, effectively clearing it for sale and distribution in Brazil. SUPRI Artigos Médicos Hospitalares Ltda. will serve as distribution partner.

- Completed an $11.5 million follow-on underwritten public offering, which included $1.5 million from the exercise by the underwriter of its full over-allotment option for the offering.

- On June 25, 2020, the U.S. Food and Drug Administration (FDA) granted InspireMD conditional approval of its Investigational Device Exemption (IDE) application to initiate a pivotal study of CGuard™ EPS. We are in the process of addressing the Agency's remaining requests, specifically related to the stent-embolic protection device (EPD) compatibility performance testing that was previously conducted.

- Published 12-month PARDIGM trial results in the journal, *EuroIntervention*, a prestigious peer-reviewed publication covering the latest advancements in vascular intervention. The paper, titled "Routine MicroNET" details the results of 101 unselected consecutive real-life patients treated with the CGuard™ MicroNET covered stent for carotid stenosis and the 12-month prevention of post-procedural neurologic events. The results indicate that 12 months following carotid intervention the CGuard EPS MicroNET-covered stent delivers sustained protection against postprocedural neurologic events.

- Announced early results from the investigator-initiated SIBERIA randomized clinical trial of CGuard™ compared to Acculink™, evaluating 30-day silent brain infarcts in 100 patients who qualified for carotid revascularization with high risk for surgery. The results indicated that significantly fewer silent brain infarcts were associated with CGuard™ EPS versus Acculink™ at 30 days post-procedure.

“COVID-19 placed significant pressure on the operations of healthcare facilities worldwide, resulting in interruptions in elective procedure volumes, including critical carotid artery treatments. However, we are encouraged by the gradual resumption of these crucial procedures in a growing number of our key markets in Europe and other territories, and we look forward to this expansion taking hold in South America as well. We are also buoyed by the scientific validation we continue to receive in both peer-reviewed publications and opportunities to present at medical conferences where our CGuard MicroNet technology is being recognized as a valued advancement in the carotid stent category,” said Marvin Slosman, InspireMD’s Chief Executive Officer. “Our expansion strategy continues to progress, with our recent Brazilian approval for CGuard™ MicroNet® introducing us to the largest market for medical devices in Latin America and one of the top overall global markets for carotid artery disease. We believe this approval will set the stage for continued expansion into other countries in South America.

“We are in the process of addressing the agencies remaining requests, specifically related to the stent-embolic protection device (EPD) compatibility performance testing to gain full FDA approval of our Investigational Device Exemption (IDE) application to initiate a pivotal study of CGuard™ EPS. We have already completed the testing of additional stents according to the FDA’s specifications, and have employed alternative visualization modalities that, we believe, will ultimately allow us to gain full approval. Having an approved IDE is an extremely significant step towards enabling us to initiate a pivotal trial in the United States, clearly one of the world’s most important markets for carotid artery disease and other vascular treatments. We previously indicated that the FDA has concurred with our clinical study design and data requirements to support the market approval of the device. Accordingly, we believe that we are well positioned from a regulatory perspective in terms of our ability to initiate a trial.

“In addition, we believe the completion of our $11.5M financing will help ensure we are capable of advancing our commercial expansion and research and development activities as a pillar of our growth objectives. Although the pandemic has put a spotlight on the supply chain infrastructure challenges many in our field are facing, we stand at the ready to fulfill the needs of physicians and their patients for these serious and lifesaving procedures,” Mr. Slosman concluded.

Financial Results for the Second Quarter and Six Months ended June 30, 2020

For the three months ended June 30, 2020, revenue decreased by $1,041,000, or 76.9%, to $313,000, from $1,354,000 during the three months ended June 30, 2019. This decrease was predominantly driven by a 75.7% decrease in sales volume of CGuard EPS from $1,116,000 during the three months ended June 30, 2019, to $271,000 during the three months ended June 30, 2020. This decrease was mainly due to the fact that procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, were mostly postponed as hospitals shifted resources to patients affected by COVID-19. The decrease was also due to the large shipments of CGuard EPS that we made during the three months ended June 30, 2019 of backlog that accumulated in the three months ended March 31, 2019 that we were unable to ship previously due to our former third-party sterilizer equipment failures. Those large shipments did not recur during the three months ended June 30, 2020. In addition, there was an 82.4% decrease in sales volume of MGuard Prime EPS, from $238,000 during the three months ended June 30, 2019, to $42,000 during the three months ended June 30, 2020, mainly due to similar reasons as mentioned above.

The company recorded a gross loss for the quarter ended June 30, 2020 of $120,000, compared to a gross profit of $442,000 for the same period in 2019. This decrease in gross profit resulted primarily from a $448,000 decrease in revenues (as described above), less the related material and labor costs, and a decrease following a receipt of $135,000 compensation received in the quarter ended June 30, 2019 from our former third-party sterilizer for the delays related to the product sterilization interruption during the three months ended March 31, 2019, which did not reoccur in the three months ended June 30, 2020, offset by a $21,000 decrease in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased to (38.3)% during the three months ended June 30, 2020 from 32.6% during the three months ended June 30, 2019, driven by the reasons mentioned above.

Total operating expenses for the quarter ended June 30, 2020 were $2,326,000, a decrease of 11.4% compared to $2,625,000 for the same period in 2019. This decrease was primarily due to a reduction of $382,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, $235,000 in compensation related to temporary salary reductions due to the immediate impact of COVID-19 on cash flow, and $82,000 of miscellaneous expense reductions offset by an increase of $400,000 due to a settlement agreement with the underwriter of our prior offerings.

Financial expenses for the quarter ended June 30, 2020 were $34,000 compared to $23,000 for the same period in 2019. Net loss for the second quarter of 2020 totaled $2,480,000, or $0.20 per basic and diluted share, compared to a net loss of $2,206,000, or $1.59 per basic and diluted share, for the same period in 2019.

For the six months ended June 30, 2020, revenue decreased by $422,000, or 23.9%, to $1,347,000, from $1,769,000 during the six months ended June 30, 2019. This decrease was predominantly driven by a 16.8% decrease in sales volume of CGuard EPS from $1,492,000 during the six months ended June 30, 2019, to $1,242,000 during the six months ended June 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 62.1% decrease in sales volume of MGuard Prime EPS from $277,000 during the six months ended June 30, 2019, to $105,000 during the six months ended June 30, 2020, mainly due to the impact of COVID-19, as mentioned above.

For the six months ended June 30, 2020, gross profit decreased by $194,000, or 52.6%, to $175,000 from $369,000 for the same period in 2019. This decrease in gross profit resulted primarily from a $225,000 decrease in revenues (as mentioned above), less the related material and labor costs and a $61,000 increase in write-offs driven by a non-recurring component supply issue. This decrease was partially offset by a decrease of $69,000 of expenses related to upgrades made to our production facilities during the six months ended June 30, 2019, which did not reoccur during the six months ended in June 30, 2020 and a decrease of $23,000 in miscellaneous expenses during the six months ended June 30, 2020. Gross margin (gross profits as a percentage of revenue) decreased to 13.0% during the six months ended June 30, 2020 from 20.9% during the six months ended June 30, 2019, driven by the reasons mentioned above.

Total operating expenses for the six months ended June 30, 2020 were $4,642,000, a decrease of 18.3% compared to $5,682,000 for the same period in 2019. This decrease was primarily due to a reduction of $710,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, $354,000 due to settlement expenses that were paid to a former service provider pursuant to a settlement agreement during the six months ended June 30, 2019, $235,000 in compensation expenses, primarily related to temporary salary reductions due to the immediate impact of COVID-19 on cash flow, and $141,000 of miscellaneous expense reductions offset by an increase of $400,000 due to a settlement agreement with the underwriter of our prior offerings.

Financial income for the six months ended June 30, 2020 was $9,000 compared to $100,000 of financial expenses for the same period in 2019. Net loss for the six months ended June 30, 2020 totaled $4,458,000, or $0.52 per basic and diluted share, compared to a net loss of $5,413,000, or $4.86 per basic and diluted share, for the same period in 2019.

As of June 30, 2020, cash and cash equivalents were $13,861,000 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, 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: http://dpregister.com/10146840. 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 for the InspireMD call. The conference call will also be available through a live webcast, which can be accessed through the following link: https://services.choruscall.com/links/nspr200805.html .

The link is also available through the company's website at 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 November 4, 2020 at the above links. A telephonic replay of the call will be available through August 19, 2020 and may be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10146840.

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 June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues	$ 313	$ 1,354	$ 1,347	$ 1,769
Cost of revenues	433	912	1,172	1,400
Gross Profit	(120)	442	175	369
Operating Expenses:				
Research and development	444	865	967	1,990
Selling and marketing	377	620	1,001	1,254
General and administrative	1,505	1,140	2,674	2,438
Total operating expenses	2,326	2,625	4,642	5,682
Loss from operations	(2,446)	(2,183)	(4,467)	(5,313)
Financial income (expenses)	(34)	(23)	9	(100)
Net Loss	$ (2,480)	$ (2,206)	$ (4,458)	$ (5,413)
Net loss per share – basic and diluted	$ (0.20)	$ (1.59)	$ (0.52)	$ (4.86)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	12,681,757	1,383,238	8,652,396	1,112,888

CONSOLIDATED BALANCE SHEETS [2]

(U.S. dollars in thousands)

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,861	$ 5,514
Accounts receivable:		
Trade, net	416	823
Other	152	150
Prepaid expenses	40	87
Inventory	1,402	1,236
Total current assets	15,871	7,810
Non-current assets:		
Property, plant and equipment, net	459	547
Operating lease right of use assets	790	937
Funds in respect of employee rights upon retirement	620	586
Total non-current assets	1,869	2,070
Total assets	$ 17,740	$ 9,880

	June 30, 2020	December 31, 2019
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 458	$ 646
Other	2,774	2,449
Contract liability	17	20
Total current liabilities	3,249	3,115
Long-term liabilities:		
Operating lease liabilities	476	653
Liability for employees rights upon retirement	801	729
Total long-term liabilities	1,277	1,382
Total liabilities	4,526	4,497
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2020 and December 31, 2019; 33,358,994 and 3,916,134 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	3	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at June 30, 2020 and December 31, 2019; 17,303 shares issued and outstanding at June 30, 2020 and December 31, 2019.	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2020 and December 31, 2019; 2,343 and 34,370 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	-	-
Additional paid-in capital	175,301	163,015
Accumulated deficit	(162,090)	(157,632)
Total equity	13,214	5,383
Total liabilities and equity	$ 17,740	$ 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 June 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.