INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/10/21 for the Period Ending 08/10/21

Telephone	(888) 776-6804
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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, DC 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 10, 2021**

InspireMD, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-35731	**26-2123838**
(Commission File Number)	(IRS Employer Identification No.)
4 Menorat Hamaor St. **Tel Aviv, Israel** (Address of Principal Executive Offices)	**6744832** (Zip Code)

(888) 776-6804
(Registrant's Telephone Number, Including Area Code)

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 each exchange on which registered
Common Stock, par value $0.0001 per share	NSPR	The Nasdaq Capital Market LLC
Series B Warrants, exercisable for one share of Common Stock	NSPRZ	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 10, 2021, InspireMD, Inc. (the "Company") issued a press release announcing the Company's financial and operating results and recent highlights for the quarter and six months ended June 30, 2021. 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 10, 2021 (furnished herewith pursuant to Item 2.02)

SIGNATURES

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

INSPIREMD, INC.

Date: August 10, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Announces Strong Second Quarter 2021 Financial Results

Revenue rebound, strong procedural recovery

Management to host investor conference call today, August 10, 2021, at 8:30am ET

Tel Aviv, Israel— August 10, 2021 – InspireMD, Inc. (Nasdaq: 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 as of and for the second quarter ended June 30, 2021.

Second Quarter 2021 and recent highlights

- Revenue of $1,038,000 an increase of 231.6% compared to the same period in 2020
- Initiated U.S. enrollment in the "C-Guardians" IDE clinical trial. Eleven (11) patients treated and enrolled in the first 2 weeks at Ballad Health Systems (Kingsport, TN) by Principal Investigator Dr. Christopher Metzger
- Transferred the listing of the company's common stock and warrants to the Nasdaq Capital Market for access to broader and more fundamental investor base
- Appointed seasoned marketing executive Kathryn Arnold to the company's Board of Directors
- Appointed acclaimed interventional cardiologist Kenneth Rosenfield, M.D. as Chair of the company's newly formed Medical Advisory Board (MAB)

Marvin Slosman, InspireMD CEO commented, "We are pleased with our second quarter results that showed strong procedural recovery and market demand of CGuard EPS. Our ultimate goal is to change the standard of care in the treatment of carotid artery disease away from surgical endarterectomy to the minimally invasive use of CGuard EPS Carotid Stent System.

“Our commercial efforts in driving global expansion, through expanding use of CGuard EPS in our 33 served markets, combined with growing our footprint into the U.S. and Asia, has created awareness of the clinical advantages of CGuard EPS. Initiating our U.S Food and Drug Administration (FDA) C-Guardians IDE trial this quarter marked a milestone for the company in establishing awareness and experience with CGuard EPS among U.S. physicians treating carotid artery disease. To date, Interventional Cardiologist Chris Metzger, M.D., our principal investigator, and system chair of clinical research at Ballad Health System (Kingsport, TN) has already enrolled 11 patients in the trial in the first two weeks.

“During the second quarter, we successfully transferred the listing of our shares and warrants to the Nasdaq Capital Market, which we believe will help broaden our shareholder base and increase interest by institutional and fundamental investors to create additional long-term shareholder value.

“Additionally, we appointed seasoned MedTech marketing executive Kathryn Arnold to our Board of Directors. Ms. Arnold brings more than two decades of strategy and commercialization experience in the medical device industry. Her knowledge and leadership will be invaluable in helping the company shape our strategic planning and expanding our commercial and business development.

“We also formed a Medical Advisory Board composed of global Key Opinion Leaders (KOL’s) who treat carotid artery disease to provide the company guidance and direction on clinical strategy, product pipeline, and technology advancements. To lead this Board, we have appointed acclaimed interventional cardiologist, Kenneth Rosenfield, M.D. as Chair. Dr. Rosenfield is the Section Head for Vascular Medicine and Intervention and chairs the Acute Myocardial Infarction (STEMI) Committee for the Cardiac Catheterization Laboratory at Massachusetts General Hospital.

“We continue to advance our global growth plans in our Asian markets. In China we are progressing with our distributor partners to initiate our regulatory trial toward market approval, and we continue our commercial expansion efforts into the markets of Japan, Taiwan and South Korea.

“We are making significant progress advancing our product pipeline with new innovation and offerings. CGuard Prime, our next generation trans-femoral delivery system is scheduled for regulatory submission in early 2022 with commercial launch in the second half 2022. Additionally, we are making great progress on a new embolic protection device (EPD) and delivery system, expanding our toolset and offerings to the vascular surgical community,” concluded Mr. Slosman.

Financial Results for the Second Quarter ended June 30, 2021

For the three months ended June 30, 2021, revenue increased by $725,000, or 231.6%, to $1,038,000, from $313,000 during the three months ended June 30, 2020. This increase was predominantly driven by a 276.0% increase in sales volume of CGuard EPS from $271,000 during the three months ended June 30, 2020, to $1,019,000 during the three months ended June 30, 2021. This sales increase was mainly due to the fact that in the three months ended June 30, 2021, procedures with CGuard EPS, which are generally scheduled for non-emergency cases, began to return to normal levels as compared to the three months ended June 30, 2020, when procedures with CGuard EPS were mostly postponed as hospitals shifted resources to patients affected by COVID-19. This increase in sales of CGuard EPS was partially offset by a decrease of 54.8% in sales of MGuard Prime EPS from $42,000 during the three months ended June 30, 2020, to $19,000 during the three months ended June 30, 2021, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients.

For the three months ended June 30, 2021, gross profit (revenue less cost of revenues) increased by $382,000, to $262,000, from a gross loss of $120,000 during the three months ended June 30, 2020. This increase in gross profit resulted from a $237,000 increase in revenues less the related material and labor costs (as described above), a decrease in write-offs of $144,000, which were driven mainly by changes related to components supply issues and a decrease of $1,000 in miscellaneous expenses during the three months ended June 30, 2021. Gross margin (gross profits as a percentage of revenue) increased to 25.2% during the three months ended June 30, 2021 from (38.3)% during the three months ended June 30, 2020, driven mainly by the decrease in write-offs mentioned above.

Total operating expenses for the quarter ended June 30, 2021 were $3,702,000, an increase of 59.2% compared to $2,326,000 for the same period in 2020. This increase was primarily due to increases of $705,000 in salary expenses and related accrual expenses mainly driven by temporary salary reductions during the three months ended June 30, 2020, that were implemented in response to the COVID-19 effect on revenues as well as additional resources mainly in our product development and sales infrastructure, $437,000 in expenses related to the commencement of the C-Guardians FDA study, $315,000 in share-based compensation-related expenses due to the expense recognition of grants made after June 30, 2020, $297,000 in development expenses associated with CGuard EPS accessory solutions, and $108,000 of Directors' and Officers' Liability Insurance expense due to increased premiums caused by recent trends in the overall insurance industry. This increase was partially offset by a decrease of $400,000 relating to a settlement agreement with an underwriter of our prior offerings which occurred in the three months ended June 30, 2020 and a reduction of $86,000 of miscellaneous expense.

For the three months ended June 30, 2021, financial expenses were $67,000, compared to $34,000 during the three months ended June 30, 2020. Net loss for the second quarter of 2021 totaled $3,507,000, or $0.46 per basic and diluted share, compared to a net loss of $2,480,000, or $2.93 per basic and diluted share, for the same period in 2020. The average amount of shares outstanding used for the earnings per share calculation were 7,704,707 in Q2 2021 and 845,451 in Q2 2020, both adjusted to reflect the 1:15 reverse split effected by us on April 26, 2021.

Financial Results for the Six Months ended June 30, 2021

For the six months ended June 30, 2021, revenue increased by $697,000, or 51.7%, to $2,044,000, from $1,347,000 during the six months ended June 30, 2020. This increase was predominantly driven by a 60.0% increase in sales volume of CGuard EPS from $1,242,000 during the six months ended June 30, 2020, to $1,987,000 during the six months ended June 30, 2021. This sales increase was mainly due to the fact that in the six months ended June 30, 2021, procedures with CGuard EPS, which are generally scheduled for non-emergency procedures began to return to normal levels as compared to the six months ended June 30, 2020, when procedures with CGuard EPS were postponed as hospitals shifted resources to patients affected by COVID-19 beginning in February 2020. This increase in sales of CGuard EPS was partially offset by a decrease of 45.7% in sales of MGuard Prime EPS from $105,000 during the six months ended June 30, 2020, to $57,000 during the six months ended June 30, 2021, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients.

For the six months ended June 30, 2021, gross profit (revenue less cost of revenues) increased by $193,000, to $368,000, compared to a $175,000 for the same period in 2020. This increase in gross profit resulted from a $257,000 increase in revenues less the related material and labor costs (as described above). This increase was partially offset by an increase of $64,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 18.0% during the six months ended June 30, 2021 from 13.0% during the six months ended June 30, 2020, driven by the reasons mentioned above.

Total operating expenses for the six months ended June 30, 2021 were $7,122,000, an increase of 53.4% compared to $4,642,000 for the same period in 2020. This increase was primarily due to increases of $1,136,000 in salary expenses and related accrual expenses mainly driven by temporary salary reductions during the six months ended June 30, 2020, that were implemented in response to the COVID-19 effect on revenues as well as additional resources mainly in our product development and sales infrastructure, $563,000 in share-based compensation-related expenses due to the expense recognition of grants made after June 30, 2020, $521,000 in development expenses associated with CGuard EPS accessory solutions, $483,000 in expenses related to the commencement of the C-Guardians FDA study, $226,000 of Directors' and Officers' Liability Insurance expense due to increased premiums caused by recent trends in the overall insurance industry. This increase was partially offset by a decrease of $400,000 relating to a settlement agreement with an underwriter of our prior offerings which occurred in the three months ended June 30, 2020 and a reduction of $49,000 of miscellaneous expense.

For the six months ended June 30, 2021, financial income was $4,000, compared to $9,000 during the six months ended June 30, 2020. Net loss for the six months ended June 2021 totaled $6,750,000, or $0.98 per basic and diluted share, compared to a net loss of $4,458,000, or $7.73 per basic and diluted share, for the same period in 2020. The average amount of shares outstanding used for the earnings per share calculation were 6,918,090 for the six months ended June 2021 and 576,827 for the six months ended June 2020, both adjusted to reflect the 1:15 reverse split effected by us on April 26, 2021.

As of June 30, 2021, cash and cash equivalents were $41.4 million compared to $12.6 million as of December 31, 2020.

Conference Call and Webcast Details

Management will host a conference call at 8:30AM ET today, August 10, 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), or 1-412-317-5739 (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/mediaframe/webcast.html?webcastid=a2t5MXpf.

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 November 10, 2021, at the above links. A telephonic replay of the call will be available through August 24, 2021, and may be accessed by calling 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and using access code 10158721.

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 Nasdaq under the ticker symbol NSPR, and certain warrants are quoted on the Nasdaq under the symbol NSPRZ.

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", "scheduled" or similar words. For example, the company is using forward-looking statements when it discusses its future plans with respect to its CGuard EPS stent, its belief that its efforts has created potential future momentum for its CGuard EPS stent, the potential benefits of its listing on Nasdaq, the intends regulatory submission and commercial launch of its CGuard Prime and the belief that it has sufficient cash reserves and liquidity to fund its planned operations. 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.

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INSPIREMD

CONSOLIDATED STATEMENTS OF OPERATIONS [1]

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

	Three months ended June 30,		Six months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues	$ 1,038	$ 313	$ 2,044	$ 1,347
Cost of revenues	776	433	1,676	1,172
Gross Profit	262	(120)	368	175
Operating Expenses:				
Research and development	1,290	444	2,129	967
Selling and marketing	636	377	1,344	1,001
General and administrative	1,776	1,505	3,649	2,674
Total operating expenses	3,702	2,326	7,122	4,642
Loss from operations	(3,440)	(2,446)	(6,754)	(4,467)
Financial income (expenses)	(67)	(34)	4	9
Net Loss	$ (3,507)	$ (2,480)	$ (6,750)	$ (4,458)
Net loss per share – basic and diluted	$ (0.46)	$ (2.93)	$ (0.98)	$ (7.73)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,704,707	845,451	6,918,090	576,827

CONSOLIDATED BALANCE SHEETS [2]
(U.S. dollars in thousands)

	June 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 41,419	$ 12,645
Accounts receivable:		
Trade, net	962	476
Other	136	146
Prepaid expenses	63	334
Inventory	1,342	1,415
Receivable for sale of Shares	-	323
Total current assets	43,922	15,339
Non-current assets:		
Property, plant and equipment, net	443	448
Operating lease right of use assets	1,251	1,265
Funds in respect of employee rights upon retirement	759	725
Total non-current assets	2,453	2,438
Total assets	$ 46,375	$ 17,777

	June 30, 2021	December 31, 2020
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 739	$ 236
Other	2,940	3,469
Total current liabilities	3,679	3,705
Long-term liabilities:		
Operating lease liabilities	904	999
Liability for employees rights upon retirement	962	910
Total long-term liabilities	1,866	1,909
Total liabilities	5,545	5,614
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2021 and December 31, 2020; 7,914,339 and 3,284,322 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1	*
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at June 30, 2021 and December 31, 2020; 0 and 17,303 shares issued and outstanding at June 30, 2021 and December 31, 2020	-	*
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2021 and December 31, 2020; 1,718 and 2,343 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	*	*
Additional paid-in capital	215,755	180,339
Accumulated deficit	(174,926)	(168,176)
Total equity	40,830	12,163
Total liabilities and equity	$ 46,375	$ 17,777

(1) All 2021 financial information is derived from the Company's 2021 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; 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.

(2) All June 30, 2021 financial information is derived from the Company's 2021 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, 2020 financial information is derived from the Company's 2020 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.