
**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, 2024**

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
(State or other jurisdiction of
incorporation or organization)

26-2123838
(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
Non-accelerated filer

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 13, 2024: 24,929,825

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Item 1. Financial Statements

INSPIREMD, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED MARCH 31, 2024

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

	March 31 2024	December 31 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,389	\$ 9,640
Marketable securities	24,561	29,383
Accounts receivable:		
Trade, net	1,187	1,804
Other	483	648
Prepaid expenses	531	578
Inventory	2,360	2,106
TOTAL CURRENT ASSETS	38,511	44,159
NON-CURRENT ASSETS:		
Property, plant and equipment, net	1,186	1,060
Operating lease right of use assets	1,366	1,473
Fund in respect of employee rights upon retirement	965	951
TOTAL NON-CURRENT ASSETS	3,517	3,484
TOTAL ASSETS	\$ 42,028	\$ 47,643

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

	March 31 2024	December 31 2023
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	659	939
Other	4,218	5,081
TOTAL CURRENT LIABILITIES	4,877	6,020
LONG-TERM LIABILITIES-		
Operating lease liabilities	914	1,038
Liability for employees rights upon retirement	1,150	1,084
TOTAL LONG-TERM LIABILITIES	2,064	2,122
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	6,941	8,142
EQUITY:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at March 31, 2024 and December 31, 2023; 23,412,385 and 21,841,215 shares issued and outstanding at March 31, 2024 and December 2023, respectively	2	2
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at March 31, 2024 and December 31, 2023; 1,718 shares issued and outstanding at March 31, 2024 and December 31 2023, respectively	*	*
Additional paid-in capital	263,618	261,000
Accumulated deficit	(228,533)	(221,501)
Total equity	35,087	39,501
Total liabilities and equity	\$ 42,028	\$ 47,643

*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,	
	2024	2023
REVENUES	\$ 1,511	\$ 1,239
COST OF REVENUES	1,219	866
GROSS PROFIT	292	373
OPERATING EXPENSES:		
Research and development	2,625	1,843
Selling and marketing	1,237	788
General and administrative	3,844	2,123
Total operating expenses	7,706	4,754
LOSS FROM OPERATIONS	(7,414)	(4,381)
FINANCIAL INCOME, net	382	125
NET LOSS	\$ (7,032)	\$ (4,256)
NET LOSS PER SHARE - basic and diluted	(0.21)	(0.53)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING		
NET LOSS PER SHARE - basic and diluted	34,242,976	8,093,340

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)

	<u>Common stock</u>		<u>Series C Convertible Preferred Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
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	<u>8,326,648</u>	<u>1</u>	<u>1,718</u>	<u>*</u>	<u>219,266</u>	<u>(205,841)</u>	<u>13,426</u>

*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)

	<u>Common stock</u>		<u>Series C Convertible Preferred Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
BALANCE AT January 1, 2024	21,841,215	2	1,718	*	261,000	(221,501)	39,501
Net loss						(7,032)	(7,032)
Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 75,090 shares	1,571,170				2,618		2,618
BALANCE AT March 31, 2024	<u>23,412,385</u>	<u>2</u>	<u>1,718</u>	<u>*</u>	<u>263,618</u>	<u>(228,533)</u>	<u>35,087</u>

*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	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (7,032)	\$ (4,256)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	69	55
Change in fair value of markable securities, net of interest received	(218)	-
Change in liability for employees rights upon retirement	66	36
Other financial expenses	4	22
Change in operating right of use asset and operating leasing liability	(25)	(34)
Share-based compensation expenses	2,618	289
Loss on amounts funded in respect of employee rights upon retirement, net	14	23
Decrease in interest receivable on short term deposits	-	14
Changes in operating asset and liability items:		
Decrease in prepaid expenses	47	261
Decrease (Increase) in trade receivables	617	(383)
Decrease (Increase) in other receivables	165	(97)
Increase in inventory	(254)	(76)
Decrease in trade payables	(280)	(52)
Decrease in other payables	(855)	(633)
Net cash used in operating activities	<u>(5,064)</u>	<u>(4,831)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(195)	(25)
Investment in short-term bank deposits	-	(2,500)
Withdrawal from short-term bank deposits	-	7,000
Investments in marketable securities	(1,960)	-
Proceeds from matured marketable securities	7,000	-
Amounts funded in respect of employee rights upon retirement	(28)	(26)
Net cash provided by (used in) investing activities	<u>4,817</u>	<u>4,449</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net cash provided by (used in) financing activities	-	-
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS		
	<u>(4)</u>	<u>(22)</u>
DECREASE IN CASH AND CASH EQUIVALENTS	<u>(251)</u>	<u>(404)</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	<u>9,640</u>	<u>4,632</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	<u>\$ 9,389</u>	<u>\$ 4,228</u>

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

INSPIREMD, INC.
UNAUDITED NOTES TO 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 markets its product through distributors in international markets, mainly in Europe.

As of the date of issuance of these 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 product, CGuard™ EPS, reaches 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.

b. Risks Related to the Company’s Operations in Israel including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel’s war against them.

In October 2023, Israel was attacked by a terrorist organization and entered a state of war. As of the date of these consolidated financial statements, the war in Israel is ongoing and continues to evolve. The Company operations, including its production facility, are located in Israel. Currently, such activities in Israel remain largely unaffected. During the three months ended March 31, 2024, the impact of this war on the Company’s results of operations and financial condition was immaterial, but such impact may increase, which could be material, as a result of the continuation, escalation or expansion of such war.

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, 2024 and its results of operations, changes in equity and cash flows for the three months ended March 31, 2024 and 2023. 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, 2023, as found in the Company’s Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 5, 2024. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting pronouncements

In August 2020, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2020-06 “Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815 – 40).” This guidance simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. This ASU is effective for the Company for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company adopted the provisions of this update as of January 1, 2024 with no material impact on its consolidated financial statements.

Recently issued accounting pronouncement, not yet adopted

- 1) In November 2023, the FASB issued ASU 2023-07 “Segment Reporting: Improvements to Reportable Segment Disclosures”. This guidance expands public entities segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment’s profit or loss and assets. Public entities with a single reportable segment are required to provide the new disclosures and all the disclosures required under Accounting Standards Codification (“ASC”) 280. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments are required to be applied retrospectively to all prior periods presented in an entity’s financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements related disclosures.
- 2) In December 2023, the FASB issued ASU 2023-09 “Income Taxes (Topic 740): Improvements to Income Tax Disclosures”. This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

NOTE 4 – FAIR VALUE MEASUREMENTS

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

As of March 31, 2024				
(\$ in thousands)				
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents-				
Money market funds	\$ 3,745	\$ 3,745	\$ -	\$ -
Marketable securities-				
U.S government bonds	\$ 24,561	\$ -	\$ 24,561	\$ -
As of December 31, 2023				
(\$ in thousands)				
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents-				
Money market funds	\$ 7,094	\$ 7,094	\$ -	\$ -
Marketable securities-				
U.S government bonds	\$ 29,383	\$ -	\$ 29,383	\$ -

The Company's debt securities are classified within Level 2 because it uses quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair value.

The cost of marketable securities as of March 31, 2024 is \$23,878 thousand.

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.

As of March 31, 2024, and December 31, 2023, allowance for expected credit loss was immaterial.

NOTE 5 - MARKETABLE SECURITIES

The following table sets forth the Company's marketable securities for the indicated period:

	March 31, 2023	December 31, 2023
	(\$ in thousands)	
U.S government bonds	\$ 24,561	\$ 29,383

The following table summarizes the fair value of the Company's marketable securities classified by maturity as of March 31, 2024, and December 31, 2023:

	March 31, 2024	December 31, 2023
	(\$ in thousands)	
Amounts maturing within one year	\$ 23,573	\$ 24,523
Amounts maturing after one year through two years	988	4,860
	\$ 24,561	\$ 29,383

The table below sets forth a summary of the changes in the fair value of the Company's marketable securities for the three month period ended March 31, 2024:

	Three months ended March 31, 2024
	(\$ in thousands)
Balance at beginning of the period	\$ 29,383
Additions	1,960
Maturity	(7,000)
Interest Received	(75)
Changes in fair value during the period	293
Balance at end of the period	24,561

NOTE 6 - EQUITY:

- a. As of March 31, 2024, there were 1,718 shares of Series C preferred stock outstanding, convertible into an aggregate of 7,952 shares of the Company's common stock, with a total stated value of \$10,997.
- b. As of March 31, 2024, there are 15,254,623 outstanding pre-funded warrants.

c. As of March 31, 2024, the Company has outstanding warrants to purchase an aggregate of 53,396,008 shares of common stock as follows:

	Number of underlying Common stock	Exercise price
Series E Warrants	198,159	\$ 27.0000
Series F Warrants	433,878	\$ 7.4250
Series G Warrants	1,092,344	\$ 10.2300
Series H Warrants	12,914,086	\$ 1.3827
Series I Warrants	12,914,078	\$ 1.3827
Series J Warrants	12,914,086	\$ 1.3827
Series K Warrants	12,914,078	\$ 1.3827
Underwriter Warrants	15,299	\$ 7.4250
Total Warrants	53,396,008	\$

As of March 31, 2024, 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.

d. During the three months ended March 31, 2024, the Company granted 1,634,403 restricted shares of the Company’s common stock to employees and directors. The shares to employees are subject to a three-year vesting period, with one-third of such awards vesting each year. The shares to directors are subject to a one-year vesting period.

The fair value of the above restricted shares was approximately \$5.07 million.

During the three months ended March 31, 2024, the Company granted 563,499 restricted share units of the Company’s common stock to the chief executive officer. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted share units was approximately \$1.77 million

During the three months ended March 31, 2024, the Company granted to employees and directors options to purchase a total of 715,614 shares of the Company’s common stock. The options have an exercise prices ranging from \$2.71-\$3.14 per share, which was the fair market value of the Company’s common stock on the respective dates of the grant. The options to employees are subject to a three-year vesting period, with one-third of such awards vesting each year. The options to directors are subject to a one-year vesting period.

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 96.40%-119.38%; and risk-free interest rate ranging from 3.93%-4.10%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$1.85 million.

NOTE 7 – RELATED PARTIES TRANSACTIONS

During the three months ended March 31, 2024, a member of the immediate family of the CEO provided certain administrative services in connection with the Company's expansion to the U.S. in the amount of \$15 thousand.

NOTE 8 - 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, pre-funded warrants and fully vested restricted stock units outstanding during the period. The calculation of diluted net loss per share excludes the effect of potential dilution of share options, warrants, and unvested restricted stocks, unvested restricted stock units and Series C preferred stock as the effect is anti-dilutive.

For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the pre-funded warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them. For the three month period ended March 31, 2024, the Company had weighted average pre-funded warrants to purchase 15,254,623 share of common stock, which was used in the computation of net loss per share for the quarter.

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, which were excluded from the calculations of diluted loss per share were 62,556,668 and 2,773,675 for the three month period ended March 31, 2024 and 2023. This amount includes 4,611,500 and 342,766 of unvested restricted stock included in the number of issued and outstanding shares as of March 31, 2024 and 2023.

NOTE 9 - INVENTORY:

	March 31, 2024	December 31, 2023
	(\$ in thousands)	
Finished goods	\$ 73	\$ 210
Work in process	917	562
Raw materials and supplies	1,370	1,334
	<u>\$ 2,360</u>	<u>\$ 2,106</u>

NOTE 10 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2024	December 31, 2023
	(\$ in thousands)	
Employees and employee institutions	1,207	2,188
Accrued vacation and recreation pay	348	287
Accrued expenses	1,101	1,115
Clinical trial accrual	826	744
Current Operating lease liabilities	549	557
Other	187	190
	<u>\$ 4,218</u>	<u>\$ 5,081</u>

NOTE 11 - 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	
	2024	2023
	(\$ in thousands)	
Italy	\$ 295	\$ 267
Germany	242	214
Poland	152	119
Other	822	639
	\$ 1,511	\$ 1,239

By principal customers:

	Three months ended	
	March 31	
	2024	2023
Customer A	16%	17%
Customer B	12%	13%
Customer C	10%	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, 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;
- 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;
- market acceptance of our products;
- 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 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;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and 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;
- intense competition in our industry, with competitors having substantially 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;

- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or 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 instability in each jurisdiction;
- security, political and economic instability in the Middle East that could harm our business, including due to the current war between Israel and Hamas; 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. In January 2024, we received CE mark recertification under the EU’s Medical Device Regulation regulatory framework. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries.

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 (“CAS”). The study, which completed enrollment in June 2023, enrolled 316 patients across 24 trial sites in the U.S. and Europe and from April 2023 included deployment of the CGuard stent using CGuard Prime, our next generation CAS stent platform.

The primary endpoint is a composite of: (1) incidence of major adverse events including Death (all-cause mortality), any Stroke, and Myocardial Infarction (DSMI) through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure. All events are adjudicated by an independent clinical events committee. 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.

In November 2023, we announced positive 30-day follow up results from the C-GUARDIANS trial in which stenting with the CGuard Carotid Stent System in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%, measured from the date of the procedure through 30 days follow-up post-procedure. We anticipate reporting primary endpoint results from the C-GUARDIANS trial at the end of May 2024 that may support the submission of a premarket approval, or PMA, application in the third quarter of 2024 with a view to potential FDA approval of the CGuard Prime stent system in the first half of 2025.

We continue to invest in current and future potential new indications, products and manufacturing enhancements for CGuard that are expected to reduce cost of goods and/or provide the best-in-class performing delivery systems, such as CGuard Prime. In furtherance of our strategy that focuses on establishing the CGuard Carotid Stent System as a viable alternative to vascular surgery, we are developing a new transcrotid artery revascularization (TCAR) system, SwitchGuard™ neuroprotection system (“SwitchGuard NPS”), for transcrotid access and neuro protection. In addition, we intend to explore new indications for CGuard 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 Carotid Stent System and SwitchGuard NPS to be both symptomatic and asymptomatic individuals with diagnosed high-grade carotid artery stenosis 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, we estimate that the addressable market for CGuard Carotid Stent System and SwitchGuard NPS is approximately \$1.3 billion (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 treatment for all individuals diagnosed with high-grade carotid artery stenosis, we estimate the total available market for CGuard Carotid Stent System and SwitchGuard NPS to be approximately \$9.3 billion, which may grow over time if expanded treatment options such as CGuard Carotid Stent System and SwitchGuard NPS lead to increased patient screening for carotid artery disease.

In October 2023, the Centers for Medicare and Medicaid Service (“CMS”) issued its final National Coverage Determination (“NCD”), expanding coverage of CAS to include both asymptomatic and standard risk patients, significantly expanding the U.S. CAS addressable market.

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 Carotid Stent System and SwitchGuard NPS.

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

Recent Developments

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. In addition, since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with the Hezbollah terror organization) and southern border (with the Houthi movement in Yemen). It is possible that hostilities with Hezbollah in Lebanon will escalate, and that other terrorist organizations, including Palestinian military organizations in the West Bank as well as other hostile countries will join the hostilities. In addition, Iran recently launched a direct attack on Israel involving hundreds of drones and missiles and has threatened to continue to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. Such clashes may escalate in the future into a greater regional conflict. We cannot currently predict the intensity or duration of Israel's war against Hamas, nor can we predict how this war will ultimately affect our business and operations or Israel's economy in general.

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, 2023. There have not been any material changes to such critical accounting policies since December 31, 2023.

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

Results of Operations

Three months ended March 31, 2024, compared to the three months ended March 31, 2023

Revenues. For the three months ended March 31, 2024, revenue increased by \$272,000, or 22.0%, to \$1,511,000, from \$1,239,000 during the three months ended March 31, 2023. This increase was predominantly driven by growth in existing markets.

With respect to geographical regions, the increase in revenue was primarily attributable to a \$169,000 increase in Europe, a \$115,000 increase in Latin America, \$50,000 increase in Asia and a \$10,000 increase in other geographies, for reasons mentioned in the paragraph above. This increase was offset by a \$59,000 decrease in the United States as we completed in June 2023 the enrollment of all patients in our C-Guardians IDE clinical trial and accordingly there were no further enrollments in the three months ended March 31, 2024 and a \$13,000 decrease in other territories.

Gross Profit. For the three months ended March 31, 2024, gross profit (revenue less cost of revenues) decreased by \$81,000, or 21.6%, to \$292,000, from \$373,000 during the three months ended March 31, 2023. This decrease in gross profit resulted from a \$85,000 increase in training costs for new hires to build capacity for anticipated increased volume requirements, offset by \$4,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased to 19.4% during the three months ended March 31, 2024, from 30.1% during the three months ended March 31, 2023, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended March 31, 2024, research and development expenses increased by \$782,000, or 42.4%, to \$2,625,000, from \$1,843,000 during the three months ended March 31, 2023. This increase resulted primarily from an increase in compensation expenses of \$567,000, mainly due to an increase of share-based compensation-related expenses due to the expense recognition of grants made during the second quarter of 2023 and the first quarter of 2024 and due to the hiring of the Executive Vice President and General Manager of North America in connection with our expansion plans in the United States, an increase of \$159,000 related to an early feasibility study of CGuard Prime for the treatment of acute stroke patients with tandem lesions and an increase of \$56,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended March 31, 2024, selling and marketing expenses increased by \$449,000, or 57.0%, to \$1,237,000, from \$788,000 during the three months ended March 31, 2023. This increase resulted primarily from an increase in compensation expenses of \$381,000, mainly due to an increase of share-based compensation-related expenses due to the expense recognition of grants made during the second quarter of 2023 and the first quarter of 2024 and an increase of \$68,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended March 31, 2024, general and administrative expenses increased by \$1,721,000, or 81.1%, to \$3,844,000, from \$2,123,000 during the three months ended March 31, 2023. This increase resulted primarily from an increase in compensation expenses of \$1,682,000, mainly due to an increase of share-based compensation-related expenses due to the expense recognition of grants made during the second quarter of 2023 and the first quarter of 2024, and an increase of \$39,000 in miscellaneous expenses.

Financial Income. For the three months ended March 31, 2024, financial income increased by \$257,000 or 205.6%, to \$382,000, from \$125,000 during the three months ended March 31, 2023. The increase in financial income primarily resulted from a \$264,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Tax Expenses. For the three months ended March 31, 2024, there was no change in our tax expenses as compared to the three months ended March 31, 2023.

Net Loss. Our net loss increased by \$2,776,000, or 65.2%, to \$7,032,000, for the three months ended March 31, 2024, from \$4,256,000 during the three months ended March 31, 2023. The increase in net loss resulted primarily from an increase of \$2,952,000 in operating expenses and a decrease of \$81,000 in gross profit, partially offset by an increase of \$257,000 in financial income.

Liquidity and Capital Resources

As of March 31, 2024, 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 our products (primarily CGuard™ EPS) reach 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.

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.

In May 2023, we closed a private placement offering 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 that resulted in aggregate gross proceeds of approximately \$42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by us. If the Warrants issued in the private placement offering are exercised in cash in full this would result in an additional \$71.4 million of gross proceeds.

Three months ended March 31, 2024 compared to the Three months ended March 31, 2023

General. At March 31, 2024, we had cash and cash equivalents of \$9,389,000 and marketable securities of \$24,561,000 as compared to cash and cash equivalents of \$9,640,000 and short-term bank deposits of \$29,383,000 as of December 31, 2023. 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, 2024, net cash used in our operating activities increased by \$233,000, or 4.8%, to \$5,064,000, from \$4,831,000 during the same period in 2023. The primary reason for the increase in cash used in our operating activities was an increase of \$917,000 in payments for third party related expenses and for professional services, an increase of \$547,000 in compensation costs paid during the three months ended March 31, 2023, from \$3,128,000 in the three months ended March 31, 2023 to \$3,675,000 during the same period in 2024, offset in part by an increase of \$1,185,000 in payments received from customers, and an increase of \$46,000 in interest income received from money market funds and marketable securities.

Cash provided in our investing activities was \$4,817,000 during the three months ended March 31, 2024, compared to cash provided of \$4,449,000 during the three months ended March 31, 2023. The primary reason for the increase in cash provided by our investing activities is a withdrawal of marketable securities of \$5,040,000, net of investment in marketable securities in the three months ended March 31, 2024, compared to a withdrawal of short-term bank deposits of \$4,500,000, net of investment in short-term bank deposits in the three months ended March 31, 2023, offset by an increase of \$170,000 in payments made for purchase of property, plant and equipment during the three months ended March 31, 2024.

There was no cash provided by financing activities for the three months ended March 31, 2024 and for the three months ended March 31, 2023.

As of March 31, 2024, our current assets exceeded our current liabilities by a multiple of 7.9. Current assets decreased by \$5,648,000 during the period and current liabilities decreased by \$1,143,000 during the period. As a result, our working capital decreased by \$4,505,000 to \$33,634,000 as of March 31, 2024.

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, 2024, there were no material changes to our contractual obligations and commitments since the year ended December 31, 2023.

Recently Adopted and Issued Accounting Pronouncements

See Note 3 to our condensed financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q for new accounting pronouncements adopted.

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, 2024, 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, 2024.

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, 2024, 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 as set forth below in this Item 1A and the Risk Factors included in our previous filings made with the SEC, 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 5, 2024.

If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.

Our executive office, sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors.

In October 2023, Hamas terrorists infiltrated Israel’s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel’s border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel’s security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. In addition, since the commencement of these events, there have been continued hostilities along Israel’s northern border with Lebanon (with the Hezbollah terror organization) and southern border (with the Houthi movement in Yemen, as described below). It is possible that hostilities with Hezbollah in Lebanon will escalate, and that other terrorist organizations, including Palestinian military organizations in the West Bank as well as other hostile countries will join the hostilities. In addition, Iran recently launched a direct attack on Israel involving hundreds of drones and missiles and has threatened to continue to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Additionally, Yemeni rebel group, the Houthis, launched series of attacks on global shipping routes in the Red Sea, causing disruptions of supply chain. Such clashes may escalate in the future into a greater regional conflict.

In connection with the Israeli security cabinet’s declaration of war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service, including five full time employees in Israel of ours. Although many of such military reservists have since been released, including the majority of our employees, they may be called up for additional reserve duty, depending on developments in the war in Gaza and along Israel’s other borders. As of the date hereof, two of our non-management employees in Israel. Military service call ups that result in absences of personnel from us for an extended period of time may materially and adversely affect our business, prospects, financial condition and results of operations. As of the date hereof, we currently have 56 full-time employees located in Israel and 12 employees located outside of Israel.

Since the war broke out on October 7, 2023, our operations have not been adversely affected by this situation, and we have not experienced disruptions to our clinical studies. None of the clinical sites currently participating in our clinical studies are located in Israel however we currently manufacture our CGuard at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility or our ability to procure raw materials and ship our products, we would have no other means of manufacturing and distributing CGuard until we were able to restore the manufacturing and distribution capability at our facility or develop alternative manufacturing facilities and distribution capabilities.

The intensity and duration of Israel's current war against Hamas is difficult to predict at this stage, as are such war's economic implications on the Company's business and operations and on Israel's economy in general. If the war extends for a long period of time or expands to other fronts, such as Lebanon, Syria and the West Bank, our operations may be adversely affected.

Our commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several organizations and countries may restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

Finally, political conditions within Israel may affect our operations. Israel has held five general elections between 2019 and 2022, and prior to October 2023, the Israeli government pursued extensive changes to Israel's judicial system, which sparked extensive political debate and unrest. To date, these initiatives have been substantially put on hold. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and growth prospects.

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

During the quarter ended March 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

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)
3.11	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 13, 2023)
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 13, 2024

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

Date: May 13, 2024

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

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 13, 2024

/s/ Marvin Slosman

Marvin Slosman
Chief Executive Officer
(Principal Executive Officer)

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 13, 2024

/s/ Craig Shore

Craig Shore
Chief Financial Officer, Secretary and Treasurer
(Principal Financial and Accounting Officer)

**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, 2024 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 13, 2024

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

**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, 2024 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 13, 2024

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