# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended: June 30, 2026**

**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 August 14, 2026: 46,489,118

**Item 1. Financial Statements**

**INSPIREMD, INC.**
CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED JUNE 30, 2026

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

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 15,149 | $ 8,939 |
| Marketable securities | 15,272 | 45,272 |
| Accounts receivable: | | |
| Trade, net | 1,816 | 2,168 |
| Other | 592 | 400 |
| Prepaid expenses | 1,098 | 1,296 |
| Inventory | 2,701 | 3,396 |
| **TOTAL CURRENT ASSETS** | 36,628 | 61,471 |
| | | |
| **NON-CURRENT ASSETS:** | | |
| Long term deposit | 450 | 442 |
| Property, plant and equipment, net | 3,858 | 3,584 |
| Operating lease right of use assets | 2,428 | 2,758 |
| Fund in respect of employee rights upon retirement | 1,277 | 1,149 |
| **TOTAL NON-CURRENT ASSETS** | 8,013 | 7,933 |
| **TOTAL ASSETS** | $ 44,641 | $ 69,404 |

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

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| **LIABILITIES AND EQUITY** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accruals: | | |
| Trade | 1,654 | 1,255 |
| Other | 7,992 | 9,457 |
| **TOTAL CURRENT LIABILITIES** | 9,646 | 10,712 |
| **LONG-TERM LIABILITIES** | | |
| Operating lease liabilities net of current maturities | 1,969 | 2,224 |
| Liability for employee rights upon retirement and others | 1,515 | 1,267 |
| **TOTAL LONG-TERM LIABILITIES** | 3,484 | 3,491 |
| **TOTAL LIABILITIES** | 13,130 | 14,203 |
| **COMMITMENTS AND CONTINGENT LIABILITIES** | | |
| **EQUITY:** | | |
| Common stock, par value $0.0001 per share; 250,000,000 and 150,000,000 shares authorized at June 30, 2026 and December 31, 2025, respectively; 46,921,061 and 43,532,281 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively | 5 | 4 |
| Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2026 and December 31, 2025; 1,718 shares issued and outstanding at June 30, 2026 and December 31 2025 | * | * |
| Additional paid-in capital | 361,811 | 357,489 |
| Accumulated deficit | (330,305) | (302,292) |
| Total equity | 31,511 | 55,201 |
| Total liabilities and equity | $ 44,641 | $ 69,404 |

* 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 June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | **2026** | **2025** | **2026** | **2025** |
| **REVENUES** | $ 1,771 | $ 1,778 | $ 5,169 | $ 3,307 |
| **COST OF REVENUES** | 2,545 | 1,465 | 5,256 | 2,702 |
| **GROSS PROFIT (LOSS)** | (774) | 313 | (87) | 605 |
| **OPERATING EXPENSES:** | | | | |
| Research and development | 4,295 | 3,834 | 9,058 | 7,893 |
| Selling and marketing | 5,221 | 4,172 | 10,401 | 6,922 |
| General and administrative | 4,155 | 5,326 | 8,877 | 10,269 |
| Total operating expenses | 13,671 | 13,332 | 28,336 | 25,084 |
| **LOSS FROM OPERATIONS** | (14,445) | (13,019) | (28,423) | (24,479) |
| **FINANCIAL INCOME (EXPENSE), net:** | 121 | (132) | 410 | 162 |
| **NET LOSS** | $ (14,324) | $ (13,151) | $ (28,013) | $ (24,317) |
| **NET LOSS PER SHARE - basic and diluted** | $ (0.17) | $ (0.26) | $ (0.33) | $ (0.48) |
| **WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted** | 84,659,943 | 51,003,900 | 84,236,742 | 50,508,660 |

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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** | | | | | | **(24,317)** | **(24,317)** |
| **Exercise of pre-funded warrants**** | **1,411,553** | * | | | | | * |
| **Issuance of common stock, included at the market offering net of $22 issuance costs** | **273,621** | * | | | **696** | | **696** |
| **Exercise of Warrants Series I to common stock, net of $109 issuance costs** | **1,408,752** | * | | | **1,838** | | **1,838** |
| **Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 288,207 shares** | **2,847,929** | * | | | **5,940** | | **5,940** |
| **BALANCE AT June 30, 2025** | **32,552,888** | **3** | **1,718** | * | **298,063** | **(277,823)** | **20,243** |

* Represents an amount less than $1 thousand
** Represents cashless exercise of pre-funded warrants

**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 April 1, 2025** | **29,752,661** | **3** | **1,718** | * | **293,014** | **(264,672)** | **28,345** |
| **Net loss** | | | | | | **(13,151)** | **(13,151)** |
| **Exercise of pre-funded warrants**** | **767,693** | * | | | | | * |
| **Exercise of Warrants Series I to common stock, net of $109 issuance costs** | **1,408,752** | * | | | **1,838** | | **1,838** |
| **Share-based compensation related to stock, restricted stock, restricted stock units and stock options award, net of forfeitures of 258,912 shares** | **623,782** | * | | | **3,211** | | **3,211** |
| **BALANCE AT June 30, 2025** | **32,552,888** | **3** | **1,718** | * | **298,063** | **(277,823)** | **20,243** |

* Represents an amount less than $1 thousand
** Represents cashless exercise of pre-funded warrants

**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 January 1, 2026** | **43,532,281** | **4** | **1,718** | ***** | **357,489** | **(302,292)** | **55,201** |
| **Net loss** | | | | | | **(28,013)** | **(28,013)** |
| **Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 336,437 shares** | **3,388,780** | **1** | | | **4,322** | | **4,323** |
| **BALANCE AT June 30, 2026** | **46,921,061** | **5** | **1,718** | ***** | **361,811** | **(330,305)** | **31,511** |

***** 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 April 1, 2026** | **46,838,963** | **4** | **1,718** | ***** | **359,594** | **(315,981)** | **43,617** |
| **Net loss** | | | | | | **(14,324)** | **(14,324)** |
| **Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 60,064 shares** | **82,098** | **1** | | | **2,217** | | **2,218** |
| **BALANCE AT June 30, 2026** | **46,921,061** | **5** | **1,718** | ***** | **361,811** | **(330,305)** | **31,511** |

***** 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)

| | Six months ended June 30 | |
|---|---|---|
| | **2026** | **2025** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (28,013) | $ (24,317) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 307 | 205 |
| Change in fair value of marketable securities, net of interest received | - | (155) |
| Change in liability for employee rights upon retirement | 248 | 277 |
| Other financial income | (18) | (58) |
| Change in operating right of use asset and operating leasing liability | 64 | 377 |
| Share-based compensation expenses | 4,323 | 5,940 |
| Gains on amounts funded in respect of employee rights upon retirement, net | (84) | (95) |
| Changes in operating assets and liability items: | | |
| Decrease in prepaid expenses | 198 | 113 |
| Decrease (increase) in trade receivables | 352 | (20) |
| Decrease (increase) in other receivables | (192) | 186 |
| Decrease (increase) in inventory | 695 | (484) |
| Increase in trade payables | 399 | 264 |
| Increase (decrease) in other payables | (1,511) | 642 |
| Net cash used in operating activities | (23,232) | (17,125) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property, plant and equipment | (524) | (935) |
| Investments in marketable securities | - | (11,749) |
| Proceeds from matured marketable securities | 30,000 | 19,760 |
| Amounts funded in respect of employee rights upon retirement | (44) | (52) |
| Net cash provided by investing activities | 29,432 | 7,024 |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from exercise of warrants | - | 1,947 |
| Proceeds from issuance of shares, net of $22 issuance costs | - | 696 |
| Net cash provided by financing activities | - | 2,643 |
| **EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS** | 10 | 51 |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | 6,210 | (7,407) |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD** | 8,939 | 18,916 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD** | $ 15,149 | $ 11,509 |
| **SUPPLEMENT NON-CASH INVESTING AND FINANCING ACTIVITIES:** | | |
| Issuance Costs not yet paid | - | 109 |
| Acquisition of right-of-use assets by means of lease liabilities | - | 994 |
| Non-cash purchase of property and equipment | 57 | - |

**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 in Israel and Germany, is a medical device company specializing in the development and commercialization of products for the treatment of carotid artery disease and other vascular conditions. The Company's portfolio includes two commercial products based on its proprietary CGuard™ carotid stent technology, designed to provide market-leading embolic protection during and after stenting procedures. A stent is an expandable scaffold-like metallic device placed in an artery to widen the lumen and restore blood flow.

The Company's first product, the CGuard™ Carotid Embolic Prevention System ("CGuard EPS"), integrates a self-expanding nitinol stent with a MicroNet™ mesh sleeve as a single device for carotid artery revascularization. The Company has received CE Mark recertification for CGuard EPS under the EU Medical Device Regulation ("MDR"). The Company's CGuard EPS previously held CE Mark approval under the former Medical Device Directive ("MDD"). CGuard EPS is marketed in over 30 countries outside the United States, mainly in Europe, through a network of distributors. In the first quarter of 2026, the Company submitted a premarket approval ("PMA") to the U.S. Food and Drug Administration ("FDA") for the CGuard EPS.

The Company's second product, the CGuard™ Prime Carotid Stent System ("CGuard Prime"), uses the same stent and MicroNet mesh with a differentiated deployment mechanism. CGuard Prime received PMA by the FDA on June 23, 2025. CGuard Prime also received MDR CE Mark approval on June 12, 2025.

In May 2026, the Company announced a voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA after the Company determined during a controlled launch that the technical success rate of its delivery system during CAS procedures did not meet performance expectations. The voluntary action was limited to the CGuard Prime delivery system and did not involve the CGuard stent implant. The Company's assessment did not identify new safety concerns for patients who had previously received a CGuard implant.

As of June 30, 2026, substantially all affected products were returned and credits were issued to customers. The Company recorded approximately $734,000 as a reduction of revenue related to these returns. In addition, the Company recorded approximately $612,000 of inventory impairment associated with the recall.

**b. Liquidity**

The Company has an accumulated deficit as of June 30, 2026, 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 the Company expands its commercial revenue to a scale that funds its commercial resources, development activities and support functions. 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.

On July 17, 2026, the Company received a notification letter from the Nasdaq Listing Qualifications notifying the Company that it is not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

Management's plans include the continued commercialization of the Company's products and raising capital through the sale of additional equity securities, debt or capital inflows from potential strategic partnerships and exercises 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**

On October 7, 2023, Hamas launched a series of attacks on civilian and military targets in Southern Israel and Central Israel, to which the Israel Defense Forces responded. In addition, Iran, Hezbollah and the Houthi movement attacked military and civilian targets in Israel, to which Israel responded, including through increased air and/or ground operations in Lebanon, Syria, Yemen and Iran. Following years of conflict in the region, on October 9, 2025, Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. On February 28, 2026, the United States and Israel launched joint combat operations in Iran to which Iran and Hezbollah responded with ballistic missile and drone attacks on Israel as well as other countries and U.S. military bases in the region. Although the United States and Iran have announced ceasefire and de-escalation arrangements from time to time, including a memorandum of understanding entered into on June 17, 2026 that contemplates the termination of military operations on multiple fronts, hostilities have resumed and may continue or escalate. How long and how severe the current conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region last and become is unknown at this time and any continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. The intensity and duration of the security situation in Israel have been difficult to predict, as are the economic implications on our business and operations and on Israel's economy in general. As of the date of these condensed consolidated financial statements, conflict continues in parts of the region. The Company's current manufacturing facility, certain of its key personnel and one of its offices are located in Israel. At this time, these activities remain largely unaffected.

During the three and six months ended June 30, 2026 and 2025, 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 condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of the Company, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of its financial position as of June 30, 2026, and its results of operations, changes in equity and cash flows for the three and six months ended June 30, 2026, and 2025. These unaudited 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, 2025, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 18, 2026. The results of operations for the six and three months ended June 30, 2026 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 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 expense 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 consolidated financial statements and disclosures.
2) In December 2025, the FASB issued ASU 2025-11, "Interim Reporting (Topic 270) Narrow-Scope Improvements." The amendments in this Update clarify interim disclosure requirements and the applicability of Topic 270. The objective of the update is to provide clarity about current interim requirements. The amendments in this update also include a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The amendments in this ASU are required to be adopted for interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company does not expect ASU 2025-11 to have a material impact on its consolidated financial statements disclosures.

## NOTE 4 – FAIR VALUE MEASUREMENTS

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

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

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

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

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

| | As of June 30, 2026 ($ in thousands) | | | |
|---|---|---|---|---|
| | **Total** | **Level 1** | **Level 2** | **Level 3** |
| **Assets:** | | | | |
| Cash equivalents- | | | | |
| Money market funds | $ 12,182 | $ 12,182 | $ - | $ - |
| Marketable securities- | | | | |
| U.S government bonds | $ 15,272 | $ - | $ 15,272 | $ - |

| | As of December 31, 2025 ($ in thousands) | | | |
|---|---|---|---|---|
| | **Total** | **Level 1** | **Level 2** | **Level 3** |
| **Assets:** | | | | |
| Cash equivalents- | | | | |
| Money market funds | $ 5,116 | $ 5,116 | $ - | $ - |
| Marketable securities- | | | | |
| U.S government bonds | $ 45,272 | $ - | $ 45,272 | $ - |

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 June 30, 2026, and December 31, 2025, is $15,239 and $45,091 thousand, respectively.

**NOTE 5 - MARKETABLE SECURITIES**

As of June 30, 2026, and December 31, 2025, all of the Company's marketable securities had contractual maturities 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 six-month period ended June 30, 2026, and 2025:

| | Six months ended June 30, | |
|---|---|---|
| | 2026 | 2025 |
| | ($ in thousands) | |
| Balance at beginning of the period | $ 45,272 | $ 15,721 |
| Additions | - | 11,749 |
| Maturity | (30,000) | (19,760) |
| Interest received | (522) | (109) |
| Changes in fair value during the period | 522 | 264 |
| Balance at end of the period | 15,272 | 7,865 |

**NOTE 6 - EQUITY:**

**a. Authorized Capital Stock**

As of June 30, 2026, the Company had 255,000,000 authorized shares of capital stock, par value $0.0001 per share, of which 250,000,000 are shares of common stock and 5,000,000 are shares of "blank check" preferred stock.

**b. Preferred Stock**

As of June 30, 2026, 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.

**c. Pre-Funded Warrants**

As of June 30, 2026, there are 43,092,107 outstanding pre-funded warrants.

**d. Warrants**

As of June 30, 2026, the Company has outstanding warrants to purchase an aggregate of 25,828,164 shares of common stock as follows:

| | Number of underlying Common stock | Exercise price | Expiration date |
|---|---|---|---|
| Series J Warrants | 12,914,086 | 1.3827 | * |
| Series K Warrants | 12,914,078 | 1.3827 | * |
| Total Warrants | 25,828,164 | | |

* 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 cm and (B) in the case of 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 CGuard Prime in the U.S. begins. Following the commencement of the first commercial sales of CGuard Prime in the United States, which occurred during the third fiscal quarter of 2025 in July 2025, the Series K Warrants are scheduled to expire twenty (20) trading days after the end of the fourth fiscal quarter thereafter, which is October 28, 2026.

During the six months ended June 30, 2026, a total of 1,092,344 Series G warrants expired unexercised.

**e. Share-Based Compensation**

During the six months ended June 30, 2026, the Company granted 3,725,216 restricted shares of the Company's common stock to employees and directors. The shares granted to employees are subject to a three-year vesting period, with one-third of such awards vesting each year, subject to continued service. The shares granted to directors are subject to a one-year vesting period, subject to continued service.

The fair value of the above restricted shares was approximately $5.8 million.

During the six months ended June 30, 2026, the Company granted 1,114,792 restricted stock units convertible into shares of the Company's common stock to the Company's chief executive officer. The restricted stock units are subject to a three-year vesting period, with one-third of such awards vesting each year, subject to continued service.

The fair value of the above restricted stock units was approximately $1.8 million

**NOTE 7 – RELATED PARTIES TRANSACTIONS**

During the three and six months ended June 30, 2025, administrative services provided by a member of the chief executive officer's immediate family in connection with the Company's expansion to the U.S. amounted to $24 and $48 thousand, respectively. The engagement with the related party was terminated in July 2025.

**NOTE 8 - NET LOSS PER SHARE:**

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

For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the pre-funded warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them.

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 38,356,174 and 49,201,359 for the six and three-month periods ended June 30, 2026 and 2025, respectively. This amount includes 6,734,737 and 5,456,724 of unvested restricted stock included in the number of issued and outstanding shares as of June 30, 2026 and 2025, respectively.

For the six and three months ended June 30, 2026, and 2025, the weighted average number of common stock used in computing net loss per share - basic and diluted was as follows:

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Weighted average number of common stock | 39,903,736 | 25,292,694 | 39,598,447 | 24,419,172 |
| Weighted average Vested restricted stock units | 1,664,100 | 941,744 | 1,546,188 | 834,115 |
| Weighted average Pre-funded Warrants | 43,092,107 | 24,769,462 | 43,092,107 | 25,255,373 |
| Total Weighted average number of common stock used in computing net loss per share - basic and diluted | 84,659,943 | 51,003,900 | 84,236,742 | 50,508,660 |

**NOTE 9 - FINANCIAL INSTRUMENTS:**

**a. Fair value of financial instruments**

As of June 30, 2026, and December 31, 2025, the carrying amounts of accounts payable, accounts receivable and other receivables approximate their fair values due to the short-term maturities of these instruments.

The carrying amount of the long-term deposit approximates its fair value since it is measured at its present value applying prevailing interest rates.

**b.** As of June 30, 2026, and December 31, 2025, the allowance for expected credit loss was immaterial.

**NOTE 10- INVENTORY:**

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| | ($ in thousands) | |
| Finished goods | $ 120 | $ 352 |
| Work in process | 981 | 930 |
| Raw materials and supplies | 1,600 | 2,114 |
| | $ 2,701 | $ 3,396 |

***** The Company recorded approximately $612 thousand of inventory impairment in connection with the voluntary recall during the six months ended June 30, 2026.

**NOTE 11 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:**

| | June 30, 2026 | December 31, 2025 |
|---|---|---|
| | ($ in thousands) | |
| Employees and employee institutions | $ 3,135 | $ 4,925 |
| Accrued vacation and recreation pay | 716 | 430 |
| Accrued expenses | 1,016 | 1,545 |
| Clinical trial accrual | 1,184 | 1,155 |
| Current Operating lease liabilities | 1,056 | 1,066 |
| Customer credit balances* | 581 | 2 |
| Other | 304 | 334 |
| | $ 7,992 | $ 9,457 |

* Customer credit balances primarily represent credits issued to customers in connection with the voluntary recall of CGuard Prime products (see note 1a).

**NOTE 12 - DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:**

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

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| | ($ in thousands) | | | |
| Germany | $ 265 | $ 360 | $ 520 | $ 602 |
| Italy | 304 | 324 | 658 | 586 |
| Poland | 262 | 249 | 563 | 474 |
| Argentina | 180 | 160 | 347 | 180 |
| USA** | (351) | 27 | 827 | 54 |
| Other* | 1,111 | 658 | 2,254 | 1,411 |
| | $ 1,771 | $ 1,778 | $ 5,169 | $ 3,307 |

* Other countries do not exceed 10% in the six and three months ended June 30, 2026 and 2025.

** Approximately $734 thousand of credits issued in connection with the voluntary recall were deducted from U.S revenues for the three and six months ended June 30, 2026, which resulted in negative net revenues in the United States for the three months ended June 30 (see note 1a).

By principal customers (part of revenues):

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| Customer A | 15% | 20% | 10% | 18% |
| Customer B | 13% | 12% | 9% | 12% |
| Customer C | 10% | 9% | 7% | 5% |

**NOTE 13 - 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 chief executive officer, 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 loss 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 June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| **Revenues** | **1,771** | **1,778** | **5,169** | **3,307** |
| **Cost of Revenues:** | | | | |
| Material and Labor | 1,631 | 1,138 | 3,322 | 2,163 |
| Other cost of revenues | 302 | 327 | 849 | 539 |
| Inventory write-off | 612 | - | 1,085 | - |
| **Total Cost of Revenues** | **2,545** | **1,465** | **5,256** | **2,702** |
| **Research and development (R&D)** | | | | |
| Payroll and Benefits | 1,282 | 1,120 | 2,882 | 1,974 |
| Share based compensation | 435 | 645 | 610 | 1,314 |
| Clinical trials | 972 | 1,125 | 2,473 | 2,287 |
| Other R&D | 1,606 | 944 | 3,093 | 2,318 |
| **Total Research and development** | **4,295** | **3,834** | **9,058** | **7,893** |
| **Selling and marketing (S&M)** | | | | |
| Payroll and Benefits | 3,932 | 2,779 | 7,795 | 4,757 |
| Share based compensation | 543 | 595 | 1,124 | 812 |
| Other S&M | 746 | 798 | 1,482 | 1,353 |
| **Total Selling and marketing** | **5,221** | **4,172** | **10,401** | **6,922** |
| **General and administrative (G&A)** | | | | |
| Payroll and Benefits | 1,365 | 1,729 | 3,172 | 3,309 |
| Share based compensation | 1,177 | 1,920 | 2,466 | 3,700 |
| Other G&A | 1,613 | 1,677 | 3,239 | 3,260 |
| **Total General and administrative** | **4,155** | **5,326** | **8,877** | **10,269** |
| Financial Income (expenses), net; | 121 | (132) | 410 | 162 |
| Segment net loss | (14,324) | (13,151) | (28,013) | (24,317) |

**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 our 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;
- any impact of a product recall, including the current recall in the U.S. regarding the CGuard Prime 135cm Carotid Stent System, on our business, results of operations and financial conditions;
- 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 specializing in the development and commercialization of products for the treatment of carotid artery disease and other vascular conditions. Our portfolio includes two commercial products based on our proprietary CGuard carotid stent technology, designed to provide market-leading embolic protection during and after stenting procedures. A stent is an expandable scaffold-like metallic device placed in an artery to widen the lumen and restore blood flow.

Our first product, the CGuard Carotid Embolic Prevention System ("CGuard EPS"), integrates a self-expanding nitinol stent with a MicroNet mesh sleeve as a single device for carotid artery revascularization. In January 2024, we received CE Mark recertification for CGuard EPS under the EU Medical Device Regulation ("MDR"). Our CGuard EPS previously held CE Mark approval under the former Medical Device Directive ("MDD"). CGuard EPS is marketed in over 30 countries outside the United States through a network of distributors. In the first quarter of 2026, we submitted a premarket approval for the CGuard EPS with a view to potential FDA approval in the second half of 2026.

Our second product, the CGuard Prime Carotid Stent System ("CGuard Prime"), uses the same stent and MicroNet mesh as the CGuard EPS with a differentiated deployment mechanism. CGuard Prime received premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") on June 23, 2025. In May 2026, we announced a voluntary recall in the U.S. of CGuard Prime, undertaken in consultation with the FDA after a controlled launch demonstrated that the technical success of its delivery system during CAS procedures did not meet performance expectations, with the voluntary action pertaining specifically to the delivery system and not to the CGuard stent implant. For additional information, see "*FDA Matters*" below. CGuard Prime also received MDR CE Mark approval on June 12, 2025.

In October 2024, the FDA approved the Company's IDE to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80 cm carotid stent system during transcarotid revascularization ("TCAR") procedures. In the first quarter of 2026, we completed enrollment in the CGUARDIANS II pivotal study, and in June 2026, we announced summary 30-day outcome data from the study, which showed acute device success of 100% with no major adverse events. In May 2026, the FDA approved the Company's IDE to initiate the CGUARDIANS III pivotal study of its CGuard Prime 80 cm carotid stent system during TCAR procedures, and in June 2026, we announced enrollment of the first patient.

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

In November 2025, the results of the CREST-2 study were released, which showed that CAS combined with medical therapy demonstrated a significantly lower stroke risk as compared to intensive medical management alone in patients with severe asymptomatic carotid stenosis. CREST-2 was an independent study sponsored by the National Institute of Health (NIH) with a set of two parallel, observer-blinded clinical trials across 155 centers globally. CREST-2 showed that, among patients with high-grade carotid stenosis without recent neurological symptoms, the addition of stenting led to significantly better outcomes than intensive medical management alone, as measured by a decreased risk of the composite of perioperative stroke or death or ipsilateral stroke within four years. In a separate arm of the same trial, carotid endarterectomy ("CEA") did not achieve a significant benefit for these patients as compared to intensive medical management alone.

We continue to invest in new product generations and potential new clinical indications for the CGuard platform with a strategy of focusing on advancing a "stent-first" approach to carotid revascularization. As part of this strategy, we are evaluating CGuard Prime in TCAR-based clinical programs, including the CGUARDIANS II pivotal trial, which studies the use of the CGuard Prime 80 cm carotid stent system in conjunction with an established neuroprotection device, and the CGUARDIANS III pivotal trial, which evaluates our proprietary SwitchGuard neuroprotection system ("SwitchGuard NPS") paired with CGuard Prime to enable flow-reversal neuroprotection during TCAR. In parallel, we are pursuing new clinical applications outside TCAR, including the treatment of acute ischemic stroke with tandem lesions, which is currently being studied in an early feasibility study conducted with the Jacobs Institute. In this acute-stroke setting, the flexible, low-metal-burden design and MicroNet mesh of CGuard Prime may offer advantages where traditional embolic-protection devices cannot be used.

We consider our current addressable market for our CGuard EPS, CGuard Prime, 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 patients eligible for either CAS or TCAR procedures, but also individuals who are candidates for CEA, as all three approaches can be options to treat these patients. Assuming full penetration of the intervention caseload, we estimate that the addressable market for CGuard EPS, CGuard Prime, 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 EPS, CGuard Prime, and SwitchGuard NPS to be approximately $9.3 billion, which may grow over time if expanded treatment options such as our products lead to increased patient screening for carotid artery disease.

*FDA Matters*

In May 2026, we announced a voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA. The Company acted after determining during a controlled launch that the technical success rate of the delivery system during CAS procedures had not met performance expectations. The voluntary action was limited to the CGuard Prime delivery system and did not involve the CGuard stent implant. The Company's assessment did not identify new safety concerns for patients who had previously received a CGuard implant. We believe we have identified the root cause of the deployment resistance and are implementing design modifications intended to address the issue. We are currently performing verification and validation testing of these modifications in support of a PMA supplement to the FDA which we expect to submit in the fourth quarter of 2026. We cannot provide any assurance that the FDA will be satisfied with the corrective actions we are implementing in connection with the voluntary recall, or as to the timing of the resolution of such issues. Until these issues are resolved to the FDA's satisfaction, we may be unable to resume commercialization of CGuard Prime in the United States. If the FDA determines that our corrective actions are inadequate or requires additional remediation, testing, validation or regulatory submissions, such requirements could increase costs, delay or prevent FDA acceptance or approval of our proposed PMA supplement, extend the duration of the voluntary recall, delay our ability to reintroduce CGuard Prime to the U.S. market or otherwise adversely affect our future commercialization plans, which could have a material adverse effect on our business, financial condition and results of operations. During the six months ended June 30, 2026, substantially all affected products were returned, and credits were issued to customers. We recorded approximately $734,000 as a reduction of revenue related to these returns and approximately $612,000 of inventory impairment associated with the recall.

*Workforce Reduction Initiative*

Subsequent to June 30, 2026, we commenced implementation of a workforce reduction as part of a broader initiative to reduce our operating expenses, improve operational efficiency and better align our resources with our strategic priorities. The workforce reduction is expected to reduce the number of positions in the organization by almost 20%. We expect the initiative to result in annualized operating expense savings of approximately $9.0 million, primarily through reduced personnel-related expenses resulting from both the elimination of certain employee positions and the decision not to fill certain currently vacant positions. These estimates are based on management's current expectations regarding personnel reductions and hiring plans, and actual cost savings may differ from those currently anticipated.

We expect to incur aggregate restructuring charges of approximately $0.9 million to $1.2 million, consisting primarily of employee severance and related employee termination costs. Because the workforce reduction was initiated after June 30, 2026, no liability associated with these actions was recorded in the accompanying consolidated financial statements as of June 30, 2026.

We expect the workforce reduction to be substantially completed by the end of the third quarter of 2026. Actual costs incurred may differ from current estimates. We expect these actions to better align our resources with key product development, regulatory, clinical and commercialization priorities while reducing our overall operating expense base.

**Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations 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, 2025. There have not been any material changes to such critical accounting policies since December 31, 2025.

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 June 30, 2026, compared to the three months ended June 30, 2025*

*Revenues*. For the three months ended June 30, 2026, revenue was $1,771,000, a decrease of $7,000, or 0.4 %, compared to $1,778,000 during the three months ended June 30, 2025. The decrease was primarily attributable to the net impact of $734,000 of credits issued in connection with the voluntary recall of CGuard Prime products in the U.S. in May 2026, which offset revenues generated from direct sales of the CGuard Prime product in the U.S., and continued growth in sales of the CGuard product through distributors in international markets.

With respect to geographical regions, U.S. revenue was $(351,000) for the three months ended June 30, 2026, compared to $27,000 for the three months ended June 30, 2025. The decrease of $378,000 in the U.S., was primarily due to the aforementioned credits issued in connection with the voluntary recall of CGuard Prime products. This decrease was partially offset by 21% growth in international markets, with international revenue increasing to $2,122,000 for the three months ended June 30, 2026, compared to $1,751,000 for the three months ended June 30, 2025, including increases of $128,000 in Europe, $176,000 in Latin America and $67,000 in all other regions, reflecting continued growth in demand in these markets.

*Gross Profit (Loss)*. For the three months ended June 30, 2026, gross loss (revenue less cost of revenues) was $774,000 compared to gross profit of $313,000 for the three months ended June 30, 2025. The decrease in gross profit was primarily attributable to the voluntary recall of CGuard Prime products in the U.S., including the net credits of $734,000 issued to customers, which reduced revenues, and approximately $612,000 of inventory impairment associated with CGuard Prime inventory, which increased cost of revenues.

Gross margin represents our gross profit or loss as a percentage of revenue. Gross margin was negative 43.7% for the three months ended June 30, 2026, a decrease of 61.3 percentage points compared to gross margins of 17.6% for the three months ended June 30, 2025, primarily due to the factors discussed above.

*Research and Development Expenses*. For the three months ended June 30, 2026, research and development expenses were $4,295,000, an increase of $461,000, or 12%, compared to $3,834,000 during the three months ended June 30, 2025. This increase resulted primarily from higher development and clinical expenses for the SwitchGuard NPS and CGuard Prime 80 cm carotid stent system, regulatory activity related to the PMA for CGuard NPS, and redesign work for the CGuard Prime 135 cm.

*Selling and Marketing Expenses*. For the three months ended June 30, 2026, selling and marketing expenses were $5,221,000, an increase of $1,049,000, or 25.1%, compared to $4,172,000 during the three months ended June 30, 2025. This increase resulted primarily from higher commercial staffing levels following the commercial launch of CGuard Prime in the U.S. in July 2025.

*General and Administrative Expenses*. For the three months ended June 30, 2026, general and administrative expenses were $4,155,000, a decrease of $1,171,000, or 22%, compared to $5,326,000 during the three months ended June 30, 2025. The decrease was primarily driven by lower compensation expenses, mainly due to severance costs related to our former chief financial officer’s retirement that were recognized in the three months ended June 30, 2025, and lower share-based compensation expense.

*Financial Income*. For the three months ended June 30, 2026, financial income was $121,000 compared to financial expense of $132,000 during the three months ended June 30, 2025, representing a decline in the financial expense of $253,000, or 191.7%. The increase in financial income primarily resulted from higher income from investment in marketable securities and money market funds and lower financial expenses related to changes in exchange rates.

*Tax Expenses.* We did not incur any tax expenses during the three months ended June 30, 2026 and June 30, 2025.

*Net Loss*. For the three months ended June 30, 2026, our net loss was $14,324,000, an increase of $1,173,000, or 8.9%, compared to $13,151,000 during the three months ended June 30, 2025. The increase in net loss resulted primarily from a decrease in gross profit of $1,087,000 and an increase in total operating expenses of $339,000, partially offset by an increase in financial income of $253,000 compared to the prior-year period.

*Six months ended June 30, 2026, compared to the six months ended June 30, 2025*

*Revenues*. For the six months ended June 30, 2026, revenue was $5,169,000, an increase of $1,862,000, or 56.3%, compared to $3,307,000 during the six months ended June 30, 2025. The increase was driven mainly by direct sales of the CGuard Prime product in the U.S. and continued growth in sales of the CGuard product through distributors in international markets. The increase was partially offset by $734,000 of credits issued in connection with the voluntary recall of CGuard Prime products in the U.S. during the six months ended June 30, 2026.

With respect to geographical regions, U.S. revenue was $827,000 for the six months ended June 30, 2026, compared to $54,000 for the six months ended June 30, 2025. The increase of approximately $772,000 was driven by commercial sales of CGuard Prime, partially offset by credits issued in connection with the voluntary recall of CGuard Prime in May 2026. International revenue was $4,342,000 for the six months ended June 30, 2026, compared to $3,253,000 for the six months ended June 30, 2025. Revenue from international markets grew by $1,089,000, or 33%, including $557,000 in Europe, $348,000 in Latin America and $184,000 in all other regions. The international sales performance reflects continued growth in demand in these markets.

*Gross loss*. For the six months ended June 30, 2026, gross loss (revenue less cost of revenues) was $87,000 compared to gross profit of $605,000 for the six months ended June 30, 2025. The decrease in gross profit was primarily attributable to the voluntary recall of CGuard Prime products in the U.S., including $734,000 in net credits issued to customers, which reduced revenues, as well as inventory impairment and inventory obsolescence charges of a combined $1,085,000 related to our CGuard Prime delivery system, which increased cost of revenues. These impacts were partially offset by the increase in revenue year-over-year.

Gross margin represents our gross profit or loss as a percentage of revenue. Gross margin was negative 1.7% for the six months ended June 30, 2026, a decrease of 20.0 percentage points compared to gross margin of 18.3% for the six months ended June 30, 2025, primarily due to the factors discussed above.

*Research and Development Expenses*. For the six months ended June 30, 2026, research and development expenses were $9,058,000, an increase of $1,165,000, or 14.8%, compared to $7,893,000 during the six months ended June 30, 2025. The increase was primarily driven by higher clinical trial expenses related to the initiation of the CGUARDIANS III pivotal trial and higher compensation expenses due to the hiring of new employees in connection with our expansion in the United States. These increases were partially offset by lower clinical trial expenses due to the completion of the CGUARDIANS I and CGUARDIANS II pivotal trials.

*Selling and Marketing Expenses*. For the six months ended June 30, 2026, selling and marketing expenses were $10,401,000, an increase of $3,479,000, or 50.3%, compared to $6,922,000 during the six months ended June 30, 2025. This increase resulted primarily from higher commercial staffing levels following the commercial launch of CGuard Prime in the U.S. in July 2025.

*General and Administrative Expenses*. For the six months ended June 30, 2026, general and administrative expenses were $8,877,000, a decrease of $1,392,000, or 13.6%, compared to $10,269,000 during the six months ended June 30, 2025. The decrease was primarily driven by lower compensation expenses, mainly due to severance costs related to our former chief financial officer's retirement that were recognized in the six months ended June 30, 2025, and lower share-based compensation expense.

*Financial Income*. For the six months ended June 30, 2026, financial income was $410,000, an increase of $248,000, or 153.1%, compared to $162,000 during the six months ended June 30, 2025. The increase in financial income primarily resulted from higher income from investment in marketable securities and money market funds and lower financial expenses related to changes in exchange rates.

*Tax Expenses.* For the six months ended June 30, 2026, there was no material change in our tax expenses as compared to the six months ended June 30, 2025.

*Net Loss*. For the six months ended June 30, 2026, our net loss was $28,013,000, an increase of $3,696,000, or 15.2%, compared to $24,317,000 during the six months ended June 30, 2025. The increase in net loss resulted primarily from a decrease in gross profit and an increase in total operating expenses, partially offset by an increase in financial income compared to the prior-year period.

**Liquidity and Capital Resources**

We had an accumulated deficit as of June 30, 2026, of $330 million, as well as a net loss of $28 million for the six months ended June 30, 2026 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until we expand our commercial revenue to a scale that funds our commercial resources, development activities and support functions. 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 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, pursuant to which we issued and sold 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 12,914,078 shares of common stock (the "Series K Warrants" and together with the Series H Warrants, Series I Warrants and Series J Warrants, the "May 2023 Warrants"), at an offering price of $1.6327 per Private Placement Share and associated May 2023 Warrants and an offering price of $1.6326 per pre-funded warrant and associated May 2023 Warrants. If the May 2023 Warrants are exercised in cash in full this would result in an additional $71.4 million of gross proceeds (of which approximately $33.8 million has been received as of the date of this Quarterly Report on Form 10-Q). There can be no assurance that we will achieve any of the remaining milestones set forth in the outstanding May 2023 Warrants or that the outstanding May 2023 Warrants will be exercised in cash in full. The exercise price of the outstanding May 2023 Warrants is $1.3827 per share. The Series J Warrants expire 20 trading days after FDA approval of SwitchGuard and CGuard Prime 80 cm, while the Series K Warrants expire on October 28, 2026, which is 20 trading days after the end of the fourth fiscal quarter following the commencement of first U.S. commercial sales of CGuard Prime in July 2025. The last reported sale price of our shares of common stock on August 13, 2026 was $0.8401 per share. We believe that the likelihood that warrant holders will exercise their outstanding May 2023 Warrants, and therefore the amount of cash proceeds we would receive, is dependent upon the trading price of our shares of common stock. If the trading price of our shares of common stock is less than $1.3827 per share, we believe that warrant holders will be unlikely to exercise their outstanding May 2023 Warrants.

Following the announcement of the one year follow up study results from the Company's C-GUARDIANS trial, the Series H Warrants were exercised in full into 292,996 shares of common stock and pre-funded warrants to purchase 12,621,090 shares of common stock. The net proceeds from the exercise of the Series H Warrants were $16.9 million after deducting placement agent fees.

Following the announcement of the PMA approval of the CGuard Prime carotid stent system in the United States, the Series I warrants 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 during June and July 2025. The net proceeds from the exercise of the Series I Warrants were $16.9 million after deducting placement agent fees.

In May 2024, we entered into an Equity Distribution Agreement (the "2024 Distribution Agreement") with Piper Sandler & Co., as sales agent ("Piper Sandler"). Pursuant to the 2024 Distribution Agreement, we were able to offer and sell from time to time, at our option, through or to Piper Sandler shares of our common stock having an aggregate offering price of up to $75 million. We paid Piper Sandler a commission at a fixed rate of 3.0% of the aggregate gross proceeds from each sale of the shares under the 2024 Distribution Agreement. On April 3, 2026, we terminated the 2024 Distribution Agreement in connection with our entry into the 2026 Distribution Agreement (as defined below) with BTIG (as defined below). During the first half of 2026, we did not sell any shares pursuant to the 2024 Distribution Agreement.

In August 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 us.

In April 2026, we entered into an Equity Distribution Agreement (the "2026 Distribution Agreement") with BTIG, LLC, as sales agent ("BTIG"). Pursuant to the 2026 Distribution Agreement, we may offer and sell from time to time, at our option, through or to BTIG shares of our common stock having an aggregate offering price of up to $75 million. We will pay BTIG a commission at a fixed rate of up to 3.0% of the aggregate gross proceeds from each sale of the shares under the 2026 Distribution Agreement. As of the date hereof, we have not sold any shares pursuant to the 2026 Distribution Agreement.

*Six months ended June 30, 2026, compared to the Six months ended June 30, 2025*

**General.** As of June 30, 2026, we had cash and cash equivalents of $15,149,000 and marketable securities of $15,272,000 as compared to cash and cash equivalents of $8,939,000 and marketable securities of $45,272,000 as of December 31, 2025. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative costs, capital expenditures and general working capital.

For the six months ended June 30, 2026, net cash used in our operating activities increased by $6,107,000, or 35.7%, to $23,232,000, from $17,125,000 during the same period in 2025. The primary reasons for the increase in cash used in our operating activities were an increase of $6,741,000 in compensation costs paid during the six months ended June 30, 2026 (from $11,474,000 in the six months ended June 30, 2025 to $18,215,000 in the six months ended June 30, 2026), an increase of $1,937,000 in payments to vendors, clinical service providers and other professional service providers, offset by an increase of $2,617,000 in payments received from customers during the six months ended June 30, 2026 (from $3,380,000 in the six months ended June 30, 2025 to $5,997,000 during the six months ended June 30, 2026).

Cash provided by our investing activities was $29,432,000 during the six months ended June 30, 2026, compared to $7,024,000 during the six months ended June 30, 2025. The primary reason for the increase in cash provided by our investing activities is withdrawal of $30,000,000 from our investment in marketable securities.

There was no cash provided by financing activities for the six months ended June 30, 2026. Cash provided by financing activities for the six months ended June 30, 2025, was $2,643,000. The source of the cash provided by financing activities during the six months ended June 30, 2025, were the proceeds from exercise of Series I warrants of $1,947,000, and proceeds from issuance of shares of $696,000, net of issuance costs, received from our ATM Program.

**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, manufacturing efficiencies due to the learning curve of utilizing new materials and equipment and the costs or other consequences associated with any current or future product recall that may occur. Product recalls in particular have adversely affected and may continue to adversely affect our operating results through the direct costs of executing a recall, lost revenues resulting from the removal of affected products from the market and the interruption of sales during any remediation period, costs associated with redesigning and remanufacturing affected products, potential regulatory, litigation and other legal costs, and longer-term reputational harm that may reduce market acceptance of our current and future products. 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 six months ended June 30, 2026, there were no material changes to our contractual obligations and commitments since the year ended December 31, 2025.

**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 June 30, 2026, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of June 30, 2026.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2026, 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 18, 2026.

***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 June 30, 2026 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 June 30, 2026 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.

***If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.***

Nasdaq has established certain standards for the continued listing of a security on the Nasdaq Capital Market. The standards for continued listing include, among other things, that the minimum bid price for the listed securities not fall below $1.00 per share for a period of 30 consecutive trading days and that we maintain a minimum of $2,500,000 in stockholders' equity and a market value of listed securities of at least $5 million.

On July 17, 2026, we received a notification letter, or the Notification Letter, from the Nasdaq Listing Qualifications notifying us that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2), or the Rule, for continued listing on The Nasdaq Capital Market. The Notification Letter provides that we have 180 calendar days, or until January 13, 2027, to regain compliance with the Rule. To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of 10 consecutive business days. In the event we do not regain compliance by January 13, 2027, we may then be eligible for an additional 180 days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period. If we do not qualify for the second compliance period or fail to regain compliance during the second compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we will have an opportunity to appeal the delisting determination to a Hearings Panel.

No assurance can be given that we will be able to regain compliance with the Rule. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our common stock. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

***Our restructuring and the associated workforce reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.***

We have begun to implement a restructuring plan that includes a reduction in our workforce, and we expect to continue to implement this plan. We may incur additional expenses not currently contemplated due to events associated with the reduction in force, and our restructuring activities may subject us to reputational risks and litigation risks and expenses. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. In addition, to the extent we do not realize such anticipated operational efficiencies, we may need to undertake additional workforce reductions or restructuring activities in the future.

Furthermore, our restructuring plan may be disruptive to our operations. For example, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. The changes to our operations and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reductions in force, and a reduction in morale among our remaining employees, all of which may have an adverse effect on our business, results of operations or financial condition. If employees who were not affected by the reductions in force seek alternative employment, this could result in our seeking contractor support at unplanned additional expense or harm our productivity. Any employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, technical, and manufacturing personnel who are critical to our business. For example, the workforce reduction may negatively impact our regulatory, technical operations, and commercial functions, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our products. We may also discover that the reductions in workforce could make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Our future financial performance and our ability to develop our products or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, results of operations and financial condition.

***Our products have and may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.***

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse events and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. For example, in May 2026, we announced a voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA. This decision followed our determination during controlled launch that the technical success of the delivery system during CAS procedures had not met performance expectations. Such recall, and any recalls in the future, could result in significant current and future costs and other negative impacts associated with such recalls (including inventory write-off costs, refunds), loss of revenues, sales or customers, potential actions by regulators or other governmental entities, potential claims and lawsuits by customers and patients (including class action product liability litigation), other operational impacts and consequences such as business disruption, loss of personnel and distraction of management or other key employees, the restatement of previously issued financial statements, inability to raise capital, as well as negative publicity and damage to our reputation, which could have a material adverse impact on our business, results of operations and financial condition.

In the European Economic Area, we must comply with the medical device vigilance system under Regulation (EU) 2017/745 on medical devices, or the MDR. Under this system, manufacturers are generally required to report serious incidents involving medical devices via an electronic system incorporated into the EU database on medical devices, called EUDAMED. Furthermore, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. FSCAs must be reported to the relevant competent authorities, even if the FSCA was undertaken in a third country in relation to a device which is also legally made available on the Union market and the reason for the FSCA is not limited to the device made available in the third country.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation and financial results.

***Defects or failures associated with our products have led to recalls, and could lead to additional recalls, safety alerts or litigation, as well as significant costs and negative publicity.***

Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. For example, in May 2026, we announced a voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA. This decision followed our determination during controlled launch that the technical success of the delivery system during CAS procedures had not met performance expectations. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and could have a material adverse effect on our business, financial condition and results of operations.

The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of the neck with the brain as the end organ is dangerous and presents risks of adverse events such as bleeding, arterial dissection, cranial nerve injury, myocardial infarction, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication, not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under MDR and regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales.

***Even if products we develop receive marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability or that of any collaborators to market the product, and could cause regulatory authorities to take certain regulatory actions, which could harm our commercial operations.***

It is possible that our clinical trials may indicate an apparent positive effect of a product that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. For example, we, or others, may discover that our products are less safe and effective than previously believed. If, we, or others, discover that a product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any of our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;

- additional restrictions may be imposed on the marketing of, or the manufacturing processes of, the particular product;
- we, or any of our collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication including with the product;
- we, or any of our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- physicians and patients may stop using our product; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact our stock price.

For example, in May 2026, we announced a voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA. This decision followed our determination during controlled launch that the technical success of the delivery system during CAS procedures had not met performance expectations. Such recall, and any recalls in the future, could result in significant current and future costs and other negative impacts associated with such recalls (including inventory write-off costs, refunds), loss of revenues, sales or customers, potential actions by regulators or other governmental entities, potential claims and lawsuits by customers and patients (including class action product liability litigation), other operational impacts and consequences such as business disruption, loss of personnel and distraction of management or other key employees, or the restatement of previously issued financial statements, inability to raise capital, as well as negative publicity and damage to our reputation, which could have a material adverse impact on our business, results of operations and financial condition.

***Material modifications to our products may require new 510(k) clearances, premarket approval, or CE Marks, or may require us to recall or cease marketing our products until new clearances or approvals are obtained.***

Material modifications to the intended use or technological characteristics of our products will require new 510(k) clearances, premarket approvals ("PMA") by the FDA or CE Marks under the EU Medical Device Regulation ("MDR") prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions. In response to the voluntary recall in the U.S. of CGuard Prime, initiated in consultation with the FDA in May 2026, we intend to implement design improvements to CGuard Prime. However, there can be no assurance that such design improvements will be sufficient to obtain FDA approval, or that any such approval will be obtained in a timely manner, if at all.

***We bear the risk of warranty claims on our products.***

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer, and any recovery from such supplier or vendor may not be adequate. Furthermore, we may not have any, or have an adequate, warranty provided by our supplier. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. In addition, we have been, and in the future could be, subject to costs related to product recalls, and we could incur significant costs to correct any defects, warranty claims or other problems. Any such events could adversely affect our business, financial condition and results of operations.

***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 CGuard Prime, 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 commercialization of CGuard Prime, we have engaged Aptyx to expand our manufacturing capacity 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 adopted, proposed and considered a variety of tariff measures and other trade restrictions affecting imports from numerous countries, and additional changes to U.S. trade policy remain under active consideration. The implementation, modification, suspension, expiration, extension or judicial review of existing or proposed tariffs and trade measures has created and may continue to create significant uncertainty for companies engaged in international manufacturing and cross-border commerce. In addition, new investigations under U.S. trade laws, changes to customs rules, import restrictions, sanctions or other trade-related measures could result in additional duties, restrictions or compliance obligations affecting imported products and components.

Because we currently manufacture our products in Israel and remain dependent on shipments from Israel to serve the U.S. market while we continue efforts to expand manufacturing capacity in the United States, changes in tariffs, customs duties, import regulations or other trade measures applicable to products imported into the United States could increase our costs, reduce our margins, disrupt our supply chain, adversely affect customer demand or require us to modify our manufacturing, sourcing or distribution strategies. We cannot predict the scope, duration or outcome of current or future trade actions, related legal challenges, or any retaliatory measures by affected countries. Any of these developments could have a material adverse effect on our business, financial condition and results of operations.

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). We cannot predict whether, and to what extent, trade policies will change in the future. If tariffs or other trade restrictions are imposed on products manufactured in Israel 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.

***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.***

Although we are incorporated in the State of Delaware and our headquarters are in Miami, Florida, 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 countries and terrorist organizations active in the region, including Iran, 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 recent years, Israel has been engaged in sporadic armed conflicts with Hamas, an Islamist terrorist group that controls the Gaza Strip, with Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, and with Iranian-backed military forces in Syria. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. On October 7, 2023, Hamas launched a series of attacks on civilian and military targets in Southern Israel and Central Israel, to which the Israel Defense Forces responded. On October 9, 2025, Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas.

In addition, both Hezbollah and the Houthi movement attacked military and civilian targets in Israel, to which Israel responded, including through increased air and ground operations in Lebanon. In addition, the Houthi movement attacked international shipping lanes in the Red Sea, to which both Israel and the United States responded. While a ceasefire was brokered between Israel and Hezbollah in November 2024, in March 2026, hostilities resumed along Israel's northern border with Lebanon, when Hezbollah resumed its attacks as part of a broader regional escalation. In response, Israel resumed military operations against Hezbollah in Lebanon.

Further, in April 2024 and October 2024, Iran launched a series of drone and missile strikes against Israel, to which Israel responded. In addition, in response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 13, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. While a ceasefire was reached in June 2025 following 12 days of hostilities, on February 28, 2026, the United States and Israel launched coordinated military strikes against Iran, including attacks on strategic military infrastructure and leadership targets, with the stated aim of degrading Iran's capacity to conduct or support hostile operations against them. In response, Iran has fired missiles and drones toward population centers and military installations in Israel, Europe and neighboring countries in the Gulf region, and also launched counter-strikes against U.S. forces and allied bases throughout the Gulf region. Although the United States and Iran have announced ceasefire and de-escalation arrangements from time to time, including a memorandum of understanding entered into on June 17, 2026 that contemplates the termination of military operations on multiple fronts, hostilities have resumed and may continue or escalate. A broader regional conflict involving additional state and non-state actors remains a significant risk. How long and how severe the conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region last and become is unknown at this time and any renewed or continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. Continued military escalation, retaliatory actions, or broader regional involvement may adversely affect economic conditions, disrupt markets, and create uncertainty that could negatively impact our business, financial condition and results of operations.

Certain of our employees may be obligated to perform military reserve duty generally until they reach the age of 40 (or older, for officers or other citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity and military conflicts in Israel, there have been periods of significant call-ups of military reservists. 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.

To date, our operations have not been adversely affected by this situation. We currently manufacture our CGuard EPS and CGuard Prime 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 EPS or CGuard Prime until we were able to restore the manufacturing and distribution capability at our facility or develop alternative manufacturing facilities and distribution capabilities. However, the intensity and duration of the security situation in Israel have been difficult to predict, as are the economic implications on our business and operations and on Israel's economy in general. If the war extends for a long period of time or expands to other fronts, 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.

**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 June 30, 2026, 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 November 9, 2015) |
| 3.2 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2021) |
| 3.3 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016) |
| 3.4 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016) |
| 3.5 | Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017) |
| 3.6 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017) |
| 3.7 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017) |
| 3.8 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018) |
| 3.9 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019) |
| 3.10 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (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) |
| 3.12 | 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 June 3, 2026) |
| 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: August 14, 2026

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

Date: August 14, 2026

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: August 14, 2026

*/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: August 14, 2026

*/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 June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marvin Slosman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

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

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

Date: August 14, 2026

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

**Exhibit 32.2**

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

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended June 30, 2026 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: August 14, 2026

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