INSPIREMD, INC.

FORM 8-K
(Current report filing)

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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): **November 9, 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 November 9, 2021, InspireMD, Inc. (the "Company") issued a press release announcing the Company's financial and operating results and recent highlights for the quarter and nine months ended September 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 November 9, 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: November 9, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

InspireMD Reports Third Quarter 2021 Financial Results
and Provides Corporate Update
-CGuard™ sales generated 24% YoY revenue growth-

-CGuard™ EPS received a positive opinion from the French National Authority for Health (HAS) regarding reimbursement in France-
- $37.1 million in cash, cash equivalents and short-term bank deposits as of September 30, 2021, provides runway into first half of 2023-
-Management to host Call & Webcast Today, November 9, 2021, at 8:30am ET-

Tel Aviv, Israel— November 9, 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 third quarter ended September 30, 2021.

"This quarter has been extremely productive, and I am pleased to report our progress as we build momentum into the end of the year. On the commercial front, the successful expansion of CGuard™ into France represents further progress of our reimbursement initiative as well as growing global demand from physicians for our product when treating CAD," explained Marvin Slosman, CEO of InspireMD. "Our performance this quarter has been particularly gratifying, both year over year and sequentially, as we continue to deliver growth in the use of CGuard EPS to prevent strokes and manage CAD."

Third Quarter 2021 and Recent Highlights

- Total CGuard EPS revenue for the third quarter of $1,031,000, an increase of 23.8% compared to the same period in 2020, showed growing procedural share and return to normalized procedure levels in most geographies as the COVID pandemic has waned. For the nine months ended September 30, 2021, CGuard revenue increased by 45.4% compared to the same period in 2020.
- In November 2021, the Company announced a publications' acceptance in the Journals of the American College of Cardiology (JACC), *Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization*. This publication demonstrates the latest randomized trial of CGuard compared to first generation stents and supports the large and growing body of clinical and scientific evidence showing the superiority of the CGuard device in preventing brain embolization.
- In October 2021, the Company announced that its CGuard EPS stent system had received a positive opinion from the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDIMTS) of the French National Authority for Health (HAS) regarding reimbursement in France. The CGuard EPS was also added to the list of reimbursed medical products (LPPR) at the end of October 2021 and will now receive this preferred status. CGuard carotid stent, is commercially established in 33 markets to date, adding France to our growing global expansion.

- In July 2021, InspireMD announced the first patients enrolled in its U.S. Registration C-Guardians IDE clinical trial at the Ballad Health Systems (Kingsport, TN) under the guidance of Principal Investigator Dr. Christopher Metzger.

    - To date enrollment continues to increase at all sites as familiarity of CGuard is employed across each hospital system. A total of 315 participants are expected in the Multicenter, Single-Arm, Pivotal Study to Evaluate the Safety and Efficacy of the CGuard Carotid Stent System
    - Currently 5 trial sites have been opened and are actively enrolling:
      Avera Heart Hospital; Ballad CVA Heart Institute; Turkey Creek Medical Center; Ascension Seton of the Seton Heart Institute and Pinnacle Health Cardiovascular Institute

"We are encouraged by our commercial momentum as measured by demand for CGuard EPS in our served markets, particularly in Europe. Our trial enrollment levels for the U.S. C-Guardians trial, which began this quarter, is on track and we expect the fourth quarter of 2021 to yield additional site approvals and patient enrollments. Furthermore, we are pleased by ongoing expansion discussions in Asia with partnership plans for Japan and Taiwan. We are building our organizational resources and talent to drive CGuard EPS to be the leading Carotid stent system in the market. Lastly, I want to reiterate that investment in our pipeline of innovative solutions continues as we advance toward regulatory approvals of two new delivery systems, capable of expanding CGuard's market penetration and conversion of open surgery to endovascular procedures," Mr. Slosman commented.

Financial Results for the Third Quarter ended September 30, 2021

For the three months ended September 30, 2021, revenue increased by $91,000, or 9.3%, to $1,071,000, from $980,000 during the three months ended September 30, 2020. This increase was predominantly driven by a 23.8% increase in sales volume of CGuard EPS from $833,000 during the three months ended September 30, 2020, to $1,031,000 during the three months ended September 30, 2021. This sales increase was mainly due to the fact that in the three months ended September 30, 2021, procedures with CGuard EPS, which are generally scheduled for non-emergency cases, continued to return to normalized levels in additional territories as compared to the three months ended September 30, 2020, when procedures with CGuard EPS were still somewhat postponed as hospitals shifted resources to patients affected by COVID-19. In addition, the sales increased due to sales related to stents used in our FDA clinical trial which occurred in the three months ended September 30, 2021, but not in the corresponding period in 2020. The increase in sales of CGuard EPS was partially offset by a decrease of 72.8% in sales of MGuard Prime EPS from $147,000 during the three months ended September 30, 2020, to $40,000 during the three months ended September 30, 2021, 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 three months ended September 30, 2021, gross profit (revenue less cost of revenues) decreased by $206,000, to $92,000, from $298,000 during the three months ended September 30, 2020. This decrease in gross profit resulted from a $136,000 increase in material and labor costs (mainly due to an increase in sales volume as well as a short-term increase in production cost per unit), an increase in write-offs of $66,000, due to components supply issues, a $57,000 increase in new employee training costs, and an increase of $38,000 in miscellaneous expenses during the three months ended September 30, 2021. This decrease was partially offset by a $91,000 increase in revenues mainly due to an increase in sales volume (as mentioned above). Gross margin (gross profits as a percentage of revenue) decreased to 8.6% during the three months ended September 30, 2021 from 30.4% during the three months ended September 30, 2020, driven by the reasons mentioned above.

Total operating expenses for the quarter ended September 30, 2021 were $4,123,000, an increase of 65.4% compared to $2,493,000 for the same period in 2020. This increase was primarily due to increases of $708,000 in expenses related to the commencement of the C-Guardians FDA study, $400,000 in salary expenses and related accrual expenses due to additional resources mainly in our product development and sales infrastructure, $151,000 in development expenses associated with CGuard EPS new delivery system and accessory solutions, $147,000 in share-based compensation-related expenses due to the recognition of grants made since August 31, 2020, $102,000 in sales and marketing expenses associated with expansion of existing and new markets, $81,000 of Directors' and Officers' Liability Insurance expense due to increased premiums caused by recent trends in the overall insurance industry and $41,000 of miscellaneous expense.

For the three months ended September 30, 2021, financial expenses increased by 5.3%, or $2,000, to $40,000, from $38,000 during the three months ended September 30, 2020. Net loss for the third quarter of 2021 totaled $4,071,000, or $0.53 per basic and diluted share, compared to a net loss of $2,233,000, or $0.96 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 7,739,463 in the third quarter of 2021 and 2,325,619 in the third quarter of 2020, both adjusted to reflect the 1:15 reverse split effected by us on April 26, 2021.

As of September 30, 2021, cash, cash equivalents and short-term bank deposits were $37.1 million compared to $12.6 million as of December 31, 2020.

Conference Call and Webcast Details

Tuesday, November 9, 2021 at 8:30 a.m. ET

Domestic:	877-407-4018
International:	201-689-8471
Conference ID:	13724012
Webcast:	Webcast Link

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 that its expansion of CGuard into France represents further progress of its reimbursement initiative as well as growing global demand from physicians for its product when treating CAD, that the CGuard EPS will now receive this preferred status as a result of it being added to the list of reimbursed medical products (LPPR) at the end of October 2021, that its U.S. trial enrollment is on track, that it expects the fourth quarter of 2021 to yield additional site approvals and patient enrollments and that it continues to investment in its pipeline of innovative solutions continues as it advances toward regulatory approvals of two new delivery systems, capable of expanding CGuard's market penetration and conversion of open surgery to endovascular procedures. 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 September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenues	$ 1,071	$ 980	$ 3,115	$ 2,327
Cost of revenues	979	682	2,655	1,854
Gross Profit	92	298	460	473
Operating Expenses:				
Research and development	1,495	546	3,624	1,513
Selling and marketing	802	485	2,146	1,486
General and administrative	1,826	1,462	5,475	4,136
Total operating expenses	4,123	2,493	11,245	7,135
Loss from operations	(4,031)	(2,195)	(10,785)	(6,662)
Financial expenses, net	(40)	(38)	(36)	(29)
Net Loss	(4,071)	(2,233)	(10,821)	(6,691)
Net loss per share – basic and diluted	$ (0.53)	$ (0.96)	$ (1.50)	$ (5.75)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	7,739,463	2,325,619	7,194,379	1,164,012

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

	September 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 13,059	$ 12,645
Short-term bank deposits	24,012	-
Accounts receivable:		
Trade, net	971	476
Other	141	146
Prepaid expenses	773	334
Inventory	1,135	1,415
Receivable for sale of Shares	-	323
Total current assets	40,091	15,339
Non-current assets:		
Property, plant and equipment, net	563	448
Operating lease right of use assets	1,166	1,265
Funds in respect of employee rights upon retirement	786	725
Total non-current assets	2,515	2,438
Total assets	$ 42,606	$ 17,777

	September 30, 2021	December 31, 2020
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 556	$ 236
Other	3,164	3,469
Total current liabilities	3,720	3,705
Long-term liabilities:		
Operating lease liabilities	831	999
Liability for employees' rights upon retirement	992	910
Total long-term liabilities	1,823	1,909
Total liabilities	5,543	5,614
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2021 and December 31, 2020; 7,900,311 and 3,284,322 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	*
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at September 30, 2021 and December 31, 2020; 0 and 17,303 shares issued and outstanding at September 30, 2021 and December 31, 2020	-	*
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2021 and December 31, 2020; 1,718 and 2,343 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	*	*
Additional paid-in capital	216,059	180,339
Accumulated deficit	(178,997)	(168,176)
Total equity	37,063	12,163
Total liabilities and equity	$ 42,606	$ 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 September 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.