

**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: **September 30, 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
(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 November 7, 2023: 21,549,639

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Item 1. Financial Statements

INSPIREMD, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED SEPTEMBER 30, 2023

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

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,839	\$ 4,632
Short-term bank deposits	-	13,171
Marketable securities	29,159	-
Accounts receivable:		
Trade, net	1,045	1,034
Other	363	213
Prepaid expenses	476	655
Inventory	1,846	1,621
TOTAL CURRENT ASSETS	46,728	21,326
NON-CURRENT ASSETS:		
Property, plant and equipment, net	907	917
Operating lease right of use assets	1,538	1,554
Fund in respect of employee rights upon retirement	847	856
TOTAL NON-CURRENT ASSETS	3,292	3,327
TOTAL ASSETS	\$ 50,020	\$ 24,653

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

	September 30, 2023	December 31, 2022
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	600	659
Other	4,090	4,411
TOTAL CURRENT LIABILITIES	4,690	5,070
LONG-TERM LIABILITIES-		
Operating lease liabilities	1,062	1,195
Liability for employees' rights upon retirement	1,011	995
TOTAL LONG-TERM LIABILITIES	2,073	2,190
COMMITMENTS AND CONTINGENT LIABILITIES		
TOTAL LIABILITIES	6,763	7,260
EQUITY:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at September 30, 2023 and December 31, 2022; 21,400,163 and 8,330,918 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2	1
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at September 30, 2023 and December 31, 2022; 1,718 shares issued and outstanding at September 30, 2023 and December 31 2022, respectively	*	*
Additional paid-in capital	259,351	218,977
Accumulated deficit	(216,096)	(201,585)
Total equity	43,257	17,393
Total liabilities and equity	\$ 50,020	\$ 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)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
REVENUES	\$ 1,556	1,431	\$ 4,444	\$ 4,145
COST OF REVENUES	1,118	1,065	3,142	3,226
GROSS PROFIT	438	366	1,302	919
OPERATING EXPENSES:				
Research and development	2,110	2,061	5,946	5,797
Selling and marketing	876	845	2,556	2,577
General and administrative	3,091	2,070	8,135	6,322
Total operating expenses	6,077	4,976	16,637	14,696
LOSS FROM OPERATIONS	(5,639)	(4,610)	(15,335)	(13,777)
FINANCIAL INCOME, net:	461	81	824	131
NET LOSS	\$ (5,178)	(4,529)	\$ (14,511)	\$ (13,646)
NET LOSS PER SHARE - basic and diluted	\$ (0.15)	(0.58)	\$ (0.69)	\$ (1.75)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	33,984,953	7,838,506	21,148,538	7,816,974

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, 2022	8,296,256	1	1,718	*	216,625	(183,094)	33,532
Net loss						(13,646)	(13,646)
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 6,144 shares	39,350				1,984		1,984
BALANCE AT September 30, 2022	<u>8,335,606</u>	<u>1</u>	<u>1,718</u>	*	<u>218,609</u>	<u>(196,740)</u>	<u>21,870</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 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 July 1, 2022	8,323,200	1	1,718	*	217,952	(192,211)	25,742
Net loss						(4,529)	(4,529)
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 1,581 shares	12,406				657		657
BALANCE AT September 30, 2022	<u>8,335,606</u>	<u>1</u>	<u>1,718</u>	<u>*</u>	<u>218,609</u>	<u>(196,740)</u>	<u>21,870</u>

* Represents an amount less than \$1 thousand

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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						(14,511)	(14,511)
Issuance of common shares, pre-funded warrants and warrants, net of \$4,635 issuance costs	10,266,270	1			37,533		37,534
Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 14,019 shares	2,802,975	*			2,841		2,841
BALANCE AT September 30, 2023	<u>21,400,163</u>	<u>2</u>	<u>1,718</u>	<u>*</u>	<u>259,351</u>	<u>(216,096)</u>	<u>43,257</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 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 July 1, 2023	21,192,204	2	1,718	*	257,729	(210,918)	46,813
Net loss						(5,178)	(5,178)
Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 9,749 shares	207,959	*			1,622		1,622
BALANCE AT September 30, 2023	21,400,163	2	1,718	*	259,351	(216,096)	43,257

* 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)

	Nine months ended September 30	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	(14,511)	\$ (13,646)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	171	134
Gain from sale of property, plant and equipment	(4)	-
Loss on amounts funded in respect of employee rights upon retirement	70	114
Changes in fair value of marketable securities	(321)	
Change in liability for employees' rights upon retirement	16	(83)
Other financial expenses	72	138
Change in operating right of use asset and leasing liability	(39)	(78)
Share-based compensation expenses	2,841	1,984
Decrease (increase) in interest receivable on short term deposits	171	(75)
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	179	(198)
Decrease (increase) in trade receivables	(11)	58
Increase in other receivables	(150)	(42)
Increase in inventory	(225)	(271)
Decrease in trade payables	(59)	(489)
Increase (decrease) in other payables	(399)	107
Net cash used in operating activities	<u>(12,199)</u>	<u>(12,347)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in short-term bank deposits	(5,500)	(17,000)
Purchase of property, plant and equipment	(166)	(378)
Proceeds from sale of property, plant and equipment	9	-
Investments in marketable securities	(28,838)	-
Withdrawal from short-term bank deposits	18,500	22,000
Amounts funded in respect of employee rights upon retirement	(61)	(67)
Net cash provided by (used in) investing activities	<u>(16,056)</u>	<u>4,555</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance costs of At The Market offering	-	(140)
Proceeds from issuance of shares and warrants net of \$4,635 issuance costs,	37,534	-
Net cash provided by (used in) financing activities	<u>37,534</u>	<u>(140)</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	<u>(72)</u>	<u>(138)</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	9,207	(8,070)
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	<u>\$ 13,839</u>	<u>\$ 3,934</u>
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	419	835
Non-cash lease incentive	45	
Decrease in right-of-use assets and lease liabilities due to shortening lease term	131	

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

INSPIREMD, INC.
NOTES TO THE CONDENSED 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.

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. 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 (“EU”) nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, the Company must comply with EU law on medical devices, which, until May 26, 2021 was governed by the Medical Device Directive 93/42/EEC (“MDD”), by presenting comprehensive technical files for 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 European Medical Device Regulation (MDR 2017/745) (“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 EU. 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.

c. Risks Related to Our 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, 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 the 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 thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas and other terrorist organizations in parallel to their continued rocket and terror attacks. The Company cannot currently predict the intensity or duration of Israel's war against Hamas, nor can predict how this war will ultimately affect the Company's business and operations or Israel's economy in general.

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 nine and three months ended September 30, 2023, the Company's sales to Russia and Belarus were 13.1% and 19.6% ,respectively, compared to 11.9% and 21.5% in the nine and three months ended September 30, 2022, 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 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 for the year ended December 31, 2022. In the opinion of the Company, all adjustments considered necessary for a fair statement of the results of the interim periods reported herein have been included (consisting only of normal recurring adjustments). These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 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 and nine months ended September 30, 2023, are not necessarily indicative of results that could be expected for the entire fiscal year.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of September 30, 2023, cash and cash equivalents consisted of cash, short-term deposits (up to three months from the date of deposit) and money market funds. As of December 31, 2022, this balance consisted solely of cash.

Marketable securities

Marketable securities consist of debt securities. The Company elected the fair value option to measure and recognize its investments in debt securities in accordance with ASC 825, Financial Instruments as the Company manages its portfolio and evaluates the performance on a fair value basis. Changes in fair value, realized gains and losses on sales of marketable securities, are reflected in the statements of operation as finance expense (income), net.

NOTE 3 - NEW ACCOUNTING PRONOUNCEMENT

Recently adopted accounting pronouncement

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 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.

Recently issued accounting pronouncement, not yet adopted

In August 2020, the FASB issued 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 is currently evaluating the impact of the adoption of ASU 2020-06 on the Company's consolidated financial statements.

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 September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents-				
Money market funds	<u>\$ 7,268</u>	<u>\$ 7,268</u>	<u>\$ -</u>	<u>\$ -</u>
Marketable securities-				
U.S government bonds	<u>\$ 29,159</u>	<u>\$ -</u>	<u>\$ 29,159</u>	<u>\$ -</u>

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 September 30, 2023 is \$28,838 thousands.

NOTE 5 - MARKETABLE SECURITIES

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(\$ in thousands)</u>	
U.S government bonds	\$ 29,159	\$ -

The following table summarizes the fair value of the Company's marketable securities classified by maturity as of September 30, 2023, and December 31, 2022:

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(\$ in thousands)</u>	
Amounts maturing within one year	\$ 23,417	\$ -
Amounts maturing after one year through two years	5,742	-
	<u>\$ 29,159</u>	<u>\$ -</u>

The table below sets forth a summary of the changes in the fair value of the Company's marketable securities for the nine months period ended September 30, 2023:

	<u>Nine months ended</u> <u>September 30,</u> <u>2023</u>
	<u>(\$ in thousands)</u>
Balance at beginning of the period	\$ -
Additions	28,838
Sale or maturity	-
Changes in fair value during the period	321
Balance at end of the period	<u>29,159</u>

NOTE 6 - EQUITY:**a. Private Placement**

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 12,914,078 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 Private Placement Offering closed on May 16, 2023.

Aggregate gross proceeds to the Company in respect of the Private Placement Offering were \$42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company which amounted to approximately \$4.6 million. If the Warrants are exercised in cash in full this would result in an additional \$71.4 million of gross proceeds.

The Pre-Funded Warrants are immediately exercisable at an exercise price of \$0.0001 per share and will not expire until exercised in full. The Warrants are immediately exercisable upon issuance at an exercise price of \$1.3827 per share. 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 (PMA) from the Food and Drug Administration, or 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 transcatheter system and CGuard Prime 80 cm 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 begin. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the warrants.

As of September 30, 2023, there are 15,561,894 outstanding Pre-Funded Warrants.

Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company’s Series C Preferred Stock, the conversion price of the outstanding shares of the Series C Preferred Stock was reduced to \$1.3827 per share, effective as of the date of the securities purchase agreement entered for the Offering, and the number of shares of common stock issuable upon conversion of the Series Series C Preferred Stock increased by 5,668 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 1,718 shares of Series C Preferred Stock outstanding as of May 16, 2023.

As of September 30, 2023, 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.

- b. As of September 30, 2023, 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 September 30, 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.

- c. During the nine months ended September 30, 2023, the Company granted 2,774,600 restricted shares of the Company's common stock to employees and directors. 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 shares was approximately \$5.23 million.

- d. During the nine months ended September 30, 2023, the Company granted 1,045,150 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 \$1,839 thousand.

- e. On January 6, 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 5.125-6.5 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.

On May 17, 2023, the Company granted to employees and directors options to purchase a total of 1,011,930 shares of the Company's common stock. The options have an exercise prices of \$1.76 per share, which was the fair market value of the Company's common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

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 of 116.76%-123.30%; and risk-free interest rate of 3.58%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$1.56 million.

On May 17, 2023, the Company granted to consultants options to purchase a total of 575,000 shares of the Company's common stock. The options have an exercise price of \$1.76 per share, which was the fair market value of the Company's common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

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 of 116.76%-123.30%; and risk-free interest rate of 3.58%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$885 thousand.

On August 28, 2023 and September 10, 2023 the Company granted to employees options to purchase a total of 38,740 shares of the Company's common stock. The options have an exercise prices of \$3.37-\$3.57 per share, which was the fair market value of the Company's common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

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 of 114.25%-123.07%; and risk-free interest rate of 4.34%-4.39%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$120,000 thousand.

f. Election to Receive Shares of Common Stock in lieu of Cash Compensation

Beginning on January 1, 2023, non-employee directors may elect to receive all or a portion of their cash retainer amount in shares of the Company's common stock under the 2021 Equity Incentive Plan. If a director makes that election, a stock award under the 2021 Equity Incentive Plan will be paid quarterly on the first day of each next quarter ("Issuance Dates") and will become fully vested on the Issuance Dates. The stock award will be determined by dividing (x) the product of the cash retainer amount and percentage of the cash retainer amount elected to be taken in shares by (y) the "Fair Market Value" (as defined in the 2021 Equity Incentive Plan) of a share on the Issuance Dates. If a director's service on the board terminates for any reasons prior to an Issuance Date, he/she will receive a pro rata portion of shares or cash based on the number of days served on the board during the relevant quarter.

On April 1, 2023, the Company issued 29,746 shares of common stock to non-employee directors who elected to receive all or a portion of their cash retainer amount for the three months ended March 31, 2023 in shares of the Company's common stock under the 2021 Equity Incentive Plan.

On July 1, 2023, the Company issued 12,648 shares of common stock to non-employee directors who elected to receive all or a portion of their cash retainer amount for the three months ended June 30, 2023 in shares of the Company's common stock under the 2021 Equity Incentive Plan.

As of September 30, 2023, there was an accrual for \$55,000 for director's fees for the three months ended September 30, 2023. Out of this an amount of \$22,875 will be paid in cash and \$32,125 will be issued in shares of the Company's common stock under the 2021 Equity Incentive Plan and accordingly On October 1, 2023 the company issued 9,735 shares.

NOTE 7 – RELATED PARTIES TRANSACTIONS

- 1) During the nine and three months ended September 30, 2022, a consulting company whose founder and CEO is a member of the company's board of directors, provided certain marketing services in the amount of \$9,276 and \$500, respectively. During the nine and three months ended September 30, 2023, no marketing services were provided.
- 2) On September 15, 2023, the board approved the company's entry into a consultancy agreement with a member of the immediate family of the CEO for certain administrative projects in connection with the Company's expansion to the U.S. until a full-time Company employee is retained in such capacity. Pursuant to the Consultancy Agreement, the Company will pay a fixed hourly fee of \$50 for a maximum of 20 hours per week and customary expenses. The Company may terminate this Agreement for any reason or no reason, at any time, upon 30 days prior written notice to consultant.

Consulting expenses for the nine and three-month periods ended September 30, 2023, were \$4,000.

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 potential share issuances of common stock upon the exercise 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 nine and three-month periods ended September 30, 2023, we had weighted average Pre-funded Warrants of 7,866,452 and 15,561,894, respectively, which were used in the computations of net loss per share for the nine and three-month periods.

The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 75,315,352 for the nine and three-month periods ended September 30, 2023. This amount includes 3,073,821 of unvested restricted stock included in the number of issued and outstanding shares as of September 30, 2023.

The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 2,932,284 for the nine and three month periods ended September 30, 2022. This amount includes 497,767 of unvested restricted stock included in the number of issued and outstanding shares as of September 30, 2022.

NOTE 9 – LEASE AGREEMENTS

- 1) The Company’s Israeli subsidiary has a lease agreement for a facility in Israel, which expires on December 31, 2026. On August 24, 2023, the Company amended the lease agreement mentioned above, leasing additional space in the facility and shortened the lease term of another space in the building. The balances of right of use assets and lease liabilities increased due to the newly leased space and decreased due to the lease that was shortened.
- 2) Operating lease cost for the nine and three-month periods ended September 30, 2023 were \$337,000 and \$112,000 respectively

Supplemental information related to leases are as follows:

	September 30	December 31
	2023	2022
	(\$ in thousands)	(\$ in thousands)
Operating lease right-of-use assets	1,538	1,554
Current operating lease liabilities	(497)	(419)
Non-current operating lease liabilities	(1,062)	(1,195)
Weighted Average Remaining Lease Term	3.25	4
Weighted Average Discount Rate	9.73%	8.69%

Other information:

	Nine months ended September 30, 2023	Twelve months ended December 31, 2022
Operating cash flows from operating leases (cash paid in thousands)	(307)	(436)

Maturities of lease liabilities are as follows:

	Amount (\$ in thousands)
2023	113
2024	536
2025	541
2026	606
Total lease payments	1,796
Less imputed interest	(237)
Total	1,559

NOTE 10 - FINANCIAL INSTRUMENTS:

a. Fair value of financial instruments

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

b. As of September 30, 2023, and December 31, 2022, allowance for expected credit loss was immaterial.

NOTE 11- INVENTORY:

	September 30, 2023	December 31, 2022
	(\$ in thousands)	
Finished goods	\$ 191	\$ 179
Work in process	634	510
Raw materials and supplies	1,021	932
	\$ 1,846	\$ 1,621

NOTE 12 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	September 30, 2023	December 31, 2022
(\$ in thousands)		
Employees and employee institutions	1,571	1,853
Accrued vacation and recreation pay	273	197
Accrued expenses	926	554
Clinical trial accrual	708	1,258
Current Operating lease liabilities	497	419
Other	115	130
	<u>4,090</u>	<u>4,411</u>

NOTE 13 - 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(\$ in thousands)			
Italy	\$ 328	\$ 240	\$ 932	\$ 713
Russia	250	250	483	381
Germany	209	191	699	866
Other	769	750	2,330	2,185
	<u>\$ 1,556</u>	<u>\$ 1,431</u>	<u>\$ 4,444</u>	<u>\$ 4,145</u>

By product:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
	(\$ in thousands)			
CGuard	\$ 1,556	\$ 1,431	\$ 4,444	\$ 4,097
MGuard	-	-	-	48
	<u>\$ 1,556</u>	<u>\$ 1,431</u>	<u>\$ 4,444</u>	<u>\$ 4,145</u>

By principal customers:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Customer A	16%	17%	11%	9%
Customer B	13%	13%	16%	21%
Customer C	13%	7%	10%	8%
Customer D	8%	9%	11%	9%

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 our 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;
- 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. 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 Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial was designed to enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication. 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 June 2023, we completed enrollment of 316 patients across 24 trial sites in the U.S. and Europe in our IDE clinical trial.

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, $\geq 70\%$ 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. Under the terms of the Pre-Funded Warrants and Warrants, certain of the selling stockholders may not exercise the Pre-Funded Warrants or Warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99% of our then outstanding common stock following such exercise, excluding for purposes of such determination common stock issuable upon exercise of the Pre-Funded Warrants or Warrants which have not been exercised. The Warrants may be exercised into pre-funded warrants if the selling stockholder is unable to exercise the Warrant due to the foregoing beneficial ownership limitation or at the selling shareholder's election.

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, or if we fail to maintain the effectiveness of the Registration Statement. The Registration Statement was subsequently filed on May 23, 2023 and declared effective on June 1, 2023. We paid LifeSci Capital LLC, a placement fee equal to 5.6% of the aggregate gross proceeds from the closing of the Private Placement Offering, or approximately \$2.4 million, and legal expenses of \$41,600. In addition, we paid Piper Sandler & Co. a financial advisory fee of \$1.5 million, AGP/Alliance Global Partners a financial advisory fee of \$250,000 and lead investor counsel expenses of \$125,000.

30-Day Results from the U.S. Investigational Device Exemption (IDE) clinical trial

On November 1, 2023, the Company released 30-day results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial. From July 2021 to June 2023, 316 patients were prospectively enrolled in a single-arm carotid artery stenting study performed at 24 sites in the United States and the European Union. The primary endpoint in the clinical trial was a composite of: (1) incidence of major adverse events including death (all-cause mortality), any stroke, or myocardial infarction ("DSMI") through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure. Stenting with the C-Guard 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.

Recent Developments Potentially Affecting Our Business.

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 the 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 thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and commenced a military campaign against Hamas and other terrorist organizations in parallel to their continued rocket and terror attacks. 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, 2022. Other than the following new accounting policies, there have not been any material changes to such critical accounting policies since December 31, 2022.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of September 30, 2023, cash and cash equivalents consisted of cash, short-term deposits (up to three months from the date of deposit) and money market funds. As of December 31, 2022, this balance consisted solely of cash.

Marketable securities

Marketable securities consist of debt securities. we elected the fair value option to measure and recognize its investments in debt securities in accordance with ASC 825, Financial Instruments as we manage our portfolio and evaluates the performance on a fair value basis. Changes in fair value, realized gains and losses on sales of marketable securities, are reflected in the statements of operation as finance expense (income), net.

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 September 30, 2023, compared to the three months ended September 30, 2022

Revenues. For the three months ended September 30, 2023, revenue increased by \$125,000, or 8.7%, to \$1,556,000, from \$1,431,000 during the three months ended September 30, 2022. This increase was predominantly driven by growth in existing markets.

With respect to geographical regions, the increase in revenue was primarily attributable to a \$84,000 increase in Europe, a \$52,000 increase in Asia and a \$30,000 increase in other geographies, for reasons mentioned in the paragraph above. This increase was offset by a \$41,000 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 September 30, 2023.

Gross Profit. For the three months ended September 30, 2023, gross profit (revenue less cost of revenues) increased by \$72,000, or 19.7%, to \$438,000, from \$366,000 during the three months ended September 30, 2022. This increase in gross profit resulted from a \$85,000 increase in revenues less the associated related material and labor offset by \$13,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 28.1% during the three months ended September 30, 2023, from 25.6% during the three months ended September 30, 2022, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended September 30, 2023, research and development expenses increased by \$49,000, or 2.4%, to \$2,110,000, from \$2,061,000 during the three months ended September 30, 2022. This increase resulted primarily from an increase of \$178,000 in expenses related to the SwitchGuard regulatory and approval process, an increase in compensation expenses of \$145,000, 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 an increase of \$107,000 in miscellaneous expenses. These increases were partially offset by a \$381,000 decrease in expenses related to the C-Guardians FDA study. The enrollment of all patients in our IDE clinical trial was completed in June 2023, resulting in no enrollment expenses for the three months ended September 30, 2023.

Selling and Marketing Expenses. For the three months ended September 30, 2023, selling and marketing expenses increased by \$31,000, or 3.7%, to \$876,000, from \$845,000 during the three months ended September 30, 2022. This increase resulted from an increase of \$31,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended September 30, 2023, general and administrative expenses increased by \$1,021,000, or 49.3%, to \$3,091,000, from \$2,070,000 during the three months ended September 30, 2022. This increase resulted primarily from an increase in compensation expenses of \$941,000, mainly due to an increase of approximately \$755,000 of share-based compensation-related expenses due to the expense recognition of grants made during the second quarter of 2023 and an increase in salary expenses and related accruals of \$186,000 mainly due to hiring of a General Manager of North America and VP of Global Marketing (who was subsequently promoted to the Company's Chief Commercial Officer in the third quarter of 2023) and an increase of \$80,000 in miscellaneous expenses.

Financial Income. For the three months ended September 30, 2023, financial income increased by \$380,000, to \$461,000, from \$81,000 during the three months ended September 30, 2022. The increase in financial income primarily resulted from a \$412,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Tax Expenses. For the three months ended September 30, 2023, there was no change in our tax expenses as compared to the three months ended September 30, 2022.

Net Loss. Our net loss increased by \$649,000, or 14.3%, to \$5,178,000, for the three months ended September 30, 2023, from \$4,529,000 during the three months ended September 30, 2022. The increase in net loss resulted primarily from an increase of \$1,101,000 in operating expenses partially offset by an increase of \$380,000 in financial income and an increase of \$72,000 in gross profit.

Nine months ended September 30, 2023, compared to the Nine months ended September 30, 2022

Revenues. For the nine months ended September 30, 2023, revenue increased by \$299,000, or 7.2%, to \$4,444,000, from \$4,145,000 during the Nine months ended September 30, 2022. This increase was predominantly driven by a 8.5% increase in sales volume of CGuard EPS from \$4,097,000 during the nine months ended September 30, 2022, to \$4,444,000 during the nine months ended September 30, 2023. This sales increase was mainly due to growth in existing markets.

With respect to geographical regions, the increase in revenue was primarily attributable to a \$251,000 increase in Europe, a \$90,000 increase in Asia, and a \$4,000 increase in the Middle East. This increase in sales was partially offset by a \$46,000 decrease in other geographies mainly driven by 41,000 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 September 30, 2023.

Gross Profit. For the nine months ended September 30, 2023, gross profit (revenue less cost of revenues) increased by 41.7%, or \$383,000, to \$1,302,000, compared to a \$919,000 for the same period in 2022. This increase in gross profit resulted from a \$246,000 increase in revenues less the associated related material and labor costs and a decrease in write-offs of \$199,000. This increase was partially offset by an increase of \$62,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 29.3% during the nine months ended September 30, 2023, from 22.2% during the Nine months ended September 30, 2022, driven by the reasons mentioned above.

Research and Development Expenses. *Research and Development Expenses.* For the nine months ended September 30, 2023, research and development expenses increased by 2.6%, or \$149,000, to \$5,946,000, from \$5,797,000 during the nine months ended September 30, 2022. This increase resulted primarily from an increase of compensation expenses of \$314,000, an increase of \$187,000 in expenses related to the SwitchGuard regulatory and approval process, an increase of \$130,000 in expenses related to the CGuard Prime regulatory and approval process and an increase of \$261,000 in miscellaneous expenses offset, in part, by a decrease of \$743,000 in expenses related to the C-Guardians FDA study.

Selling and Marketing Expenses. For the nine months ended September 30, 2023, selling and marketing expenses decreased by 0.8%, or \$21,000, to \$2,556,000, from \$2,577,000 during the nine months ended September 30, 2022. This decrease resulted from a decrease of \$21,000 in miscellaneous expenses.

General and Administrative Expenses. For the nine months ended September 30, 2023, general and administrative expenses increased by 28.7%, or \$1,813,000, to \$8,135,000, from \$6,322,000 during the nine months ended September 30, 2022. This increase resulted primarily from an increase in compensation expenses of \$1,148,000, mainly due to an increase of approximately \$702,000 of share-based compensation-related expenses due to the expense recognition of grants made during the second quarter of 2023 and an increase in salary expenses and related accruals of \$446,000 mainly due to hiring of a General Manager of North America and VP of Global Marketing (who was subsequently promoted to the Company's Chief Commercial Officer in the third quarter of 2023), an increase in legal expenses of \$254,000, an increase in regulatory expenses of \$215,000 related to MDR registration process and an increase of \$196,000 in miscellaneous expenses.

Financial Income. For the nine months ended September 30, 2023, financial income increased by \$693,000, to \$824,000 of financial income, from \$131,000 of financial income during the nine months ended September 30, 2022. The increase in financial income primarily resulted from a \$689,000 increase in interest income from investment in marketable securities, money market funds and short-term bank deposits.

Tax Expenses. For the nine months ended September 30, 2023, there was no change in our tax expenses as compared to the nine months ended September 30, 2022.

Net Loss. Our net loss increased by \$865,000, or 6.3%, to \$14,511,000, for the nine months ended September 30, 2023, from \$13,646,000 during the nine months ended September 30, 2022. The increase in net loss resulted primarily from an increase of \$1,941,000 in operating expenses, offset by an increase of \$693,000 in financial income and increase of \$383,000 in gross profit.

Liquidity and Capital Resources

As of September 30, 2023, 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 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 the Company. If the Warrants from the Private Placement Offering are exercised in cash in full this would result in an additional \$71.4 million of gross proceeds.

Nine months ended September 30, 2023 compared to the Nine months ended September 30, 2022

General. At September 30, 2023, we had cash and cash equivalents of \$13,839,000 and marketable securities of \$29,159,000 as compared to cash and cash equivalents of \$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 nine months ended September 30, 2023, net cash used in our operating activities decreased by \$148,000, or 1.2%, to \$12,199,000, from \$12,347,000 during the same period in 2022. The primary reason for the decrease in cash used in our operating activities was an increase of \$613,000 in interest income received from money market funds and short-term bank deposits, an increase of \$298,000 in payments received from customers, to \$4,433,000 during the nine months ended September 30, 2023 from \$4,135,000 during the same period in 2022, offset in part by an increase of \$637,000 in compensation costs paid during the nine months ended September 30, 2023 from \$6,695,000 in the nine months ended June 30, 2022 to \$7,332,000 during the same period in 2023 and an increase of \$127,000 in payments for third party related expenses and for professional services.

Cash used in our investing activities was \$16,056,000 during the nine months ended September 30, 2023, compared to cash provided of \$4,555,000 during the nine months ended September 30, 2022. The primary reason for the increase in cash used by our investing activities is an investment in marketable securities of \$28,838,000, offset by an increase in withdrawal from short-term bank deposits, net of investment in short-term deposits, of \$8,000,000, and a decrease of \$212,000 in payments made for purchase of property, plant and equipment during the nine months ended September 30, 2023.

Cash provided by financing activities for the nine months September 30, 2023, was \$37,534,000. The principal source of the cash provided by financing activities during the nine months ended September 30, 2023 were the proceeds from the Private Placement Offering in May 2023 that resulted in approximately \$37,534,000 of aggregate net proceeds. Cash used by financing activities for the nine months ended September 30, 2022 was \$140,000, the cash used by financing activities during the nine months ended September 30, 2022 were due to issuance costs associated with a shelf registration statement on Form S-3 filed with the SEC on June 3, 2022.

As of September 30, 2023, our current assets exceeded our current liabilities by a multiple of 10.0. Current assets increased by \$25,402,000 during the period and current liabilities decreased by \$380,000 during the period. As a result, our working capital increased by \$25,782,000 to \$42,038,000 as of September 30, 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 September 30, 2023, there were no material changes to our contractual obligations and commitments.

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 September 30, 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 September 30, 2023.

Changes in Internal Control over Financial Reporting

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

Security, political and economic instability in the Middle East may harm our business.

Our principal research and development facilities and sole manufacturing facility are located in Israel. In addition, part of our key employees, officers and directors are residents of Israel. Accordingly, political, economic and military conditions in the Middle East may affect our business directly. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region, including Hamas (an Islamist militia and political group in the Gaza Strip) and Hezbollah (an Islamist militia and political group in Lebanon).

In particular, 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 the 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 thousands of deaths and injuries, and Hamas additionally kidnapped many Israeli civilians and soldiers. Following the attack, Israel’s security cabinet declared war against Hamas and commenced a military campaign against Hamas and these terrorist organizations in parallel to their continued rocket and terror attacks.

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.

Additionally, political uprisings, social unrest and violence in various countries in the Middle East, including Israel’s neighbor Syria, have affected the political stability of those countries. This instability may lead to deterioration of the political relationships that exist between Israel and certain countries and have raised concerns regarding security in the region and the potential for armed conflict. In addition, Iran has threatened to attack Israel. Iran is also believed to have a strong influence among the Syrian government, Hamas and Hezbollah. These situations may potentially escalate in the future into more violent events which may affect Israel and us. These situations, including conflicts which involved missile strikes against civilian targets in various parts of Israel have in the past negatively affected business conditions in Israel.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could have a material adverse effect on our business. The political and security situation in Israel may result in parties with whom we have contracts claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions. These or other Israeli political or economic factors could harm our operations and product development. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations and could make it more difficult for us to raise capital. We could experience disruptions if acts associated with such conflicts result in any serious damage to our facilities. Furthermore, several countries, as well as certain companies and organizations, continue to restrict business with Israel and Israeli companies, which could have an adverse effect on our business and financial condition. Our business interruption insurance may not adequately compensate us for losses, if at all, that may occur as a result of an event associated with a security situation in the Middle East, and any losses or damages incurred by us could have a material adverse effect on our business.

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 September 30, 2023, 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

<u>Exhibit No.</u>	<u>Description</u>
3.1	<u>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)</u>
3.2	<u>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)</u>
3.3	<u>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)</u>
3.4	<u>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)</u>
3.5	<u>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)</u>
3.6	<u>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)</u>
3.7	<u>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)</u>
3.8	<u>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)</u>
3.9	<u>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)</u>
3.10	<u>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)</u>
3.11	<u>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)</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
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: November 6, 2023

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

Date: November 6, 2023

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: November 6, 2023

/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: November 6, 2023

/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 September 30, 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: November 6, 2023

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 September 30, 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: November 6, 2023

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