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, 2025

OR

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

For the transition period from to

Commission file number: 001-35731

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

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

6303 Waterford District Drive
Suite 215
Miami, Florida 33126
(Address of principal executive offices)
(Zip Code)

(888) 776-6804
(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 ☒	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 10, 2025: 42,370,995

Item 1. Financial Statements

INSPIREMD, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED SEPTEMBER 30, 2025

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 63,403	$ 18,916
Marketable securities	-	15,721
Accounts receivable:		
Trade, net	1,961	1,572
Other	475	682
Prepaid expenses	945	1,060
Inventory	3,607	2,570
TOTAL CURRENT ASSETS	70,391	40,521
NON-CURRENT ASSETS:		
Long term deposit	438	426
Property, plant and equipment, net	3,403	2,371
Operating lease right of use assets	2,915	2,360
Fund in respect of employee rights upon retirement	1,325	1,129
TOTAL NON-CURRENT ASSETS	8,081	6,286
TOTAL ASSETS	$ 78,472	$ 46,807

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

	September 30, 2025	December 31, 2024
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	1,753	1,254
Other	9,063	6,424
TOTAL CURRENT LIABILITIES	10,816	7,678
LONG-TERM LIABILITIES-		
Operating lease liabilities net of current maturities	2,367	1,796
Liability for employees' rights upon retirement and others	1,175	1,247
TOTAL LONG-TERM LIABILITIES	3,542	3,043
TOTAL LIABILITIES	14,358	10,721
COMMITMENTS AND CONTINGENT LIABILITIES		
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2025 and December 31, 2024; 41,919,141 and 26,611,033 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	4	3
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2025 and December 31, 2024; 1,718 shares issued and outstanding at September 30, 2025 and December 31 2024, respectively	*	*
Additional paid-in capital	354,641	289,589
Accumulated deficit	(290,531)	(253,506)
Total equity	64,114	36,086
Total liabilities and equity	$ 78,472	$ 46,807

* Represents an amount less than $1 thousand

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
REVENUES	$ 2,523	$ 1,810	$ 5,830	$ 5,060
COST OF REVENUES	1,659	1,396	4,361	4,023
GROSS PROFIT	864	414	1,469	1,037
OPERATING EXPENSES:				
Research and development	3,635	3,915	11,528	9,941
Selling and marketing	4,392	1,472	11,314	4,154
General and administrative	5,888	3,489	16,157	11,078
Total operating expenses	13,915	8,876	38,999	25,173
LOSS FROM OPERATIONS	(13,051)	(8,462)	(37,530)	(24,136)
FINANCIAL INCOME, net:	343	572	505	1,305
NET LOSS	$ (12,708)	$ (7,890)	$ (37,025)	$ (22,831)
NET LOSS PER SHARE - basic and diluted	$ (0.17)	$ (0.16)	$ (0.64)	$ (0.58)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	73,466,501	48,369,412	58,245,368	39,413,004

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INSPIREMD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(Unaudited)
(U.S. dollars in thousands, except share data)

	Common stock		Preferred C shares		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2024	**21,841,215**	**2**	**1,718**	*****	**261,000**	**(221,501)**	**39,501**
Net loss						**(22,831)**	**(22,831)**
Exercise of pre-funded warrants	**1,728,382**	*****					*****
Exercise of Warrants Series H to 12,621,090 pre-funded warrants and 292,996 common stock, net of $1,000 issuance costs	**292,996**	**1**			**16,853**		**16,854**
Issuance of common shares, Included at the market offering net of $1 issuance costs	**12,961**				**35**		**35**
Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 112,382 shares	**1,844,078**	*****			**7,792**		**7,792**
BALANCE AT September 30, 2024	**25,719,632**	**3**	**1,718**	*****	**285,680**	**(244,332)**	**41,351**

***** Represents an amount less than $1 thousand

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

INSPIREMD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(Unaudited)
(U.S. dollars in thousands, except share data)

	Common stock		Preferred C shares		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT July 1, 2024	**25,196,479**	**3**	**1,718**	*****	**283,202**	**(236,442)**	**46,763**
Net loss						**(7,890)**	**(7,890)**
Exercise of pre-funded warrants	**199,992**	*****					*****
Issuance of common shares, Included at the market offering net of $1 issuance costs	**12,961**				**35**		**35**
Share-based compensation related to stock, restricted stock, restricted stock units and stock options award	**310,200**				**2,443**		**2,443**
BALANCE AT September 30, 2024	**25,719,632**	**3**	**1,718**	*****	**285,680**	**(244,332)**	**41,351**

***** 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)

	Common stock		Preferred C shares		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2025	**26,611,033**	**3**	**1,718**	*****	**289,589**	**(253,506)**	**36,086**
Net loss						**(37,025)**	**(37,025)**
Exercise of pre-funded warrants	**2,381,651**	*****					*****
Issuance of common stock, included at the market offering and pre-funded warrants net of $3,148 issuance costs	**7,510,293**	**1**			**38,713**		**38,714**
Exercise of Warrants Series I to 10,561,685 pre-funded warrants and 2,352,393 common stock, net of $1,000 issuance costs	**2,352,393**	*****			**16,855**		**16,855**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 322,919 shares	**3,063,771**	*****			**9,484**		**9,484**
BALANCE AT September 30, 2025	**41,919,141**	**4**	**1,718**	*****	**354,641**	**(290,531)**	**64,114**

***** Represents an amount less than $1 thousand

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

INSPIREMD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(Unaudited)
(U.S. dollars in thousands, except share data)

	Common stock		Preferred C shares		Additional paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT July 1, 2025	**32,552,888**	**3**	**1,718**	*****	**298,063**	**(277,823)**	**20,243**
Net loss						**(12,708)**	**(12,708)**
Exercise of pre-funded warrants	**970,098**	*****					*****
Exercise of Warrants Series I to 10,561,685 pre-funded warrants and 943,641 common stock, net of $891 issuance costs	**943,641**	*****			**15,017**		**15,017**
Issuance of common stock, included at the market offering and 9,764,804 pre-funded warrants net of $3,126 issuance costs	**7,236,672**	**1**			**38,017**		**38,018**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 34,712 shares	**215,842**	*****			**3,544**		**3,544**
BALANCE AT September 30, 2025	**41,919,141**	**4**	**1,718**	*****	**354,641**	**(290,531)**	**64,114**

* Represents an amount less than $1 thousand

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

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

	Nine months ended September 30	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (37,025)	$ (22,831)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	333	205
Gain from sale of property, plant and equipment	(15)	-
Changes in fair value of marketable securities, net of interest received	(178)	(757)
Change in liability for employees' rights upon retirement	371	99
Other financial income	(113)	(8)
Change in operating right of use asset and operating leasing liability	480	(39)
Share-based compensation expenses	9,484	7,792
Loss (gain) on amounts funded in respect of employee rights upon retirement, net	(121)	21
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	115	(698)
Decrease (increase) in trade receivables	(389)	274
Decrease (increase) in other receivables	207	(93)
Increase in inventory	(1,037)	(339)
Increase in trade payables	499	366
Increase in other payables	1,631	890
Net cash used in operating activities	(25,758)	(15,118)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,264)	(1,091)
Proceeds from sale of property, plant and equipment	15	-
Investments in marketable securities	(11,749)	(14,444)
Proceeds from matured marketable securities	27,648	20,000
Amounts funded in respect of employee rights upon retirement	(75)	(66)
Net cash provided by investing activities	14,575	4,399
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants, net of $1,000 issuance costs	16,855	16,854
Proceeds from issuance of shares and pre-funded warrants, net of $3,148 and $1 issuance costs, respectively	38,714	35
Net cash provided by financing activities	55,569	16,889
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	101	8
INCREASE IN CASH AND CASH EQUIVALENTS	44,487	6,178
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	18,916	9,640
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 63,403	$ 15,818
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	994	-
Non- cash purchase of property and equipment	101	-

The accompanying notes are an integral part of 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.

On June 13, 2025, the Company received CE Mark approval under the European Medical Device Regulation for the CGuard Prime carotid stent system. On June 23, 2025, the U.S. Food and Drug Administration ("FDA") granted premarket application (PMA) approval of the CGuard Prime Carotid Stent System in the United States, and in July 2025, the Company announced the official commercial launch of the CGuard Prime carotid stent system in the United States. In the United States, following FDA approval of the PMA of the CGuard Prime Carotid Stent System, the Company markets and sells its product through a direct sales organization. In addition, the Company also markets and sells its product through distributors in international markets, mainly in Europe.

b. Liquidity

The Company has an accumulated deficit as of September 30, 2025, as well as a history of net losses and negative operating cash flows. The Company expects to continue incurring losses and negative cash flows from operations until its product, CGuard™ EPS, reaches commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations for at least the next 12 months. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

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

c. Risks Related to the Company's Operations in Israel

In October 2023, Israel was attacked by the Hamas terrorist organization and entered a state of war on several fronts. In June 2025, following escalating threats and intelligence reports of imminent attacks, Israel conducted preemptive strikes on military and nuclear infrastructure in Iran. Iran responded with drones and missiles attacks, some of which caused civilian casualties and infrastructure damage. After 12 days of hostilities, a ceasefire between Israel and Iran was reached in June 2025. As of October 9, 2025, Israel and Hamas entered into a ceasefire agreement calling for a permanent end of the war. However, there are no assurances that such agreements will hold. As a result, while the ceasefire marks a potential shift towards stability in the region, the situation remains volatile, and the risk of broader regional escalation involving additional actors persists. As of the date of these consolidated financial statements, conflict continues in parts of the region. The Company's operations, including its current production facility, are located in Israel. At this time, these activities remain largely unaffected.

During the nine and three months ended September 30, 2025 and 2024, the impact of this war on the Company's results of operations and financial condition was immaterial, but such impact may increase, which could be material, as a result of the continuation, escalation or expansion of such war.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of the company, 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 condensed 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, 2024, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 12, 2025. The results of operations for the nine and three months ended September 30, 2025 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

Recently issued accounting pronouncement, not yet adopted

1) In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements and disclosures.

2) In November 2024, the FASB issued ASU No. 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40). The ASU improves the disclosures about a public business entity's expenses and provides more detailed information about the types of expenses in commonly presented expense captions. The amendments require that at each interim and annual reporting period an entity will, inter alia, disclose amounts of purchases of inventory, employee compensation, depreciation and amortization included in each relevant expense caption (such as cost of sales, G&A, S&M and research and development) as well as disclosures about selling expenses. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating this ASU to determine its impact on the Company's financial statements and disclosures.

3) In July 2025, the FASB issued Accounting Standards Update 2025-05, Financial Instruments- Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets ("ASU 2025-05"). ASU 2025-05 provides a practical expedient that all entities can use when estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606, Revenue from Contracts with Customers. Under this practical expedient, an entity is allowed to assume that the current conditions it has applied in determining credit loss allowances for current accounts receivable and current contract assets remain unchanged for the remaining life of those assets. ASU 2025-05 is effective for fiscal years beginning after December 15, 2025, and interim reporting periods in those years. Entities that elect the practical expedient and, if applicable, make the accounting policy election are required to apply the amendments prospectively. The Company is currently evaluating the potential impact of this guidance on its consolidated financial statements and disclosures.

NOTE 4 – FAIR VALUE MEASUREMENTS

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

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

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

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

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

	As of September 30, 2025			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents-				
Money market funds	$ 53,889	$ 53,889	$ -	$ -

	As of December 31, 2024			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents-				
Money market funds	$ 6,281	$ 6,281	$ -	$ -
Marketable securities-				
U.S. government bonds	$ 15,721	$ -	$ 15,721	$ -

The Company's cash equivalents, and marketable securities are classified within Level 1 and 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 December 31, 2024, is $15,277 thousand. As of September 30, 2025, all marketable securities have matured.

NOTE 5 - MARKETABLE SECURITIES

As of December 31, 2024, all of the Company's investment in marketable securities had contractual maturity of less than one year.

The table below sets forth a summary of the changes in the fair value of the Company's marketable securities for the nine-month period ended September 30, 2025, and 2024:

	Nine months ended September 30,	
	2025	**2024**
	($ in thousands)	
Balance at beginning of the period	$ 15,721	29,383
Additions	11,749	14,444
Maturity	(27,648)	(20,000)
Interest received	(109)	(217)
Changes in fair value during the period	287	974
Balance at end of the period	-	24,584

The Company elected the fair value option to measure and recognize its investments in debt securities in accordance with Accounting Standards Codification ASC 825, Financial Instruments as the Company managed and evaluated the performance on a fair value basis.

NOTE 6 - EQUITY:

a. As of September 30, 2025, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 7,952 shares of the Company's common stock, with a total stated value of $10,997.

b. As of September 30, 2025, there are 44,092,107 outstanding pre-funded warrants.

Prior to June 30, 2025, pre-funded warrants were exercised on a cashless basis; from July 1, 2025 through September 30, 2025, pre-funded warrants were exercised for cash.

c. As of September 30, 2025, the Company has outstanding warrants to purchase an aggregate of 26,935,323 shares of common stock as follows:

	Number of underlying Common stock		Exercise price	Expiration date
Series F Warrants	14,815	$	7.4250	October 16, 2025
Series G Warrants	1,092,344	$	10.230	February 8, 2026
Series J Warrants	12,914,086	$	1.3827	*
Series K Warrants	12,914,078	$	1.3827	*
Total Warrants	26,935,323			

* The Series J Warrants and Series K Warrants have a term of the earlier of (i) May 15, 2028 and (ii) (A) 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 (B) 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.

On October 16, 2025, a total of 14,815 Series F warrants expired.

d. Exercise of Series I Warrant

Following the Company's announcement on June 24, 2025, that the FDA approved the PMA of the CGuard Prime Carotid Stent System in the United States, and as of September 30, 2025, an aggregate of 12,914,078 Series I Warrants were exercised into 2,352,393 shares of common stock at an exercise price of $1.3827 per share and 10,561,685 pre- funded warrants at an exercise price of $1.3826 per pre-funded warrant, resulting in gross proceeds of approximately $17,855 thousand dollars. After deducting issuance costs of $1,000 thousand, the net proceeds amounted to approximately $16,855 thousand.

e. Private Placement

On July 30, 2025, the Company entered into a securities purchase agreement (the "Purchase Agreement") with investors pursuant to which the Company issued and sold in a private placement (the "Private Placement Offering) of an aggregate of 6,791,380 shares (the "Private Placement Shares") of the Company's common stock, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 9,764,804 shares of common stock, at an offering price of $2.42 per Private Placement Share and $2.4199 per Pre-Funded Warrant. 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 Private Placement Offering resulted in gross proceeds to the Company of approximately $40.1 million and closed on August 1, 2025**.** The issuance costs amounted to $3,084 thousand.

f. During the nine months ended September 30, 2025, 718,913 shares of common stock have been sold under the ATM program for total gross proceeds of approximately $1.8 million and total fees of approximately $64 thousand.

g. As of September 30, 2025, 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.

h. During the nine months ended September 30, 2025, the Company granted 3,303,618 restricted shares of the Company's common stock to employees and directors. The shares to employees are subject to a three-year vesting period, with one-third of such awards vesting each year. The shares to directors are subject to a one-year vesting period.

The fair value of the above restricted shares was approximately $8.69 million.

During the nine months ended September 30, 2025, the Company granted 558,417 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 $1.54 million.

During the nine months ended September 30, 2025, the Company granted to employees and directors options to purchase a total of 1,092,851 shares of the Company's common stock. The options have exercise prices ranging from $2.24-$2.79 per share, which was the fair market value of the Company's common stock on the respective dates of the grant. The options to employees are subject to a three-year vesting period, with one-third of such awards vesting each year. The options to directors are subject to a one-year vesting period.

In calculating the fair value of the above options, the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility ranging from 75.74%-92.69%; and risk-free interest rate ranging from 3.89%-4.68%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $2.18 million.

NOTE 7 – RELATED PARTIES TRANSACTIONS

During the nine and three months ended September 30, 2024, and 2025, a member of the immediate family of the CEO provided certain administrative services in connection with the Company's expansion to the U.S. in the amount of $55 and $25 thousand, for 2024, and $56 and $8 thousand for 2025, respectively. In July 2025, the engagement with the related party was terminated.

NOTE 8 - NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock, pre-funded warrants and fully vested restricted stock units outstanding during the period. The calculation of diluted net loss per share excludes the effect of potential dilution of share options, warrants, and unvested restricted stocks, unvested restricted stock units and Series C preferred stock as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C preferred stock, which were excluded from the calculations of diluted loss per share were 37,695,155 and 48,619,222 for the nine and three-month periods ended September 30, 2025 and 2024, respectively. This amount includes 5,385,272 and 3,979,486 of unvested restricted stock included in the number of issued and outstanding shares for the nine and three-month periods ended September 30, 2025 and 2024, respectively.

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 months ended September 30, 2025 and 2024, the weighted average number of ordinary shares used in computing net loss per share - basic and diluted was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Weighted average number of ordinary shares	33,741,698	21,633,309	27,560,829	20,048,335
Weighted average Vested restricted stock units	1,121,678	536,606	931,022	348,383
Weighted average Pre-funded Warrants	38,603,125	26,199,497	29,753,517	19,016,286
Total Weighted average number of ordinary shares used in computing net loss per share - basic and diluted	73,466,501	48,369,412	58,245,368	39,413,004

NOTE 9 – LEASE AGREEMENTS

1) On May 18, 2025, the Company took possession of Suite 280 at its U.S. headquarters in Miami, Florida, following the landlord's completion of construction. This date represents the commencement of the lease for Suite 280, in accordance with the terms of the U.S. Lease. In connection with the commencement, the Company recognized an increase of 302 thousand dollars in both operating lease right-of-use assets and operating lease liabilities.

2) On May 28, 2025, the Company amended the Israeli Lease, extending the lease term through December 31, 2028, and leasing additional space within the facility. The amendment resulted in an increase of 692 thousand dollars to the Company's operating lease right-of-use assets and lease liabilities to reflect the extended lease term and additional leased area.

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, due to the relatively short-term maturities of certain instruments or they are measured using interest rates close to prevailing market rates.

b. As of September 30, 2025, and December 31, 2024, allowance for expected credit loss was immaterial.

NOTE 11- INVENTORY:

	September 30, 2025	December 31, 2024
	($ in thousands)	
Finished goods	$ 576	$ 18
Work in process	733	638
Raw materials and supplies	2,298	1,914
	$ 3,607	$ 2,570

NOTE 12 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	September 30, 2025	December 31, 2024
	($ in thousands)	
Employees and employee institutions	5,357	3,414
Accrued vacation and recreation pay	683	369
Accrued expenses	735	1,325
Clinical trials accrual	1,013	519
Current Operating lease liabilities	1,006	542
Other	269	255
	9,063	6,424

NOTE 13 - DISAGGREGATED REVENUE:

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,	
	2025	2024	2025	2024
	($ in thousands)			
USA	497	7	551	29
Germany	380	306	982	855
Italy	293	306	878	865
Poland	211	176	686	534
Russia	-	190	-	375
Other*	1,142	825	2,733	2,402
	$ 2,523	$ 1,810	$ 5,830	$ 5,060

* Other individual countries do not exceed 10% in the nine and three months ended September 30, 2025 and 2024.

By principal customers:

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Customer A	15%	17%	17%	17%
Customer B	8%	10%	12%	11%
Customer C	-	11%	-	7%
Customer D	8%	10%	9%	9%

NOTE 14 – SEGMENT INFORMATION

The Company has one operating and reporting segment, that develops, manufactures and markets products for the treatment of carotid artery disease and other vascular disease, including the Company's proprietary CGuard™ stent platform. The Company's Chief Operating Decision Maker ("CODM"), who is the CEO evaluates the Company's performance based on its internal reporting which is consistent with the presentation in the Company's consolidated financial statements. Accordingly, our CODM uses consolidated net income to measure segment profit or loss, allocate resources, and assess performance.

The CODM examines, within each operational function the employee salaries including the bonus and share based compensation. In addition, the CODM examines the clinical trials expenses within the research and development operations.

	Three months ended September 30,		Nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues	**2,523**	**1,810**	**5,830**	**5,060**
Cost of Revenues:				
Material and Labor	1,391	1,209	3,554	3,373
Other cost of revenues	268	187	807	650
Total Cost of Revenues	**1,659**	**1,396**	**4,361**	**4,023**
Research and development (R&D)				
Payroll and Benefits	1,089	715	3,063	2,066
Share based compensation	576	644	1,889	1,795
Clinical trials	1,105	1,289	3,401	3,240
Other R&D	865	1,267	3,175	2,840
Total Research and development	**3,635**	**3,915**	**11,528**	**9,941**
Selling and marketing (S&M)				
Payroll and Benefits	2,975	907	7,732	2,522
Share based compensation	567	277	1,379	791
Other S&M	850	288	2,203	841
Total Selling and marketing	**4,392**	**1,472**	**11,314**	**4,154**
General and administrative (G&A)				
Payroll and Benefits	1,707	889	5,015	2,539
Share based compensation	2,351	1,460	6,051	4,970
Other G&A	1,830	1,140	5,091	3,569
Total General and administrative	**5,888**	**3,489**	**16,157**	**11,078**
Financial Income, net;	343	572	505	1,305
Segment net Loss	(12,708)	(7,890)	(37,025)	(22,831)

NOTE 15 – SUBSEQUENT EVENTS

Subsequent to September 30, 2025, the Company granted an aggregate of 451,853 restricted shares of the Company's common stock to employees, directors and consultants. Of these, 360,185 shares of common stock granted to employees and consultants are subject to a three-year vesting period, with one-third of such awards vesting each year, 48,000 shares of common stock granted to directors are subject to a one-year vesting period and the remaining 43,668 shares granted to a consultant are fully vested

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

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

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

Forward-Looking Statements

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- the clinical development, commercialization and market acceptance of our products;
- whether the clinical trial results for our products will be predictive of real-world results;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq listing standards;
- our ability to generate significant revenues from our products;
- estimates of our expenses, future revenues, capital requirements and our needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercial launch of our products;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;

- product malfunctions;
- price increases for supplies and components;
- whether access to our products is achieved in a commercially viable manner and whether our products receive adequate reimbursement by governmental and other third-party payers;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- security, political and economic instability in the Middle East that could harm our business, including due to the current security situation in Israel;
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and
- changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements and the impact of such policies on us, our customers and suppliers, and the global economic environment.

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 products for the treatment of carotid artery disease and other vascular disease, including our proprietary CGuard™ stent platform. On June 23, 2025, CGuard Prime, our next generation carotid artery stenting ("CAS") stent platform, was granted premarket application ("PMA") approval the U.S. Food and Drug Administration ("FDA"). A stent is an expandable scaffold-like device, usually constructed of a metallic material, that is inserted into the lumen of an artery to create patency and improved blood flow. A sleeve of MicroNet™ mesh is attached over a stent to provide embolic protection both during and after stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a unique self-expandable nitinol stent in a single device for use in carotid artery revascularization. Our CGuard EPS originally received CE mark approval under Medical Device Directive 93/42/EEC ("MDD") in the European Union ("EU") in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in over 30 countries and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in the Asian markets. In January 2024, we received CE mark recertification under the EU's Medical Device Regulation ("MDR") regulatory framework.

On September 8, 2020, we received approval from the 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 was 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 CAS. The study, which completed enrollment in June 2023, enrolled 316 patients across 24 trial sites in the U.S. and Europe and from April 2023 included deployment of the CGuard stent using CGuard Prime, our next generation CAS stent platform.

The primary endpoint was a composite of: (1) incidence of major adverse events including Death (all-cause mortality), any Stroke, and Myocardial Infarction (DSMI) through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure. All events were adjudicated by an independent clinical events committee. The composite index was 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 was considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025.

In November 2023, we announced positive 30-day follow up results from the C-GUARDIANS trial in which stenting with the CGuard Carotid Stent System in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%, measured from the date of the procedure through 30 days follow-up post-procedure. In May 2024, we announced positive one-year follow up results from the C-GUARDIANS trial, with a rate of 30-day DSMI and ipsilateral stroke between 31 and 365 days of 1.95%.

These data were used to support the PMA submission in September 2024, which was approved by the FDA on June 23, 2025. On June 12, 2025, we received CE Mark approval under the EU's MDR for the CGuard Prime Embolic Prevention System.

In October 2024, the FDA approved the Company's IDE to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80cm Carotid Stent System during transcarotid revascularization (TCAR) procedures.

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

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

We consider our current addressable market for our CGuard Carotid Stent System and SwitchGuard NPS to be both symptomatic and asymptomatic individuals with diagnosed high-grade carotid artery stenosis for whom intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard, we estimate that the addressable market for CGuard Carotid Stent System and SwitchGuard NPS is approximately $1.3 billion (source: Health Research International Personal Medical Systems, Inc. September 13, 2021 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets and internal estimates). According to this same report and internal estimates, assuming full penetration of treatment for all individuals diagnosed with high-grade carotid artery stenosis, we estimate the total available market for CGuard Carotid Stent System and SwitchGuard NPS to be approximately $9.3 billion, which may grow over time if expanded treatment options such as CGuard Carotid Stent System and SwitchGuard NPS lead to increased patient screening for carotid artery disease.

We were organized in the State of Delaware on February 29, 2008. In October 2024, we established our global headquarters in Miami, Florida to support the anticipated U.S. launch and commercialization of the CGuard Prime carotid stent system.

Recent Developments

PMA approval of the CGuard Prime Carotid Stent System and Commercial Launch in the United States

On June 23, 2025, the FDA granted PMA approval of the CGuard Prime Carotid Stent System in the United States.

Following such approval, in July 2025, we announced the official commercial launch of the CGuard Prime Carotid Stent System in the United States. In October 2024, we established our global headquarters in Miami, Florida to support the U.S. launch and commercialization of CGuard Prime Carotid Stent System.

CE Mark Approval for CGuard Prime EPS Under European MDR

On June 12, 2025, we received CE Mark approval under the EU's MDR for the CGuard Prime Embolic Prevention System.

Exercise of Series I Warrants

Following the announcement of the PMA approval of the CGuard Prime Carotid Stent System in the United States, Series I warrants to purchase 12,914,078 shares of common stock were exercised in full into 2,352,393 of shares of common stock and pre-funded warrants to purchase 10,561,685 shares of common stock during June and July 2025. The net proceeds to the Company from the exercise of the Series I Warrants were $16.9 million after deducting placement agent fees. The Series I warrants, each exercisable at $1.3827 per common share and $1.3826 per pre-funded warrant, were issued as part of the private placement financing that the Company consummated on May 15, 2023.

Private Placement

On July 30, 2025, the Company entered into a securities purchase agreement with investors pursuant to which the Company issued and sold in a private placement (the "Private Placement Offering") an aggregate of 6,791,380 shares (the "Private Placement Shares") of common stock and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 9,764,804 shares of common stock, at an offering price of $2.42 per Private Placement Share and $2.4199 per Pre-Funded Warrant. The Pre-Funded Warrants are immediately exercisable at an exercise price of $0.0001 per share and will not expire until exercised in full. Certain of the Company's directors participated in the Private Placement Offering. The Private Placement Offering closed on August 1, 2025.

Aggregate gross proceeds to the Company in respect of the Private Placement Offering were approximately $40.1 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company. In addition, the Company paid the placement agent for the offering a placement fee equal to 6.0% of the aggregate gross proceeds from the closing of the Private Placement Offering, or approximately $2.4 million, and expense reimbursement of $75,000.

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, 2024. There have not been any material changes to such critical accounting policies since December 31, 2024.

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

Results of Operations

Three months ended September 30, 2025, compared to the three months ended September 30, 2024

Revenues. For the three months ended September 30, 2025, revenue increased by $713,000, or 39.4%, to $2,523,000, from $1,810,000 during the three months ended September 30, 2024. Growth in the quarter was driven mainly by the commercial launch of direct sales of the CGuard Prime product in the U.S. following FDA approval in June 2025, and continued growth in sales of the CGuard product through distributors in international markets.

With respect to geographical regions, the increase in revenue was primarily attributable to a $490,000 increase in North America due to the official commercial launch of CGuard Prime in the U.S. following FDA approval in June 2025, and a $223,000 increase in international markets outside North America due to continued adoption of our CGuard technology.

Gross Profit. For the three months ended September 30, 2025, gross profit (revenue less cost of revenues) increased by $450,000, or 108.7%, to $864,000 from $414,000 during the three months ended September 30, 2024. This increase in gross profit resulted from a $529,000 increase in revenues, less the associated material and labor costs and was augmented by the contribution of revenue from direct sales in the U.S., which carry higher unit profit due to higher average selling price per unit, as compared to international sales through distributors. The increase in gross profit was partially offset by an increase in manufacturing and miscellaneous expenses of $79,000. Gross margin (gross profit as a percentage of revenue) increased to 34.2% during the three months ended September 30, 2025, from 22.9% during the three months ended September 30, 2024, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended September 30, 2025, research and development expenses decreased by $280,000, or 7.2%, to $3,635,000, from $3,915,000 during the three months ended September 30, 2024. This decrease resulted primarily due to the completion of the C-GUARDIANS clinical study and related product preparation expense prior to the FDA approval of the CGuard Prime product in June 2025, partially offset by an increase in compensation expenses due to hiring of new employees in connection with our expansion in the U.S.

Selling and Marketing Expenses. For the three months ended September 30, 2025, selling and marketing expenses increased by $2,920,000, or 198.4%, to $4,392,000 from $1,472,000 during the three months ended September 30, 2024. This increase resulted primarily from an increase in compensation and headcount related expenses from higher commercial staffing levels in connection with the commercial launch of CGuard Prime in the U.S.

General and Administrative Expenses. For the three months ended September 30, 2025, general and administrative expenses increased by $2,399,000, or 68.8%, to $5,888,000, from $3,489,000 during the three months ended September 30, 2024. The increase was primarily driven by higher compensation and headcount related expenses from new hires to support the Company's expansion of U.S. operations. General and administrative expenses were also higher due to an increase in professional services and miscellaneous expenses to support the expansion of U.S. operations following the commercial launch of CGuard Prime.

Financial Income. For the three months ended September 30, 2025, financial income decreased by $229,000 or 40.0% to $343,000, from $572,000 during the three months ended September 30, 2024. The decrease in financial income primarily resulted from a $118,000 decrease in financial income from investment in marketable securities and money market funds due to lower interest rates and a $104,000 increase in financial expenses related to changes in exchange rates.

Tax Expenses. For the three months ended September 30, 2025, there was no material change in our tax expenses as compared to the three months ended September 30, 2024.

Net Loss. Our net loss increased by $4,818,000, or 61.1%, to $12,708,000, for the three months ended September 30, 2025, from $7,890,000 during the three months ended September 30, 2024. The increase in net loss resulted primarily from an increase of $5,039,000 in operating expenses.

Nine months ended September 30, 2025, compared to the nine months ended September 30, 2024

Revenues. For the nine months ended September 30, 2025, revenue increased by $770,000, or 15.2%, to $5,830,000, from $5,060,000 during the nine months ended September 30, 2024. The increase was driven by the commercial launch of direct sales of the CGuard Prime product in the U.S. following FDA approval in June 2025, and continued growth in sales of the CGuard product through distributors in international markets.

With respect to geographical regions, the increase in revenue was primarily attributable to a $522,000 increase in North America due to the official commercial launch of CGuard Prime in the U.S. following FDA approval in June 2025, and a $248,000 increase in international markets outside North America due to continued adoption of our CGuard technology.

Gross Profit. For the nine months ended September 30, 2025, gross profit (revenue less cost of revenues) increased by $432,000, or 41.7%, to $1,469,000, compared to $1,037,000 for the same period in 2024. This increase in gross profit resulted from a $589,000 increase in revenues, less the associated material and labor costs and was augmented by the contribution of revenue from direct sales in the U.S., which carry higher unit profit due to higher average selling price per unit, as compared to international sales through distributors. The increase in gross profit was partially offset by an increase in manufacturing and miscellaneous expenses of $157,000. Gross margin (gross profit as a percentage of revenue) increased to 25.2% for the nine months ended September 30, 2025, from 20.5% for the nine months ended September 30, 2024, driven by the factors mentioned above.

Research and Development Expenses. For the nine months ended September 30, 2025, research and development expenses increased by 16.0%, or $1,587,000 to $11,528,000, from $9,941,000 during the nine months ended September 30, 2024. This increase resulted primarily due to an increase in compensation and headcount related expenses due to higher staff levels in connection with our expansion in the United States, and higher development and regulatory expenses for of the SwitchGuard NPS and CGuard Prime 80cm Carotid Stent System, respectively. These increases were partially offset by a decrease of expenses for the C-GUARDIANS clinical study, which was completed prior to the approval by the FDA in June 2025.

Selling and Marketing Expenses. For the nine months ended September 30, 2025, selling and marketing expenses increased by $7,160,000, or 172.4%, to $11,314,000, from $4,154,000 during the nine months ended September 30, 2024. This increase resulted primarily from an increase in compensation and headcount related expenses from higher commercial staffing levels in connection with the commercial launch of CGuard Prime in the U.S.

General and Administrative Expenses. For the nine months ended September 30, 2025, general and administrative expenses increased by 45.8%, or $5,079,000, to $16,157,000, from $11,078,000 during the nine months ended September 30, 2024. The increase was primarily driven higher compensation and headcount related expenses from new hires to support the Company’s expansion of U.S. operations. General and administrative expenses were also higher due to an increase in professional services and occupancy expenses related to the expansion of U.S. operations following the commercial launch of CGuard Prime.

Financial Income. For the nine months ended September 30, 2025, financial income decreased by $800,000, to $505,000 of financial income, from $1,305,000 of financial income during the nine months ended September 30, 2024. The decrease in financial income primarily resulted from a $398,000 decrease in income from investment in marketable securities and money market funds due to lower interest rates and a $393,000 increase in financial expenses related to changes in exchange rates.

Tax Expenses. For the nine months ended September 30, 2025, there was no material change in our tax expenses as compared to the nine months ended September 30, 2024.

Net Loss. Our net loss increased by $14,194,000, or 62.2%, to $37,025,000, for the nine months ended September 30, 2025, from $22,831,000 during the nine months ended September 30, 2024. The increase in net loss resulted primarily from an increase of $13,826,000 in operating expenses.

Liquidity and Capital Resources

We had an accumulated deficit as of September 30, 2025, of $291 million, as well as a net loss of $37.0 million for the nine months ended September 30, 2025 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our product, CGuard Prime, reaches commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we believe we do not have sufficient resources to fund operations for at least the next 12 months. Therefore, there is substantial doubt about our ability to continue as a going concern.

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

In May 2023, we closed a private placement offering of 10,266,270 shares of our common stock, pre-funded warrants to purchase up to 15,561,894 shares of common stock and warrants to purchase up to an aggregate of 51,656,328 shares of common stock, consisting of Series H warrants to purchase up to 12,914,086 shares of common stock (the "Series H Warrants"), Series I warrants to purchase up to 12,914,078 shares of common stock (the "Series I Warrants"), Series J warrants to purchase up to 12,914,086 shares of Common Stock (the "Series J Warrants") and Series K warrants to purchase up to 12,914,086 shares of common stock (the "Series K Warrants" and together with the Series H Warrants, Series I Warrants and Series J Warrants, the "Warrants"), at an offering price of $1.6327 per Private Placement Share and associated Warrants and an offering price of $1.6326 per Pre-Funded Warrant and associated Warrants that resulted in aggregate gross proceeds of approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by us. If the Warrants issued in the private placement offering are exercised in cash in full this would result in an additional $71.4 million of gross proceeds, of which $35.7 million have been received as of the date of this Quarterly Report on Form 10-Q.

In May 2024, we entered into an Equity Distribution Agreement with Piper Sandler & Co., as sales agent ("Piper Sandler), pursuant to which we may offer and sell, from time to time, at our option, through or to Piper Sandler up to $75,000,000 of our common stock (the "ATM Program"). As of the issuance date of this report, we have sold 920,898 shares of our common stock for total gross proceeds of approximately $2.4 million under the ATM Program.

During June 2024, Series H warrants to purchase 12,914,086 shares of common stock that were issued in the May 2023 private placement were exercised in full into 292,996 of shares of common stock and pre-funded warrants to purchase 12,621,090 shares of common stock. The net proceeds to the Company from the exercise of the Series H Warrants were $16.9 million after deducting placement agent fees.

During June and July 2025, Series I warrants to purchase 12,914,078 shares of common stock that were issued in the May 2023 private placement were exercised in full into 2,352,393 shares of common stock and pre-funded warrants to purchase 10,561,685 shares of common stock. The net proceeds to the Company from the exercise of the Series I Warrants were $16.9 million after deducting placement agent fees.

On August 1, 2025, we closed the Private Placement Offering that resulted in aggregate gross proceeds of approximately $40.1 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company.

Nine months ended September 30, 2025, compared to the Nine months ended September 30, 2024

General. At September 30, 2025, we had cash and cash equivalents of $63,403,000, as compared to cash and cash equivalents of $18,916,000 and marketable securities of $15,721,000 as of December 31, 2024. 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, 2025, net cash used in our operating activities increased by $10,640,000, or 70.4%, to $25,758,000, from $15,118,000 during the same period in 2024. The primary reasons for the increase in cash used in our operating activities were an increase of $9,005,000 in compensation costs paid during the nine months ended September 30, 2025 (from $8,838,000 in the nine months ended September 30, 2024 to $17,843,000 in the nine months ended September 30, 2025) and an increase of $1,709,000 in payments for third party related expenses and for professional services.

Cash provided by our investing activities was $14,575,000 during the nine months ended September 30, 2025, compared to $4,399,000 during the nine months ended September 30, 2024. The primary reason for the increase in cash provided by our investing activities is withdrawal of $10,343,000, net of investment in marketable securities.

Cash provided by financing activities for the nine months ended September 30, 2025, was $55,569,000. The source of the cash provided by financing activities during the nine months ended September 30, 2025, were the proceeds from the Private Placement Offering in July 2025 as well as proceeds from issuance of shares received from our ATM Program that resulted in approximately $38,714,000 of aggregate net proceeds and proceeds from exercise of Series I warrants of $16,855,000. Cash provided by financing activities for the nine months September 30, 2024, was $16,889,000. The source of the cash provided by financing activities during the nine months ended September 30, 2024, were the proceeds from exercise of Series H warrants.

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 market acceptance of the U.S. commercial launch, 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 nine months ended September 30, 2025, there were no material changes to our contractual obligations and commitments since the year ended December 31, 2024.

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, 2025, 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, 2025.

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, 2025, 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 12, 2025.

Management has concluded that there is substantial doubt about our ability to continue as a going concern, and our condensed financial statements for the quarter ended September 30, 2025 includes an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, our condensed financial statements for the quarter ended September 30, 2025 includes an explanatory paragraph as to our potential inability to continue as a going concern. The doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

We have only recently transitioned to a commercial stage medical device company in the United States, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We only recently launched the CGuard Prime Carotid Stent System in the United States following FDA approval in June 2025. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had more experience commercializing the CGuard Prime Carotid Stent System in the United States. To be profitable, we will need to successfully transition our focus to expand our commercialization capabilities through our direct sales organization and build our distribution capabilities to support the commercial launch of the CGuard Prime carotid stent system in the United State. Ultimately, we may not be successful in such a transition.

CGuard Prime has been commercially launched in the United States and we have limited experience selling, marketing or distributing products in the U.S. The timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for the CGuard Prime.

In July 2025, we announced the official commercial launch of CGuard Prime in the U.S. following FDA approval in June 2025, and we are currently executing on an independent commercialization plan for CGuard Prime in the U.S. As part of our plan, we have, and continue, to build out sales, marketing and distribution capabilities and engaged with a contract manufacturer. Historically, prior to the commencement of our commercialization activities in the U.S., we did not have experience in manufacturing, selling, marketing or distributing products in the U.S. To be able to successfully commercialize CGuard Prime, if at all, we may need to further develop our existing manufacturing, sales, marketing and distribution capabilities, which is expensive and time-consuming, or enter into arrangements with third parties to perform these services.

In October 2024, we established our global headquarters in Miami, Florida to support the U.S. commercial launch of the CGuard Prime carotid stent system. During 2024, we started the build-out of the infrastructure for commercial operations in the U.S. designed to support the commercialization of the CGuard Prime carotid stent system. In addition, to support our anticipated production growth in connection with the commercialization of the CGuard Prime carotid stent system, we have engaged Aptyx Interventional Systems (“Aptyx”), a contract manufacturer that is a developer and manufacturer of complex components and devices for the life sciences, to transfer the manufacturing of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina.

There are risks involved in establishing our own sales, marketing and distribution capabilities and partnering with a third party manufacturer. We must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective manufacturing, sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade physicians to use our stents;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- the difficulty of obtaining reimbursement from governmental and commercial payers;
- the lack of complementary products offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent manufacturing, sales and marketing organization.

We are continuing to expand our commercialization capabilities and to build our distribution capabilities to support the commercialization of the CGuard Prime carotid stent system. We expect that it will take time for this team to generate significant sales momentum, if it does so at all. We may not be successful in recruiting and retaining the manufacturing, sales and marketing personnel necessary to sell CGuard Prime, and we may not be successful in marketing CGuard Prime, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, other factors that have and may continue to inhibit our efforts to successfully commercialize CGuard Prime in the United States include our ability to access key health care decision makers, price CGuard Prime at a sufficient price point to ensure an adequate and attractive level of profitability, and maintain sufficient financial resources to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure. If we are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the United States and elsewhere, we will have difficulty successfully commercializing CGuard Prime in the U.S. market, which would adversely affect our business and financial condition.

If we are unable to establish and maintain our own manufacturing, sales, marketing and distribution capabilities or enter into successful arrangements with third parties to perform these services, our future product revenues and profitability may be materially adversely affected. If we are not successful in commercializing CGuard Prime in the United States, we may be required to collaborate or partner with a third-party medical device or biotechnology company with existing products. To the extent we collaborate or partner, the financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish CGuard Prime in the U.S. market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues

may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

CGuard Prime, or any other product candidate that may receive marketing approval in the future, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for CGuard Prime or any other product candidate may be smaller than our estimates.

CGuard Prime, or any other product candidate that may be approved in the future by the appropriate regulatory authorities for marketing and sale, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians are often reluctant to switch their patients from existing medical devices even when new and potentially more effective or convenient products enter the market.

Efforts to educate the medical community and third-party payors on the benefits of CGuard Prime over its competition have required significant resources and may not ultimately be successful. If CGuard Prime, or any other product candidate that may be approved in the future for marketing and sale in the future, does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of CGuard Prime, or any other product candidate that may be approved in the future, will depend on a number of factors, including:

- the advantages of the product compared to competitive products;
- the number of competitors approved for similar uses;
- the relative promotional effort and marketing success of us as compared with our competitors;
- how the product is positioned in physician treatment guidelines and pathways;
- the prevalence and severity of any side effects;
- the efficacy and safety of the product;
- our ability to offer the product for sale at competitive prices;
- the product's tolerability, consistency of performance, convenience and ease of administration compared to alternative product;
- the willingness of the target patient population to try, and of physicians to utilize, the product;
- limitations or warnings, including use restrictions, contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- the timing of market introduction of our approved products as well as competitive products;
- adverse publicity about the product or favorable publicity about competitive products;
- potential product liability claims;
- changes in the standard of care for the targeted indications of the product; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

In addition, the potential market opportunities for CGuard Prime and any other product are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our therapeutic candidate could be smaller than our estimates of the potential market opportunities.

If the commercial launch of CGuard Prime in the United States for which we established a direct sales organization and distribution capabilities is not successful for any reason, we could incur substantial costs and our investment in our direct sales organization and distribution capabilities would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel.

To achieve commercial success for CGuard Prime in the United States, we have expended and anticipate that we will continue to expend significant resources to support our direct sales organization and distribution capabilities. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay our ability to focus on other priorities. If the commercial launch of CGuard Prime in the United States is not successful for any reason, this would be costly, and our investment would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel or terminate on favorable terms any agreements entered into with third parties to support our commercialization efforts.

Factors that may inhibit or limit our efforts to commercialize CGuard Prime in the United States on our own include:

- our inability to train and retain adequate numbers of effective sales, marketing, training and support personnel;
- the inability of sales personnel to obtain access to physicians, including key opinion leaders, or to educate an adequate number of physicians of the benefits of CGuard Prime over alternative treatment options; and
- unforeseen costs and expenses associated with establishing and maintaining an independent sales, marketing, training and support organization.

If our direct sales organization and distribution capabilities fail, or are otherwise unsuccessful, it would materially adversely impact the commercialization of CGuard Prime in the United States, impact our ability to generate revenue and harm our business.

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

Our current manufacturing facility, certain of our key personnel and one of our offices are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring Arab countries, Hamas (an Islamist terrorist militia and political group that controls the Gaza strip), Hezbollah (an Islamist terrorist militia and political group based in Lebanon) and other terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. In January 2025, Israel and Hamas entered into a ceasefire agreement, which remained in effect until March 18, 2025, when hostilities resumed. As of October 9, 2025, Israel and Hamas entered into a renewed ceasefire agreement calling for a permanent end of the war. However, there are no assurances that such as agreement will hold. While the conflict has created heightened security concerns, disruptions to business operations, and economic instability, the ceasefire may contribute to improved regional stability. However, the security situation remains fluid, and any renewed military actions, restrictions, or government-imposed measures could adversely affect our operations, supply chains, and financial condition.

Since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with the Hezbollah terror organization) and on other fronts from various extremist groups in region, such as the Houthis in Yemen and various rebel militia groups in Syria and Iraq. In October 2024, Israel began limited ground operations against Hezbollah in Lebanon, and in November 2024, a ceasefire was brokered between Israel and Hezbollah, but there are no guarantees as to whether the agreement will hold or whether further hostilities will resume.

In addition, in April 2024 and October 2024, Iran launched direct attacks on Israel involving hundreds of drones and missiles and has threatened to continue to attack Israel and is widely believed to be developing nuclear weapons. In June 2025, in light of continued nuclear threats and intelligence assessments indicating imminent attacks, Israel launched a preemptive strike directly targeting military and nuclear infrastructure inside Iran, aimed at disrupting Iran's capacity to coordinate or launch further hostilities against Israel, as well as to degrade its nuclear program. In response, Iran launched multiple waves of drones and ballistic missiles at Israeli cities. While most of these attacks were intercepted, several caused civilian casualties and damage to infrastructure. While a ceasefire was reached between Israel and Iran in June 2025 after 12 days of hostilities, the situation remains volatile. A broader regional conflict involving additional state and non-state actors remains a significant risk. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. These situations may potentially escalate in the future to more violent events which may affect Israel and us.

In connection with the Israeli security cabinet's declaration of war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service, including five full time employees in Israel of ours. Although many of such military reservists have since been released, including all our employees, they may be called up for additional reserve duty, depending on developments in the war in Gaza and along Israel's other borders. Military service call ups that result in absences of personnel from us for an extended period of time may materially and adversely affect our business, prospects, financial condition and results of operations. As of the date hereof, we currently have 66 full-time employees located in Israel.

Since the war broke out on October 7, 2023, our operations have not been adversely affected by this situation. However, we currently manufacture our CGuard at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility or our ability to procure raw materials and ship our products, we would have no other means of manufacturing and distributing CGuard until we were able to restore the manufacturing and distribution capability at our facility or develop alternative manufacturing facilities and distribution capabilities.

While the intensity and duration of the security situation in Israel have been difficult to predict, as were the economic implications on our business and operations and on Israel's economy in general, the ceasefire marks a potential shift towards stability in the region. If sustained, this could reduce the risk of disruptions to our business and the Israeli economy in general. However, if the war is renewed or expands to other fronts, such as Lebanon, Syria and the West Bank, our operations may be harmed.

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

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

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

Changes to trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade.

We currently manufacture, package and distribute all of our products, including the CGuard Prime carotid stent system, which we commercially launched in July 2025 following FDA approval of the PMA in June 2025, at our own facility in Israel. To support our anticipated production growth following the anticipated commercialization of the CGuard Prime carotid stent system, we have engaged Aptyx to transfer the manufacturing of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina. While we are in the process of establishing manufacturing operations in the United States with Aptyx, this transition will take time, and until it is operational, we expect to rely entirely on product shipments from Israel to the U.S. market.

The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain products, including medical devices, on certain trade partners, including Israel. Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). If new tariffs are enacted while we remain dependent on Israeli manufacturing, our cost of goods sold for the U.S. market may increase materially, which could negatively impact our gross margins and limit our pricing flexibility. Additionally, changes to trade agreements or customs regulations between the U.S. and Israel could increase lead times, introduce logistical complexities, or require modifications to our supply chain planning. These or similar trade-related developments may have a material adverse effect on our business, financial condition, and results of operations.

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, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation, as amended through September 30, 2015 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 9, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2021)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)
3.6	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)
3.7	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)

3.8	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019)
3.10	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.17 to the Quarterly Report on Form 10-Q filed on May 10, 2021)
3.11	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 13, 2023)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document (the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSPIREMD, INC.

Date: November 10, 2025

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

Date: November 10, 2025

By: */s/ Michael Lawless*
Name: Michael Lawless
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Marvin Slosman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2025

/s/ Marvin Slosman

Marvin Slosman
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Michael Lawless, 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 10, 2025

/s/ Michael Lawless

Michael Lawless
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended September 30, 2025 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 10, 2025

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Lawless, 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 10, 2025

By: */s/ Michael Lawless*
Name: Michael Lawless
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)