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: March 31, 2023

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 May 14, 2023: 8,356,394

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Item 1. Financial Statements

INSPIREMD, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED MARCH 31, 2023

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

	March 31 2023	December 31 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,228	$ 4,632
Short-term bank deposits	8,657	13,171
Accounts receivable:		
Trade, net	1,417	1,034
Other	310	213
Prepaid expenses	394	655
Inventory	1,697	1,621
TOTAL CURRENT ASSETS	16,703	21,326
NON-CURRENT ASSETS:		
Property, plant and equipment, net	887	917
Operating lease right of use assets	1,472	1,554
Fund in respect of employee rights upon retirement	859	856
TOTAL NON-CURRENT ASSETS	3,218	3,327
TOTAL ASSETS	$ 19,921	$ 24,653

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

	March 31 2023	December 31 2022
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	607	659
Other	3,776	4,411
TOTAL CURRENT LIABILITIES	4,383	5,070
LONG-TERM LIABILITIES-		
Operating lease liabilities	1,081	1,195
Liability for employees rights upon retirement	1,031	995
TOTAL LONG-TERM LIABILITIES	2,112	2,190
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	6,495	7,260
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2023 and December 31, 2022; 8,326,648 and 8,330,918 shares issued and outstanding at March 31, 2023 and December 2022, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2023 and December 31, 2022; 1,718 shares issued and outstanding at March 31, 2023 and December 31 2022, respectively	*	*
Additional paid-in capital	219,266	218,977
Accumulated deficit	(205,841)	(201,585)
Total equity	13,426	17,393
Total liabilities and equity	$ 19,921	$ 24,653

*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)

	3 Months Ended March 31,	
	2023	**2022**
REVENUES	$ 1,239	$ 1,183
COST OF REVENUES	866	1,061
GROSS PROFIT	373	122
OPERATING EXPENSES:		
Research and development	1,843	1,680
Selling and marketing	788	746
General and administrative	2,123	2,182
Total operating expenses	4,754	4,608
LOSS FROM OPERATIONS	(4,381)	(4,486)
FINANCIAL INCOME, net	125	5
NET LOSS	$ (4,256)	$ (4,481)
NET LOSS PER SHARE - basic and diluted	(0.53)	(0.57)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	8,093,340	7,804,245

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	Accumulated	Total
	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT January 1, 2022	**8,296,256**	**1**	**1,718**	*	**216,625**	**(183,094)**	**33,532**
Net loss						**(4,481)**	**(4,481)**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 4,563 shares	**21,620**				**653**		**653**
BALANCE AT March 31, 2022	**8,317,876**	**1**	**1,718**	*	**217,278**	**(187,575)**	**29,704**

*Represents an amount less than $1 thousand

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

INSPIREMD, INC.
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	Accumulated	Total
	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT January 1, 2023	**8,330,918**	**1**	**1,718**	*	**218,977**	**(201,585)**	**17,393**
Net loss						**(4,256)**	**(4,256)**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 4,270 shares	**(4,270)**				**289**		**289**
BALANCE AT March 31, 2023	**8,326,648**	**1**	**1,718**	*	**219,266**	**(205,841)**	**13,426**

*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)

	Three months ended March 31	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,256)	$ (4,481)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	55	41
Change in liability for employees rights upon retirement	36	46
Other financial expenses	22	7
Change in right of use asset and leasing liability	(34)	(25)
Share-based compensation expenses	289	653
Loss on amounts funded in respect of employee rights upon retirement, net	23	18
Decrease (increase) in interest receivable on short term deposits	14	(17)
Changes in operating asset and liability items:		
Decrease in prepaid expenses	261	231
Decrease (Increase) in trade receivables	(383)	111
Decrease (Increase) in other receivables	(97)	74
Increase in inventory	(76)	(143)
Increase (Decrease) in trade payables	(52)	7
Decrease in other payables	(633)	(656)
Net cash used in operating activities	(4,831)	(4,134)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(25)	(37)
Investment in short-term bank deposits	(2,500)	(6,000)
Withdrawal from short-term bank deposits	7,000	6,000
Amounts funded in respect of employee rights upon retirement	(26)	(28)
Net cash provided by (used in) investing activities	4,449	(65)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net cash provided by (used in) financing activities		
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(22)	(7)
DECREASE IN CASH AND CASH EQUIVALENTS	(404)	(4,206)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	4,632	12,004
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 4,228	$ 7,798

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 believes 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.

b. Liquidity

The Company has an accumulated deficit as of March 31, 2023, as well as a history of net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its product, CGuard™ EPS, reaches commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company has sufficient resources to fund operations until the end of September 2023. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Management's plans include the continued commercialization of the Company's product and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations.

On May 12, 2023, the Company entered into a securities purchase agreement for the issuance and sale of Company securities in a private placement. Aggregate gross proceeds to the Company in respect of the private placement is expected to be approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company and before exercising any warrants. The offering is expected to close on or about May 15, 2023, subject to the satisfaction of customary closing conditions.

c. Failure to satisfy regulatory requirements of the new European Medical Device Regulation could prevent the Company from marketing CGuard EPS in countries requiring the CE Mark.

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 Company with EU law on medical devices, which, until May 26, 2021 was governed by the MDD, by presenting comprehensive technical files for the Company's 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 distribute 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 MDR regulations. 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. In the Company's specific case, the Company's CE mark for CGuard EPS under the MDD expired on November 12, 2022, and the Company is in the final stages of technical documentation review by the Notified Body auditor to meet the MDR requirements for recertification. In the meantime, on February 14, 2023, the Company received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing the Company to continue marketing CGuard EPS in the EU until August 15, 2023, subject to certain procedural requirements. Subsequently, on March 20, 2023 Regulation (EU) 2023/607 was published allowing the Company to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, the Company may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while the Company's MDR CE recertification is pending.

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 12.1% of total sales in Russia and Belarus in 2022 while during the three months ended March 31, 2023 and March 31,2022, The Company's sales to Russia and Belarus were 7.9% and 1.5% respectively. 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 and the EU have implemented sanctions against certain Russian individuals and entities and have made it more difficult for the Company to collect on outstanding accounts receivable from customers in this region. The Company's global operations expose the Company 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, 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 individuals and companies. While the Company believes that the executive orders currently do not preclude the Company from conducting business with the Company's current customers or vendors in Russia, and Belarus, the sanctions imposed by the U.S. government may be expanded in the future to restrict the Company 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, 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, 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. In the opinion of the Company, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of its financial position as of March 31, 2023 and its results of operations, changes in equity and cash flows for the three months ended March 31, 2023 and 2022. 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, 2022, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 30, 2023. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

Newly issued accounting pronouncements

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology. Under the new guidance, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two-tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies had an effective date for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, the Company met the definition of an SRC and adopted the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company adopted the provisions of this update as of January 1, 2023 with no material impact on its consolidated financial statements.

NOTE 4 - EQUITY:

a. As of March 31, 2023, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 2,280 shares of our common stock.

As of March 31, 2023, the Company has outstanding warrants to purchase an aggregate of 1,793,504 shares of common stock as follows:

	Number of underlying Common stock		Weighted average 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	17,966	$	7.425
Other warrants	51,157		225 and above
Total Warrants	1,793,504	$	

As of March 31, 2023, 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 three months ended March 31, 2023, the Company granted to a consultant options to purchase a total of 50,000 shares of the Company's common stock. The options have an exercise price of $1.15 per share, which was the fair market value of the Company's common stock on the date of the grant. 45,000 options are subject to a three-year vesting period (of which 20,000 options are vesting in the first year, 15,000 options are vesting in the second year and 10,000 options are vesting in the third year) and 5,000 options with performance conditions related to marketing activities.

In calculating the fair value of the above options, the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility ranging from 124.58%-125.61%; and risk-free interest rate ranging from 3.65%-3.68%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $50,658.

NOTE 5 – RELATED PARTIES TRANSACTIONS

During the three months ended March 31, 2022, a consulting company whose founder and CEO is our board member provided certain marketing services in the amount of $6,276.

NOTE 6 - 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 unvested restricted stocks and unvested restricted stock units as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units, Series C Preferred Stock excluded from the calculations of diluted loss per share were 2,773,675. This amount includes 342,766 of unvested restricted stock included in the number of issued and outstanding shares as of March 31, 2023.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units, Series C Preferred Stock excluded from the calculations of diluted loss per share were 2,903,634. This amount includes 547,383 of unvested restricted stock included in the number of issued and outstanding shares as of March 31, 2022.

NOTE 7 - FINANCIAL INSTRUMENTS:

a. Fair value of financial instruments

The carrying amounts of financial instruments included in working capital approximate their fair value due to the relatively short-term maturities of such instruments.

b. As of March 31, 2023, and December 31, 2022, allowance for expected credit loss was immaterial.

NOTE 8 - INVENTORY:

	March 31, 2023	December 31, 2022
	($ in thousands)	
Finished goods	$ 138	$ 179
Work in process	690	510
Raw materials and supplies	869	932
	$ 1,697	$ 1,621

NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2023	December 31, 2022
	($ in thousands)	
Employees and employee institutions	970	1,853
Accrued vacation and recreation pay	240	197
Accrued expenses	933	554
Clinical trial accrual	1,046	1,258
Current Operating lease liabilities	417	419
Other	170	130
	$ 3,776	$ 4,411

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 March 31	
	2023	2022
	($ in thousands)	
Italy	$ 267	$ 243
Germany	214	249
Other	758	691
	$ 1,239	$ 1,183

By product:

	Three months ended March 31	
	2023	2022
	($ in thousands)	
CGuard	$ 1,239	$ 1,161
MGuard	-	22
	$ 1,239	$ 1,183

By principal customers:

	Three months ended March 31	
	2023	2022
Customer A	17%	21%
Customer B	13%	11%

All tangible long lived assets are located in Israel.

NOTE 11 – SUBSEQUENT EVENTS

On May 12, 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") pursuant to which the Company agreed to sell and issue in a private placement (the "Private Placement Offering) an aggregate of 10,266,270 shares (the "Private Placement Shares") of the Company's common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 15,561,894 shares of common stock and warrants to purchase up to an aggregate of 51,656,328 shares of common stock, consisting of Series H warrants to purchase up to 12,914,086 shares of common stock (the "Series H Warrants"), Series I warrants to purchase up to 12,914,078 shares of common stock (the "Series I Warrants"), Series J warrants to purchase up to 12,914,086 shares of Common Stock (the "Series J Warrants") and Series K warrants to purchase up to 12,914,086 shares of common stock (the "Series K Warrants" and together with the Series H Warrants, Series I Warrants and Series J Warrants, the "Warrants"), at an offering price of $1.6327 per Private Placement Share and associated Warrants and an offering price of $1.6326 per Pre-Funded Warrant and associated Warrants.

The Pre-Funded Warrants will be immediately exercisable at an exercise price of $0.0001 per share and will not expire until exercised in full. The Warrants will be immediately exercisable upon issuance at an exercise price of $1.3827 per share, subject to adjustment as set forth therein. The Warrants have a term of the earlier of (i) five years from the date of issuance and (ii) (A) in the case of the Series H Warrants, 20 trading days following the Company's public release of primary and secondary end points related to one year follow up study results from the Company's C-Guardians pivotal trial, (B) in the case of the Series I Warrants, 20 trading days following the Company's announcement of receipt of Premarket Approval from the Food and Drug Administration ("FDA") for the CGuard Prime Carotid Stent System (135 cm), (C) in the case of the Series J Warrants, 20 trading days following the Company's announcement of receipt of FDA approval for the SwitchGuard and CGuard Prime 80 and (D) in the case on the Series K Warrants, 20 trading days following the end of the fourth fiscal quarter after the fiscal quarter in which the first commercial sales of the CGuard Carotid Stent System in the United States begins. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the warrants.

In connection with the Purchase Agreement, the Company entered into a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, the Company is required to file a resale registration statement (the "Registration Statement") with the SEC to register for resale the Private Placement Shares and the shares of common stock issuable upon exercise of the Pre-Funded Warrants and Warrants, within 20 days of the signing date of the Purchase Agreement (the "Signing Date"), and to have such Registration Statement declared effective within 45 days after the Signing Date in the event the Registration Statement is not reviewed by the SEC, or 90 days of the Signing Date in the event the Registration Statement is reviewed by the SEC. The Company will be obligated to pay certain liquidated damages if the Company fails to file the Registration Statement when required, fails to cause the Registration Statement to be declared effective by the SEC when required, of if the Company fails to maintain the effectiveness of the Registration Statement.

Aggregate gross proceeds to the Company in respect of the Private Placement Offering are expected to be approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company which are expected to amount to approximately $4.6 million. If the Warrants are exercised in cash in full this would result in an additional $71.4 million of proceeds. The Private Placement Offering is expected to close on or about May 15, 2023, subject to satisfaction of customary closing conditions.

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, including revenue growth. 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 history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- 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;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- 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 adequately protect our intellectual property rights;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards;
- 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;
- 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
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

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.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform for the treatment of carotid artery disease and other vascular disease. A stent is an expandable “scaffold-like” device, usually constructed of a metallic material, that is inserted into the lumen of the artery to create patency and revascularization of blood flow. MicroNet, a micron mesh sleeve, is attached over a stent to provide embolic protection both during and after stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS™") combines MicroNet and a unique self-expandable nitinol stent in a single device for use in carotid artery revascularization. Our CGuard EPS originally received CE mark approval under Medical Device Directive 93/42/EEC ("MDD") in the European Union ("EU") in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in over 30 countries and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in the Asian markets. 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 under the MDD expired on November 12, 2022 and we are in the final stages of technical documentation review by the Notified Body auditor to meet the Medical Device Regulation ("MDR") (MDR 2017/745) requirements (which replaced the MDD) for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023 subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR.

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 Sten 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. The composite index will be compared to a performance goal based on the observed rate of the two components of the primary endpoint from previous pivotal stent trials which are considered industry standard. The performance goal will be considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025.

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. There are 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 enrolment phase at approximately 20 trial sites and expect it to be completed approximately at the end of the second quarter of 2023.

Additionally, we intend to continue to invest in current and future potential new indications, products and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery systems, such as CGuard Prime™for transfemoral access. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are developing a new transcarotid artery revascularization (TCAR) delivery system, SwitchGuard™, for transcarotid access and neuro protection. In addition, we intend to explore new indications for CGuard EPS to leverage the advantages of stent design and mesh protection, well suited in labels such as acute stroke with tandem lesions.

We consider our 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 $1.3 billion in 2023 (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 and internal estimates). According to this same report, and internal estimates, 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 $9.3 billion. Our mission is to offer a comprehensive set of delivery solutions (TCAR and Transfemoral) in order to deliver best in class results through patient outcomes by way of stent performance with CGuard EPS.

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

Recent Developments

Private Placement

On May 12, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") pursuant to which we agreed to sell and issue in a private placement (the "Private Placement Offering) an aggregate of 10,266,270 shares (the "Private Placement Shares") of our common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 15,561,894 shares of common stock and warrants to purchase up to an aggregate of 51,656,328 shares of common stock, consisting of Series H warrants to purchase up to 12,914,086 shares of common stock (the "Series H Warrants"), Series I warrants to purchase up to 12,914,078 shares of common stock (the "Series I Warrants"), Series J warrants to purchase up to 12,914,086 shares of Common Stock (the "Series J Warrants") and Series K warrants to purchase up to 12,914,086 shares of common stock (the "Series K Warrants" and together with the Series H Warrants, Series I Warrants and Series J Warrants, the "Warrants"), at an offering price of $1.6327 per Private Placement Share and associated Warrants and an offering price of $1.6326 per Pre-Funded Warrant and associated Warrants.

The Pre-Funded Warrants will be immediately exercisable at an exercise price of $0.0001 per share and will not expire until exercised in full. The Warrants will be immediately exercisable upon issuance at an exercise price of $1.3827 per share, subject to adjustment as set forth therein. The Warrants have a term of the earlier of (i) five years from the date of issuance and (ii) (A) in the case of the Series H Warrants, 20 trading days following the Company's public release of primary and secondary end points related to one year follow up study results from the Company's C-Guardians pivotal trial, (B) in the case of the Series I Warrants, 20 trading days following the Company's announcement of receipt of Premarket Approval from the Food and Drug Administration ("FDA") for the CGuard Prime Carotid Stent System (135 cm), (C) in the case of the Series J Warrants, 20 trading days following the Company's announcement of receipt of FDA approval for the SwitchGuard and CGuard Prime 80 and (D) in the case on the Series K Warrants, 20 trading days following the end of the fourth fiscal quarter after the fiscal quarter in which the first commercial sales of the CGuard Carotid Stent System in the United States begins. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the warrants.

In connection with the Purchase Agreement, we entered into a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, we are required to file a resale registration statement (the "Registration Statement") with the SEC to register for resale the Private Placement Shares and the shares of common stock issuable upon exercise of the Pre-Funded Warrants and Warrants, within 20 days of the signing date of the Purchase Agreement (the "Signing Date"), and to have such Registration Statement declared effective within 45 days after the Signing Date in the event the Registration Statement is not reviewed by the SEC, or 90 days of the Signing Date in the event the Registration Statement is reviewed by the SEC. We will be obligated to pay certain liquidated damages if we fail to file the Registration Statement when required, fails to cause the Registration Statement to be declared effective by the SEC when required, of if we fail to maintain the effectiveness of the Registration Statement.

Aggregate gross proceeds to us in respect of the Private Placement Offering are expected to be approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses. If the Warrants are exercised in cash in full this would result in an additional $71.4 million of proceeds.

We agreed to pay LifeSci Capital LLC, a placement fee equal to 5.6% of the aggregate gross proceeds from the closing of the Private Placement Offering and a non-accountable expense allowance of $25,000. In addition, we have agreed to pay Piper Sandler & Co. a financial advisory fee of $1.5 million and AGP/Alliance Global Partners a financial advisory fee of $250,000.

The Private Placement Offering is expected to close on or about May 15, 2023, subject to satisfaction of customary closing conditions.

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, 2022. There have not been any material changes to such critical accounting policies since December 31, 2022.

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 March 31, 2023, compared to the three months ended March 31, 2022

Revenues. For the three months ended March 31, 2023, revenue increased by $56,000, or 4.7%, to $1,239,000, from $1,183,000 during the three months ended March 31, 2022. This increase was predominantly driven by a 6.7% increase in sales of CGuard EPS from $1,161,000 during the three months ended March 31, 2022, to $1,239,000 during the three months ended March 31, 2023. During the second half of the quarter, our CE mark was reinstated under the MDD directive allowing us to resume sales and shipments to the EU countries and we spent the remainder of the quarter shipping product in order to reduce the backlog of orders that accumulated over the past few months. We believe the quarter over quarter increase in revenue is not representative of the real market demand for CGuard EPS, due to our inability to ship product for the first half of the quarter. We continue to expedite the review process for recertification under the MDR.

With respect to geographical regions, the increase in revenue was primarily attributable to a $177,000 increase in Europe, for reasons mentioned in the paragraph above, and a $13,000 increase from the Middle East. This increase was offset by a $87,000 decrease in Latin America and $52,000 decrease in revenue from other regions such as Australia and Asia due to the timing of shipments to our distributers.

Gross Profit. For the three months ended March 31, 2023, gross profit (revenue less cost of revenues) increased by $251,000, or 205.6%, to $373,000, from $122,000 during the three months ended March 31, 2022. This increase in gross profit resulted from a decrease in write-offs of $184,000 and a $71,000 increase in revenues (as mentioned above), less the associated related material and labor. Gross margin (gross profits as a percentage of revenue) increased to 30.1% during the three months ended March 31, 2023 from 10.3% during the three months ended March 31, 2022, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended March 31, 2023, research and development expenses increased by $163,000, or 9.7%, to $1,843,000, from $1,680,000 during the three months ended March 31, 2022. This increase resulted primarily from an increase of $170,000 in expenses related to the CGuard Prime regulatory and approval process and an increase of $88,000 in miscellaneous expenses offset, in part, by a decrease of $95,000 in expenses related to the C-Guardians FDA study.

Selling and Marketing Expenses. For the three months ended March 31, 2023, selling and marketing expenses increased by $42,000, or 5.6%, to $788,000, from $746,000 during the three months ended March 31, 2022. This increase resulted primarily from an increase in compensation expenses of $49,000 offset, in part, by a decrease of $7,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended March 31, 2023, general and administrative expenses decreased by $59,000, or 2.7%, to $2,123,000, from $2,182,000 during the three months ended March 31, 2022. This decrease resulted primarily from a decrease in share-based compensation-related expenses of $310,000 as no new grants were made from the fourth quarter of 2021 through March 31, 2023 offset, in part, by an increase in regulatory expenses of $171,000 related to MDR registration process and an increase of $80,000 in miscellaneous expenses.

Financial Income. For the three months ended March 31, 2023, financial income increased by $120,000, to $125,000, from $5,000 during the three months ended March 31, 2022. The increase in financial income primarily resulted from a $88,000 increase in interest income from short-term bank deposits.

Tax Expenses. For the three months ended March 31, 2023, there was no change in our tax expenses as compared to the three months ended March 31, 2022.

Net Loss. Our net loss decreased by $225,000, or 5.0%, to $4,256,000, for the three months ended March 31, 2023, from $4,481,000 during the three months ended March 31, 2022. The decrease in net loss resulted primarily from an increase of $251,000 in gross profit and an increase of $120,000 in financial income partially offset by an increase of $146,000 in operating expenses.

Liquidity and Capital Resources

We had an accumulated deficit as of March 31, 2023 of $206 million, as well as a net loss of $4,256,000 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our product, CGuard EPS, reaches commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we believe we have sufficient resources to fund operations until the end of September 2023. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include continued commercialization of our products and raising capital through sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

On May 12, 2023, we entered into a securities purchase agreement for the issuance and sale of our securities in a private placement. Aggregate gross proceeds to us in respect of the private placement is expected to be approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses payable us and before exercising any warrants. The offering is expected to close on or about May 15, 2023, subject to the satisfaction of customary closing conditions.

Three months ended March 31, 2023 compared to the three months ended March 31, 2022

General. At March 31, 2023, we had cash and cash equivalents of $4,228,000 and short-term bank deposits of $8,657,000 as compared to $4,632,000 and short-term bank deposits of $13,171,000 as of December 31, 2022. 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 three months ended March 31, 2023, net cash used in our operating activities increased by $697,000, or 16.9%, to $4,831,000, from $4,134,000 during the same period in 2022. The primary reason for the increase in cash used in our operating activities was an increase of $449,000 in compensation costs paid during the three months ended March 31, 2023 from $2,679,000 in the three months ended March 31, 2022 to $3,128,000 during the same period in 2023 and a decrease of $366,000 in payments received from customers, to $925,000 during the three months ended March 31, 2023 from $1,291,000 during the same period in 2022 ,offset in part by a decrease of $118,000 in payments for third party related expenses and for professional services

Cash provided in our investing activities was $4,449,000 during the three months ended March 31, 2023, compared to cash used of $65,000 during the three months ended March 31, 2022. The primary reasons for the increase in cash provided by our investing activities is a withdrawal of short-term deposits, net of investments of $4,500,000 of short-term deposits, offset by a decrease of $12,000 in payments made for purchase of property, plant and equipment to $25,000 during the three months ended March 31, 2023.

There was no cash provided by financing activities for the three months ended March 31, 2023 and for the three months ended March 31, 2022.

As of March 31, 2023, our current assets exceeded our current liabilities by a multiple of 3.8. Current assets decreased by $4,623,000 during the period and current liabilities decreased by $687,000 during the period. As a result, our working capital decreased by $3,936,000 to $12,320,000 as of March 31, 2023.

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. 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

During the three months ended March 31, 2023, there were no material changes to our contractual obligations and commitments.

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 March 31, 2023, 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 March 31, 2023.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2023, 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 30, 2023.

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 March 31, 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.INS*	Inline XBRL Instance Document (the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

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: May 15, 2023

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

Date: May 15, 2023

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: May 15, 2023

/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: May 15, 2023

/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 March 31, 2023 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: May 15, 2023

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 March 31, 2023 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: May 15, 2023

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