INSPIREMD, INC.

FORM 10-Q
(Quarterly Report)

Filed 08/08/22 for the Period Ending 06/30/22

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 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended: June 30, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-35731

InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4 Menorat Hamaor St.
Tel Aviv, Israel 6744832
(Address of principal executive offices)
(Zip Code)

(888) 776-6204
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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	Nasdaq Capital Market

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of August 8, 2022: 8,323,200

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CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED JUNE 30, 2022

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INSPIREMD, INC.
CONDENSED **CONSOLIDATED BALANCE SHEETS**
(Unaudited)
(U.S. dollars in thousands)

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 6,393	$ 12,004
Short-term bank deposits	20,078	22,036
Accounts receivable:		
Trade, net	1,183	1,224
Other	171	165
Prepaid expenses	221	522
Inventory	1,454	1,143
TOTAL CURRENT ASSETS	29,500	37,094
NON-CURRENT ASSETS:		
Property, plant and equipment, net	700	632
Operating lease right of use assets	1,717	1,081
Fund in respect of employee rights upon retirement	849	905
TOTAL NON-CURRENT ASSETS	3,266	2,618
TOTAL ASSETS	$ 32,766	$ 39,712

INSPIREMD, INC.
CONDENSED **CONSOLIDATED BALANCE SHEETS**
(Unaudited)
(U.S. dollars in thousands other than share and per share data)

	June 30, 2022	December 31, 2021
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	1,127	893
Other	3,585	3,454
TOTAL CURRENT LIABILITIES	4,712	4,347
LONG-TERM LIABILITIES-		
Operating lease liabilities	1,350	781
Liability for employees' rights upon retirement	962	1,052
TOTAL LONG-TERM LIABILITIES	2,312	1,833
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	7,024	6,180
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2022 and December 31, 2021; 8,323,200 and 8,296,256 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2022 and December 31, 2021; 1,718 shares issued and outstanding at June 30, 2022 and December 31 2021, respectively	*	*
Additional paid-in capital	217,952	216,625
Accumulated deficit	(192,211)	(183,094)
Total equity	25,742	33,532
Total liabilities and equity	$ 32,766	$ 39,712

*Represents an amount less than $1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.
(Unaudited)
CONDENSED **CONSOLIDATED STATEMENTS OF OPERATIONS**
(U.S. dollars in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2022	**2021**	**2022**	**2021**
REVENUES	$ 1,531	$ 1,038	$ 2,714	$ 2,044
COST OF REVENUES	1,100	776	2,161	1,676
GROSS PROFIT	431	262	553	368
OPERATING EXPENSES:				
Research and development	2,056	1,290	3,736	2,129
Selling and marketing	986	636	1,732	1,344
General and administrative	2,070	1,776	4,252	3,649
Total operating expenses	5,112	3,702	9,720	7,122
LOSS FROM OPERATIONS	(4,681)	(3,440)	(9,167)	(6,754)
FINANCIAL INCOME (EXPENSES), net:	45	(67)	50	4
LOSS BEFORE TAX EXPENSES	(4,636)	(3,507)	(9,117)	(6,750)
NET LOSS	$ (4,636)	$ (3,507)	$ (9,117)	$ (6,750)
NET LOSS PER SHARE - basic and diluted	$ (0.59)	$ (0.46)	$ (1.17)	$ (0.98)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	7,807,795	7,704,707	7,806,030	6,918,090

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.

CONDENSED **CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Unaudited)

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

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2021	**3,284,322**	*	**17,303**	*	**2,343**	*	**$ 180,339**	**$ (168,176)**	**$12,163**
Net loss								**(6,750)**	**(6,750)**
Issuance of common stock, including at the market offering net of $2,024 issuance costs	**3,133,775**	**1**	**-**	**-**	**-**	**-**	**25,241**	**-**	**25,242**
Exercise of Warrants F	**1,093,536**	*	**-**	**-**	**-**	**-**	**8,120**	**-**	**8,120**
Exercise of Warrants G	**131,876**	*	**-**	**-**	**-**	**-**	**1,349**	**-**	**1,349**
Conversion of Series B Convertible Preferred Stock to common stock	**207,528**	*	**(17,303)**	*	**-**	**-**	*	**-**	*
Conversion of Series C Convertible Preferred Stock to common stock	**831**	*	**-**	**-**	**(625)**	*	*	**-**	*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 5,959 shares	**15,083**	*	-	-	-	-	**706**	-	**706**
Round up of shares due to reverse stock split effectuated on April 26, 2021	**47,388**	*	-	-	-	-	**-**	-	**-**
BALANCE AT June 30, 2021	**7,914,339**	**1**	**-**	**-**	**1,718**	*	**$ 215,755**	**$ (174,926)**	**$40,830**

*Represents an amount less than $1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.

CONDENSED **CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Unaudited)

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

	Common stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT April 1, 2021	**7,852,791**	**1**	**1,718**	*	**$ 215,372**	**$ (171,419)**	**$ 43,954**
Net loss						**(3,507)**	**(3,507)**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 2,683 shares	**14,160**	*	**-**	**-**	**383**	**-**	**383**
Round up of shares due to reverse stock split effectuated on April 26, 2021	**47,388**	*	**-**	**-**	**-**	**-**	**-**
BALANCE AT June 30, 2021	**7,914,339**	**1**	**1,718**	*	**$ 215,755**	**$ (174,926)**	**$ 40,830**

*Represents an amount less than $1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.

CONDENSED **CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Unaudited)

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

	Common stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2022	**8,296,256**	**1**	**1,718**	*	**216,625**	**(183,094)**	**33,532**
Net loss						**(9,117)**	**(9,117)**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 4,563 shares	**26,944**	*			**1,327**		**1,327**
BALANCE AT June 30, 2022	**8,323,200**	**1**	**1,718**	*	**217,952**	**(192,211)**	**25,742**

*Represents an amount less than $1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.

CONDENSED **CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

(Unaudited)

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

	Common stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT April 1, 2022	**8,317,876**	**1**	**1,718**	*	**217,278**	**(187,575)**	**29,704**
Net loss						**(4,636)**	**(4,636)**
Share-based compensation related to restricted stock, restricted stock units and stock options award	**5,324**	*			**674**		**674**
BALANCE AT June 30, 2022	**8,323,200**	**1**	**1,718**	*	**217,952**	**(192,211)**	**25,742**

*Represents an amount less than $1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.
CONDENSED **CONSOLIDATED STATEMENTS OF CASH FLOWS**
(Unaudited)
(U.S. dollars in thousands)

	Six months ended June 30	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,117)	$ (6,750)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	84	84
Loss from sale of property, plant and equipment	-	1
Loss on amounts funded in respect of employee rights upon retirement, net	103	-
Change in liability for employees' rights upon retirement	(90)	52
Other financial expenses	132	12
Change in operating right of use asset and operating leasing liability	(63)	(69)
Share-based compensation expenses	1,327	706
Increase in interest receivable on short term deposits	(42)	-
Changes in operating asset and liability items:		
Decrease in prepaid expenses	338	271
Decrease (increase) in trade receivables	41	(486)
Decrease (increase) in other receivables	(6)	10
Decrease (increase) in inventory	(311)	73
Increase in trade payables	234	503
Increase (decrease) in other payables	127	(576)
Net cash used in operating activities	(7,243)	(6,169)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from withdrawal of (invest in) short-term deposits	2,000	-
Purchase of property, plant and equipment	(152)	(80)
Amounts funded in respect of employee rights upon retirement, net	(47)	(34)
Net cash provided by (used by) investing activities	1,801	(114)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance costs of At The Market offering	(37)	-
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants net of $1,989 issuance costs,	-	35,069
Net cash provided by financing activities	(37)	35,069
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(132)	(12)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,611)	28,774
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	12,004	12,645
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 6,393	$ 41,419
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	835	91
Issuance Costs	$ -	35

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

The Company's carotid product (CGuard™ EPS) combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease.

The Company's MGuard™ Prime™ embolic protection system ("MGuard Prime EPS") was marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or bypass surgery. MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. Over the past years there has been a shift in industry preferences away from bare-metal stents, such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients. As a result of declining sales of the MGuard Prime EPS, which the Company believe is largely driven by the predominant industry preferences favoring drug-eluting, or drug-coated, stents, during the second quarter of 2022 the Company ceased sales of the company's MGuard Prime EPS following a phase out period.

The Company markets its products through distributors in international markets, mainly in Europe.

As of the date of issuance of the consolidated financial statements, the Company has the ability to fund its planned operations for at least the next 12 months. However, the Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™ EPS) reach commercial profitability. Therefore, in order to fund the Company's operations until such time that the Company can generate substantial revenues, the Company may need to raise additional funds. See also note 1b regarding the new European Medical Device Regulation.

b. Failure to satisfy regulatory requirements of the new European Medical Device Regulation by November 12, 2022 could prevent the Company from marketing CGuard EPS in Europe.

For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, the Company must comply with EU law on medical devices, which, until May 26, 2021 was governed by the Medical Device Directive 93/42/EEC ("MDD"), by presenting comprehensive technical files for its products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by a European Notified Body. The Company has obtained ISO 13485 quality system certification and CGuard EPS that the Company currently distributes into the European Union, displays the required CE mark. In order to maintain certification, the Company is required to pass an annual surveillance audit conducted by Notified Body auditors. The European Union replaced the MDD with the new European Medical Device Regulation, or MDR (MDR 2017/745). The MDR entered into force after a transitional period of three years and a one year extension of that transition period due to the COVID-19 pandemic on May 26, 2021 and which changes several aspects of the regulatory framework in the European Union. Manufacturers had the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark. After May 26, 2021, medical devices can generally still be placed on the market under the provision of the MDD until May 26, 2024; provided the CE Mark was issued prior to this date and the manufacturer continues to comply with this directive. By May 26, 2024, all medical devices entering the EU will need to have a CE Mark under the MDR, even if they have been on the market previously under the MDD. In the Company's' particular case, CGuard EPS can continue to be marketed under the MDD until November 12, 2022. Specifically, the EU MDR requires changes in the clinical evidence required for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, Unique Device Identification ("UDI") for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, and multiple other labeling changes. Currently the Company is under technical documentation review by the Notified Body auditor which is requesting new submission of materials to meet the MDR requirements for recertification having completed the quality management system Notified Body audit in October 2021. There is no assurance that the Company will be able to satisfy MDR requirements by November 12, 2022. While the Company is seeking to expedite the review process, if the Company does not receive recertification by this time or otherwise is determined to be non-compliant, its CE Mark used under the MDD will lapse and the Company will not be able to promote and sell CGuard EPS into CE Mark European countries until the Company receives recertification, which could have a material adverse effect on its business, financial condition, results of operations or cash flows.

c. COVID-19 Pandemic

The COVID-19 global pandemic has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of COVID-19, including government-imposed quarantines, lockdowns, and other public health safety measures. The Company experienced a significant COVID-19 related impact on the company's financial condition and results of operations, primarily during the year ended December 31, 2020, which the Company primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals have shifted resources to patients affected by COVID-19. New COVID-19 variants, and potentially increasing infection rates make the current COVID-related environment highly volatile and uncertain and the Company anticipates that the continuation of the pandemic and related restrictions and safety measures will likely result in continued fluctuations in sales of the

company's products, potentially enrollments in the company's studies as well as potential disruptions to the company's supply chain for the upcoming periods.

d. Risks Related to the Geopolitical and Military Tensions Between Russia and Ukraine in Europe

In February 2022, Russia launched a military invasion into Ukraine. The Company derived approximately 10.5% of total sales in Russia, Ukraine and Belarus in 2021 while during the six and three months ended June 30, 2022 the company's sales to Russia were 6.8% and 10.9% respectively, there were no sales to Ukraine and minimal sales in Belarus. The escalation of geopolitical instability in Russia and Ukraine as well as currency fluctuations in the Russian Ruble could negatively impact the company's operations, sales, and future growth prospects in that region. As a result of the crisis in Ukraine the United States, EU have implemented sanctions against certain Russian individuals and entities and have made it more difficult for us to collect on outstanding accounts receivable from customers in this region. The company's global operations expose us to risks that could adversely affect the company's business, financial condition, results of operations, cash flows or the market price of the company's securities, including the potential for increased tensions between the United States and Russia resulting from the current situation involving Russia and Ukraine, tariffs, economic sanctions and import-export restrictions imposed by either nation, and retaliatory actions by the other nation, as well as the potential negative impact on the company's business and sales in Russia, Ukraine and Belarus. Current geopolitical instability in Russia and Ukraine and related sanctions by the U.S. government against certain companies and individuals may hinder the company's ability to conduct business with potential or existing customers and vendors in these countries. The U.S. government has imposed sanctions through several executive orders restricting U.S. companies from conducting business with specified Russian and Ukrainian individuals and companies. While the Company believe that the executive orders currently do not preclude us from conducting business with the company's current customers or vendors in Russia, Ukraine and Belarus, the sanctions imposed by the U.S. government may be expanded in the future to restrict us from engaging with them. If the Company is unable to conduct business with new or existing customers or vendors or pursue business opportunities in Russia, Ukraine or Belarus, the company's business, including revenue, profitability and cash flows, and operations could be adversely affected. The Company cannot provide assurance that current sanctions or potential future changes in sanctions will not have a material impact on the company's operations in Russia, Ukraine and Belarus or on the company's financial results.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements for the year ended December 31, 2021. In the opinion of the company, all adjustments considered necessary for a fair statement of the results of the interim periods reported herein have been included (consisting only of normal recurring adjustments). These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2021, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 7, 2022. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - EQUITY:

a. As of June 30, 2022, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 2,280 shares of the company's common stock.

As of June 30, 2022, the Company has outstanding warrants to purchase an aggregate of 1,793,815 shares of common stock as follows:

	Number of underlying Common stock		Exercise price
Series E Warrants	198,159	$	27.000
Series F Warrants	433,878	$	7.425
Series G Warrants	1,092,344	$	10.230
Underwriter Warrants	18,277	$	7.425
Other warrants	51,157		225 and above
Total Warrants	1,793,815	$	

As of June 30, 2022, the Company had 155,000,000 authorized shares of capital stock, par value $0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of "blank check" preferred stock.

b. During the six months ended June 30, 2022, the Company granted to employees and consultants' options to purchase a total of 154,508 shares of the Company's common stock. The options have an exercise price ranging from $2.61 - $2.97 per share, which was the fair market value of the Company's common stock on the date of the grant. 98,838 options are subject to a three-year vesting period, with one-third of such awards vesting each year and 55,670 options with performance conditions, mainly related to clinical activities.

In calculating the fair value of the above options, the Company used the following assumptions: dividend yield of 0% and expected term of 5.125-6.5 years; expected volatility ranging from 127.43%-130.93%; and risk-free interest rate ranging from 1.79%-2.88%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $360,356.

NOTE 4 – RELATED PARTIES TRANSACTIONS

During the six and three months ended June 30, 2022, a consulting company whose founder and CEO is a member of the company's board of directors, provided certain marketing services in the amount of $8,776 and $2,500, respectively.

NOTE 5- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 3,010,707 for the six and three-month periods ended June 30, 2022.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 2,251,468 for the six and three month periods ended June 30, 2021.

NOTE 6 – LEASE AGREEMENTS

1) The Company's Israeli subsidiary has a lease agreement for a facility in Israel, which expires on December 31, 2022 with an option to extend the agreement for two additional years until December 31, 2024 under the terms stipulated in the agreement. , The Company amended the agreement mentioned above and extended it until December 31, 2026 as well as leasing of additional space in the facility, the additional space amendment was taken in consideration when calculating the operating lease right of use assets and liabilities.

2) Operating lease cost for the six and three-month periods ended June 30, 2022 were $218,000 and $82,000 respectively.

Supplemental information related to leases are as follows:

	June 30 2022 ($ in thousands)	December 31 2021 ($ in thousands)
Operating lease right-of-use assets	1,717	1,081
Current operating lease liabilities	(424)	(420)
Non-current operating lease liabilities	(1,350)	(781)

Other information:

Operating cash flows from operating leases (cash paid in thousands)	(218)	(437)
Weighted Average Remaining Lease Term	4.5	3
Weighted Average Discount Rate	8.69%	8.38%

Maturities of lease liabilities are as follows:

	Amount ($ in thousands)
2022	220
2023	434
2024	475
2025	475
2026	515
Total lease payments	2,119
Less imputed interest	(344)
Total	
2022	1,775

NOTE 7 - FINANCIAL INSTRUMENTS:

a. Fair value of financial instruments

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments.

b. As of June 30, 2022, and December 31, 2021, allowance for doubtful accounts was $0.

NOTE 8 - INVENTORY:

	June 30, 2022	December 31, 2021
	($ in thousands)	
Finished goods	$ 188	$ 92
Work in process	414	436
Raw materials and supplies	852	615
	$ 1,454	$ 1,143

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	June 30, 2022	December 31, 2021
	($ in thousands)	
Employees and employee institutions	1,215	1,510
Accrued vacation and recreation pay	287	233
Accrued expenses	1,563	1,136
Current Operating lease liabilities	424	420
Other	96	155
	$ 3,585	$ 3,454

NOTE 10 - DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	($ in thousands)			
Germany	$ 426	$ 232	$ 675	$ 477
Italy	229	249	473	458
Poland	52	104	143	193
Other	824	453	1,423	916
	$ 1,531	$ 1,038	$ 2,714	$ 2,044

By product:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	($ in thousands)			
CGuard	$ 1,505	$ 1,019	$ 2,666	$ 1,987
MGuard	26	19	48	57
	$ 1,531	$ 1,038	$ 2,714	$ 2,044

By principal customers:

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Customer A	28%	22%	25%	23%
Customer B	8%	13%	9%	13%
Customer C	7%	11%	8%	10%
Customer D	3%	10%	5%	10%

All tangible long lived assets are located in Israel.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Form 10-Q to the "Company," "InspireMD," "we," "our" and "us" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "will," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq Capital Market listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to successfully obtain, maintain and adequately protect our intellectual property rights;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards;
- our ability to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- market acceptance of our products;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;

- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- price increases for supplies and components;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- adverse federal, state and local government regulation in the United States, Europe, Israel and other foreign jurisdictions;
- 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 volatility in certain jurisdictions;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- loss or retirement of key executives and research scientists.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described in this Quarterly Report on Form 10-Q, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

All information in this Quarterly Report on Form 10-Q relating to shares or price per share reflects the 1-for-15 reverse stock split effected by us on April 26, 2021.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. In September 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020 and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in China. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries. Our CE mark for CGuard EPS expires on November 12, 2022 and we are currently in the process of seeking recertification under the new European Medical Device Regulation (see Part II – Item 1A. Risk Factors "Failure to satisfy regulatory requirements of the new European Medical Device Regulation by November 12, 2022 could prevent us from marketing CGuard EPS in Europe").

On September 8, 2020, we received approval from the U.S. Food and Drug Administration ("FDA") of our Investigation Device Exemption ("IDE"), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States. C-Guardians is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial was designed to enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication.

On July 23, 2021, we announced the initiation of enrollment and successful completion of the first cases of our C-Guardian trial of CGuard EPS. The first patients, who were under the care of principal investigator, Chris Metzger, M.D., system chair of clinical research at Ballard Health System in Eastern Tennessee, were successfully implanted with the CGuard EPS stent device. These are the first of 315 patients who are expected to be enrolled in the trial and receive CGuard EPS in the treatment of carotid artery stenosis in symptomatic and asymptomatic patients undergoing carotid artery stenting. We are currently continuing with the enrollment phase. In April 2022, we completed our first European recruitment.

Additionally, we intend to continue to invest in current and future potential product and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery system, CGuard Prime. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are exploring adding new delivery systems and accessory solutions for procedural protection to our portfolio such as SwitchGuard.

We consider the current addressable market for our CGuard EPS to be individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS will be approximately $666 million in 2022 (source: Health Research International Personal Medical Systems, Inc. September 13, 2021 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets). According to this same report, assuming full penetration of the caseload for all individuals diagnosed with high-grade carotid artery stenosis, we estimate that the total available market for CGuard EPS in 2022 will be approximately $5 billion.

Our MGuard™ Prime™ embolic protection system ("MGuard Prime EPS") was marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or bypass surgery. MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. Over the past years there has been a shift in industry preferences away from bare-metal stents, such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients. As a result of declining sales of the MGuard Prime EPS, which we believe this is largely driven by the predominant industry preferences favoring drug-eluting, or drug-coated, stents, during the second quarter of 2022 we ceased sales of our MGuard Prime EPS following a phase out period.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to improve peripheral procedures such as the treatment of the superficial femoral artery disease and vascular disease below the knee as well as neurovascular procedures, such as the treatment of acute stroke.

Presently, none of our products may be sold or marketed in the United States, but we do derive revenues from the use of our products in the currently ongoing trials.

We were organized in the State of Delaware on February 29, 2008.

Recent Developments

The COVID-19 global pandemic has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of COVID-19, including government-imposed quarantines, lockdowns, and other public health safety measures. We experienced a significant COVID-19 related impact on our financial condition and results of operations, primarily during the year ended December 31, 2020, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals have shifted resources to patients affected by COVID-19. New COVID-19 variants, and potentially increasing infection rates make the current COVID-related environment highly volatile and uncertain and we anticipate that the continuation of the pandemic and related restrictions and safety measures will likely result in continued fluctuations in sales of our products and potentially enrollments in our studies as well as potential disruptions to our supply chain for the upcoming periods.

In February 2022, Russia launched a military invasion into Ukraine. We derived approximately 10.5% of total sales in Russia, Ukraine and Belarus in 2021 while during the six and three months ended June 30, 2022 our sales to Russia were 6.8% and 10.9% respectively, there were no sales to Ukraine and minimal sales in Belarus. The escalation of geopolitical instability in Russia and Ukraine as well as currency fluctuations in the Russian Ruble could negatively impact our operations, sales, and future growth prospects in that region. As a result of the crisis in Ukraine both the United States and the EU have implemented sanctions against certain Russian individuals and entities and have made it more difficult for us to collect on outstanding accounts receivable from customers in this region. Our global operations expose us to risks that could adversely affect our business, financial condition, results of operations, cash flows or the market price of our securities, including the potential for increased tensions between the United States and Russia resulting from the current situation involving Russia and Ukraine, tariffs, economic sanctions and import-export restrictions imposed by either nation, and retaliatory actions by the other nation, as well as the potential negative impact on our business and sales in Russia, Ukraine and Belarus. Current geopolitical instability in Russia and Ukraine and related sanctions by the U.S. government against certain companies and individuals may hinder our ability to conduct business with potential or existing customers and vendors in these countries. The U.S. government has imposed sanctions through several executive orders restricting U.S. companies from conducting business with specified Russian and Ukrainian individuals and companies. While we believe that the executive orders currently do not preclude us from conducting business with our current customers or vendors in Russia, Ukraine and Belarus, the sanctions imposed by the U.S. government may be expanded in the future to restrict us from engaging with them. If we are unable to conduct business with new or existing customers or vendors or pursue business opportunities in Russia, Ukraine or Belarus, our business, including revenue, profitability and cash flows, and operations could be adversely affected. We cannot provide assurance that current sanctions or potential future changes in sanctions will not have a material impact on our operations in Russia, Ukraine and Belarus or on our financial results.

Critical Accounting Policies

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2021. There have not been any material changes to such critical accounting policies since December 31, 2021.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ("$" or "dollar").

Contingencies

We and our subsidiaries are involved in legal proceedings that arise from time to time in the ordinary course of business. We record accruals for these types of contingencies to the extent that we conclude the occurrence of such contingencies is probable and that the related liabilities are estimable. When accruing these costs, we recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. Legal costs are expensed as incurred.

Results of Operations

Three months ended June 30, 2022, compared to the three months ended June 30, 2021

Revenues. For the three months ended June 30, 2022, revenue increased by $493,000, or 47.6%, to $1,531,000, from $1,038,000 during the three months ended June 30, 2021. This increase was predominantly driven by a 47.8% increase in sales volume of CGuard EPS from $1,019,000 during the three months ended June 30, 2021, to $1,505,000 during the three months ended June 30, 2022. This sales increase was mainly due to growth in existing and new markets and sales in the United States related to stents used in our C-Guardians FDA study which occurred in the three months ended June 30, 2022, but not in the corresponding period in 2021.

With respect to geographical regions, the increase in revenue was primarily attributable to a $279,000 increase in Europe, a $95,000 increase in Latin America, a $62,000 increase in Asia and a $2,000 decrease in other geographies. This growth was mainly due to growth in existing and new markets. In addition, there was a $59,000 increase in revenue from North America due to sales in the United States related to stents used in our C-Guardians FDA study which occurred in the three months ended June 30, 2022, but not in the corresponding period in 2021.

Gross Profit. For the three months ended June 30, 2022, gross profit (revenue less cost of revenues) increased by $169,000, or 64.4%, to $431,000, from $262,000 during the three months ended June 30, 2021. This increase in gross profit resulted from a $197,000 increase in revenues (as mentioned above), less the associated related material and labor costs and a reduction in miscellaneous expenses of $55,000, partially offset by a $83,000 reduction in costs of goods sold due to an inventory adjustment that occurred during the three months ended June 30, 2021 which did not occur during the three months ended June 30, 2022. Gross margin (gross profits as a percentage of revenue) increased to 28.1% during the three months ended June 30, 2022 from 25.2% during the three months ended June 30, 2021, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended June 30, 2022, research and development expenses increased by $766,000, or 59.4%, to $2,056,000, from $1,290,000 during the three months ended June 30, 2021. This increase resulted primarily from an increase of $738,000 in expenses related to the commencement of enrollment in the second half of 2021 of the C-Guardians FDA study and an increase of $28,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended June 30, 2022, selling and marketing expenses increased by $350,000, or 55.0%, to $986,000, from $636,000 during the three months ended June 30, 2021. This increase resulted primarily from an increase in tradeshows and travel expenses of $204,000 in light of resumed marketing activities following lifting of restrictions related to COVID-19, an increase in salary expenses of $85,000, and increase in share-based compensation expenses of $60,000 due to the expense recognition of grants made during the fourth quarter of 2021.

General and Administrative Expenses. For the three months ended June 30, 2022, general and administrative expenses increased by $294,000, or 16.6%, to $2,070,000, from $1,776,000 during the three months ended June 30, 2021. This increase resulted primarily from an increase in share-based compensation-related expenses of $147,000, mainly due to the expense recognition of grants made during the fourth quarter of 2021 ,an increase in directors' and officers' liability insurance expenses of $47,000, due to increased premiums caused by recent trends in the overall insurance industry, an increase of $75,000 in regulatory expenses mainly related to implementation of the new European Medical Devices Regulation and an increase of $25,000 in miscellaneous expenses.

Financial Income (Expenses). For the three months ended June 30, 2022, financial income increased by 167.2%, or $112,000, to $45,000 of financial income, from $67,000 of financial expenses during the three months ended June 30, 2021. The increase in financial income primarily resulted from an increase of $69,000 in financial income related to changes in exchange rates and a $45,000 increase in interest income from short-term bank deposits.

Tax Expenses. For the three months ended June 30, 2022, there was no change in our tax expenses as compared to the three months ended June 30, 2021.

Net Loss. Our net loss increased by $1,129,000, or 32.2%, to $4,636,000, for the three months ended June 30, 2022, from $3,507,000 during the three months ended June 30, 2021. The increase in net loss resulted primarily from an increase of $1,410,000 in operating expenses partially offset by an increase of $169,000 in gross profit and an increase of $112,000 in financial income.

Six months ended June 30, 2022 compared to the six months ended June 30, 2021

Revenues. For the six months ended June 30, 2022, revenue increased by $670,000, or 32.8%, to $2,714,000, from $2,044,000 during the six months ended June 30, 2021. This increase was predominantly driven by a 34.2% increase in sales volume of CGuard EPS from $1,987,000 during the six months ended June 30, 2021, to $2,666,000 during the six months ended June 30, 2021. This sales increase was mainly due to growth in existing and new markets and sales in the United States related to stents used in our C-Guardians FDA study which occurred in the three months ended June 30, 2022, but not in the corresponding period in 2021.

With respect to geographical regions, the increase in revenue was primarily attributable to a $289,000 increase in Europe, a $145,000 increase in Latin America, a $93,000 increase in Asia and a $24,000 increase in other geographies. This growth was mainly due to growth in existing and new markets. In addition, there was a $119,000 increase in revenue from North America due to sales in the United States related to stents used in our C-Guardians FDA study which occurred in the six months ended June 30, 2022, but not in the corresponding period in 2021.

Gross Profit. For the six months ended June 30, 2022, gross profit (revenue less cost of revenues) increased by 50.2%, or $185,000, to $553,000, compared to a $368,000 for the same period in 2021. This increase in gross profit resulted from a $223,000 increase in revenues (as mentioned above) less the associated related material and labor costs. This increase was partially offset by an increase of $38,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 20.4% during the six months ended June 30, 2022 from 18.0% during the six months ended June 30, 2021, driven by the reasons mentioned above.

Research and Development Expenses. *Research and Development Expenses*. For the six months ended June 30, 2022, research and development expenses increased by 75.4%, or $1,606,000, to $3,736,000, from $2,129,000 during the six months ended June 30, 2021. This increase resulted primarily from an increase of $1,648,000 in expenses related to the commencement of enrollment in the second half of 2021 of the C-Guardians FDA study offset, in part, by a decrease of $41,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the six months ended June 30, 2022, selling and marketing expenses increased by 28.9%, or $388,000, to $1,732,000, from $1,344,000 during the six months ended June 30, 2021. This increase resulted primarily from an increase in tradeshows and travel expenses of $207,000 in light of resumed marketing activities following lifting of restrictions related to COVID-19, an increase in share-based compensation expenses of $114,000 due to the expense recognition of grants made during the fourth quarter of 2021 and an increase in salary expenses of $66,000.

General and Administrative Expenses. For the six months ended June 30, 2022, general and administrative expenses increased by 16.5%, or $603,000, to $4,252,000, from $3,649,000 during the six months ended June 30, 2021. This increase resulted primarily from an increase in share-based compensation-related expenses of $363,000, mainly due to the expense recognition of grants made during the fourth quarter of 2021 ,an increase in directors' and officers' liability insurance expenses of $106,000, due to increased premiums caused by recent trends in the overall insurance industry, an increase of $95,000 in regulatory expenses mainly related to implementation of the new European Medical Devices Regulation, an increase in travel expenses of $91,000 in light of resumed activities following governments lifting restrictions related to COVID-19 offset, in part, by a decrease of $52,000 in miscellaneous expenses.

Financial Income. For the six months ended June 30, 2022, financial income increased by $46,000, to $50,000 of financial income, from $4,000 of financial income during the six months ended June 30, 2021. The increase in financial income primarily resulted from a $73,000 increase in interest income from short-term bank deposits, offset, in part, by a decrease of $18,000 in financial income related to changes in exchange rates.

Tax Expenses. For the six months ended June 30, 2022, there was no material change in our tax expenses as compared to the six months ended June 30, 2021.

Net Loss. Our net loss increased by $2,367,000, or 35.1%, to $9,117,000, for the six months ended June 30, 2022, from $6,750,000 during the six months ended June 30, 2021. The increase in net loss resulted primarily from an increase of $2,598,000 in operating expenses, offset by an increase of $185,000 in gross profit.

Liquidity and Capital Resources

As of June 30, 2022, we have the ability to fund our planned operations for at least the next 12 months from issuance date of the financial statement. However, we expect to continue incurring losses and negative cash flows from operations until CGuard™ EPS reaches commercial profitability. Therefore, in order to fund our operations until such time that we can generate substantial revenues, we may need to raise additional funds.

On June 3, 2022, we entered into a Sales Agreement with A.G.P./Alliance Global Partners, as sales agent ("A.G.P."), pursuant to which we may offer and sell from time to time, at our option, through or to A.G.P., up to an aggregate of approximately $8,313,000 of shares of our common stock. The issuance and sale of shares by us under the program will be made pursuant to our effective "shelf" registration statement on Form S-3 (Registration Statement No. File No. 333-265409) filed with the SEC on June 3, 2022, and declared effective on June 14, 2022. No shares have been sold under the program.

Six months ended June 30, 2022 compared to the six months ended June 30, 2021

General. At June 30, 2022, we had cash and cash equivalents of $6,393,000 as compared to $12,004,000 as of December 31, 2021. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative costs, capital expenditures and general working capital.

For the six months ended June 30, 2022, net cash used in our operating activities increased by $1,074,000, or 17.4%, to $7,243,000, from $6,169,000 during the same period in 2021. The primary reason for the increase in cash used in our operating activities was an increase of $1,623,000 in payments for third party related expenses and for professional services and an increase of $613,000 in compensation costs paid during the three months ended June 30, 2022 from $4,012,000 in the three months ended June 30, 2021 to $4,625,000 during the same period in 2022, offset by an increase of $1,162,000 in payments received from customers, to $2,707,000 during the three months ended June 30, 2022 from $1,545,000 during the same period in 2021.

Cash provided by our investing activities increased by $1,915,000 or $1,679.8%, to $1,801,000 during the six months ended June 30, 2022, compared to cash used of $114,000 during the six months ended June 30, 2021. The primary reasons for the increase in cash provided by our investing activities is a withdrawal of $2,000,000 of short-term deposits.

Cash used by financing activities for the six months ended June 30, 2022 was $37,000, the cash used by financing activities during the six months ended June 30, 2022 were due to issuance cost associated with a shelf registration statement on Form S-3 filed with the SEC on June 3, 2022. Cash provided by financing activities for the six months ended June 30, 2021 was $35,069,000, the principal sources of which were our February 2021 public offering of common stock and warrants, exercise of Series F and Series G warrants, proceeds from an at-the-market offering as well as proceeds from the issuance of shares to Chinese distributor that resulted in approximately $35,069,000 of aggregate net proceeds.

As of June 30, 2022, our current assets exceeded our current liabilities by a multiple of 6.3. Current assets decreased by $7,594,000 during the period and current liabilities increased by $365,000 during the period. As a result, our working capital decreased by $7,959,000 to $24,788,000 as of June 30, 2022.

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations) or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment, the impact of the COVID-19 pandemic and the ongoing conflict in the Ukraine. Our operating results could also be impacted by a weakening of the Euro and strengthening of the NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Contractual Obligations and Commitments

Except as set forth below, during the three months ended June 30, 2022, there were no material changes to our contractual obligations and commitments. As further described in Note 6 of the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q, during the three months ended June 30, 2022, we extended our lease agreement for a facility in Israel until December 31, 2026 and amended the lease to add additional space in the facility.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of June 30, 2022, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of June 30, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2022, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. There are currently no pending material legal proceedings, and we are currently not aware of any legal proceedings or claims against us or our property that we believe will have any significant effect on our business, financial position or operating results.

Item 1A. Risk Factors

Except for the Risk Factors included in our previous filings made with the SEC and as set forth below, there have been no material changes to our risk factors from those disclosed in "Part I. Item 1A. Risk Factors" in the Form 10-K filed with the SEC on March 7, 2022.

Failure to satisfy regulatory requirements of the new European Medical Device Regulation by November 12, 2022 could prevent us from marketing CGuard EPS in Europe.

For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, we must comply with EU law on medical devices, which, until May 26, 2021 was governed by the Medical Device Directive 93/42/EEC ("MDD"), by presenting comprehensive technical files for our products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by a European Notified Body. We have obtained ISO 13485 quality system certification and CGuard EPS that we currently distribute into the European Union, displays the required CE mark. In order to maintain certification, we are required to pass an annual surveillance audit conducted by Notified Body auditors. The European Union replaced the MDD with the new European Medical Device Regulation, or MDR (MDR 2017/745). The MDR entered into force after a transitional period of three years and a one year extension of that transition period due to the COVID-19 pandemic on May 26, 2021 and which changes several aspects of the regulatory framework in the European Union. Manufacturers had the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark. After May 26, 2021, medical devices can generally still be placed on the market under the provision of the MDD until May 26, 2024; provided the CE Mark was issued prior to this date and the manufacturer continues to comply with this directive. By May 26, 2024, all medical devices entering the EU will need to have a CE Mark under the MDR, even if they have been on the market previously under the MDD. In our particular case, CGuard EPS can continue to be marketed under the MDD until November 12, 2022. Specifically, the EU MDR requires changes in the clinical evidence required for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, Unique Device Identification ("UDI") for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, and multiple other labeling changes. Currently we are under technical documentation review by the Notified Body auditor which is requesting new submission of materials to meet the MDR requirements for recertification having completed the quality management system Notified Body audit in October 2021. The Notified Body is currently experiencing chronic delays in processing MDR audits and reviews and there is no assurance that we will be able to satisfy MDR requirements by November 12, 2022. While we are seeking to expedite the review process, if we do not receive recertification by this time or otherwise are determined to be non-compliant, our CE Mark used under the MDD will lapse and we will not be able to promote and sell CGuard EPS into CE Mark European countries until we receive recertification, which could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation, as amended through September 30, 2015 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2021)

3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)

3.6	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)
3.7	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)
3.8	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019)
3.10	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc., dated April 14, 2021 (incorporated by reference to Exhibit 3.17 to the Quarterly Report on Form 10-Q filed on May 10, 2021)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, formatted in inline XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.
+ Management contract or compensatory plan or arrangement.

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 thereunto duly authorized.

INSPIREMD, INC.

Date: August 8, 2022

By: */s/ Marvin Slosman*
Name: Marvin Slosman,
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2022

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Marvin Slosman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2022

/s/ Marvin Slosman

Marvin Slosman
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Craig Shore, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2022

/s/ Craig Shore

Craig Shore
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marvin Slosman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: August 8, 2022

By: */s/ Marvin Slosman*
Name: Marvin Slosman
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION
PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Craig Shore, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: August 8, 2022

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)