InspireMD Reports First Quarter 2026 Financial Results

May 4, 2026

- Reports total Q1 2026 revenue of $3.4 million, representing year-over-year growth of 122% -

- Received IDE approval from FDA to initiate the CGUARDIANS III clinical trial of its SwitchGuard neuro protection system for use in TCAR procedures -

- FDA approval of the original CGuard delivery system anticipated in Q3 2026 -

- On track for expected FDA approval of the CGuard Prime 80 cm for TCAR procedures in H2 2026, potentially doubling the Company's addressable market -

MIAMI, May 04, 2026 (GLOBE NEWSWIRE) -- InspireMD, Inc. (Nasdaq: NSPR) ("InspireMD" or the "Company"), developer of the CGuard® Prime carotid stent system for the prevention of stroke, today announced financial and operating results for the first quarter ended March 31, 2026.

Recent Business Highlights:

- Generated revenue of $3.4 million in the first quarter of 2026, up 122% year-over-year, with significant growth in demand for CGuard Prime in the U.S. and original CGuard in international markets.
- Supported over 625 cumulative carotid procedures utilizing CGuard Prime across over 100 leading U.S. hospitals and integrated delivery networks since launch.
- Filed for and anticipate FDA approval of the original, clinically proven CGuard stent delivery system in Q3 2026.
- Received Investigational Device Exemption ("IDE") approval from the FDA to initiate the CGUARDIANS III clinical trial that will evaluate the Company's next-generation SwitchGuard neuro protection system ("NPS") with CGuard Prime 80 cm for use in transcarotid artery revascularization ("TCAR") procedures.
- Initiated a voluntary recall of CGuard Prime 135 cm carotid stent delivery system to address the need for technical enhancements to improve user experience and delivery system performance.

"Our first quarter results reflect strong underlying demand and consistent clinical outcomes for our CGuard carotid stent implant both in the U.S. and internationally," stated Marvin Slosman, Chief Executive Officer of InspireMD. "While our decision to voluntarily pause commercialization of CGuard Prime 135 cm in the U.S. will impact its availability in the short term, we are in the process of implementing several enhancements to the delivery system that we are confident will elevate technical performance and accelerate rapid adoption. Importantly, our TCAR program is unaffected by this voluntary action, and we were also pleased to have recently received FDA approval to initiate the CGUARDIANS III clinical trial with our SwitchGuard NPS, which, if successful, would enable us to offer a full TCAR tool kit leveraging our best-in-class implant."

"In parallel, we are pursuing FDA approval of our commercially-proven CGuard stent delivery system which we anticipate in the third quarter of 2026. This delivery system was successfully used in over 70,000 implants globally. Having this additional delivery system available in the U.S. will enable us to offer physicians multiple options to deliver the best implant to their patients," Mr. Slosman concluded.

Financial Results for the First Quarter Ended March 31, 2026

For the first quarter of 2026, total revenue was $3.4 million, representing an increase of 122%, as compared to $1.5 million during the same period of 2025.

U.S. revenue for the first quarter of 2026 was $1.2 million, representing a quarter-over-quarter increase of 36% as compared to $0.9 million for the fourth quarter of 2025. International revenue was $2.2 million, representing a year-over-year increase of 48%, as compared to $1.5 million for the first quarter of 2025.

Gross profit for the first quarter of 2026 was $0.7 million, or 20.2% of revenue, compared to $0.3 million, or 19.1% of revenue, for the same period of 2025. The increase in gross margin (gross profit as a percentage of revenue) was driven by a favorable shift in sales mix towards significantly higher margin revenue from sales in the U.S., offset by an inventory impairment charge of $0.5 million. On a non-GAAP basis, which excludes the impact of the impairment charge as calculated in the attached non-GAAP reconciliation table, adjusted gross profit was $1.2 million, or 34.1% of revenue.

Total operating expenses for the first quarter of 2026 were $14.7 million, an increase of $2.9 million, compared to $11.8 million for the first quarter of 2025. This increase was primarily due to greater headcount-related expenses for the U.S. commercial team, as well as additional investment in resources and infrastructure to support U.S. commercialization.

Financial income, net, for the first quarter of 2026 was $0.3 million, roughly flat with the first quarter of 2025.

Net loss for the first quarter of 2026 was $13.7 million, or $0.16 per basic and diluted share, compared to a net loss of $11.2 million, or $0.22 per basic and diluted share, for the same period in 2025.

The Company currently expects the financial impact of the U.S. recall of CGuard Prime to include a reserve for customer returns of approximately $700,000 and a reserve for inventory impairment and remediation costs of approximately $650,000.

Conference Call and Webcast Details

Management will host a conference call at 4:30 pm ET today, May 4th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session. A live audio webcast and an archive of the recording will be available here and through the Investors page of InspireMD's corporate website at https://investors.inspiremd.com.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet™ mesh technology to make its products the industry standard for carotid stenting by providing outstanding acute results and durable, stroke-free long-term outcomes. InspireMD's common stock is quoted on Nasdaq under the ticker symbol NSPR. We routinely post information that may be important to investors on the Company's website. For more information, please visit www.inspiremd.com.

Forward-looking Statements

This press release contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential", "scheduled" or similar words. In particular, forward-looking statements in this press release include the Company's expectations regarding potential FDA approvals for original CGuard and the CGuard Prime 80 cm stent for TCAR procedures, the Company's expectations regarding enhancements to the CGuard Prime 135 cm delivery system, the Company's beliefs regarding the potential adoption of its products, statements relating to the Company's addressable markets and the Company's expectations regarding reserves for customer returns and inventory impairment and remediation as result of the U.S. recall of CGuard Prime. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with the voluntary U.S. recall of the CGuard Prime 135 cm delivery system, including current and future costs associated with the recall, including refunds or inventory write-off costs and other remediation costs, loss of sales and customers due to the recall or otherwise, our ability to effectively implement enhancements to CGuard Prime 135 cm delivery system, potential actions by regulators or other governmental entities associated with the recall, potential claims and lawsuits by customers and patients, including class action product liability lawsuits, other operational impacts and consequences of the recall, such as business disruption and distraction of management and other key employees; the Company's history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of its liquidity to pursue its complete business objectives, and substantial doubt regarding its ability to continue as a going concern; the Company's need to raise additional capital to meet its business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; the clinical development, commercialization and market acceptance of the Company's products; whether the clinical trial results for the Company's products will be predictive of real-world results; an inability to secure and maintain regulatory approvals for the sale of the Company's products; negative clinical trial results or lengthy product delays in key markets; the Company's ability to maintain compliance with the Nasdaq listing standards; the Company's ability to generate significant revenues from its products; estimates of the Company's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercial launch of its products; the Company's dependence on a single manufacturing facility and its ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from the Company's current and planned clinical trials may not be sufficient to demonstrate that its technology is an attractive alternative to other procedures and products; intense competition in the Company's industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than it does; entry of new competitors and products and potential technological obsolescence of the Company's products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with the Company's research and products and potential product liability claims; product malfunctions; price increases for supplies and components; whether access to the Company's products is achieved in a commercially viable manner and whether its products receive adequate reimbursement by governmental and other third-party payers; the Company's efforts to successfully obtain and maintain intellectual property protection covering its 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 the Company conducts business in multiple foreign jurisdictions, exposing it 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 the Company's 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 the Company, its customers and suppliers, and the global economic environment. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Non-GAAP Financial Measures

To supplement its consolidated financial statements, which are prepared and presented in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"), this press release and the accompanying tables include supplemental financial information, referred to as non-GAAP financial measure, that have not been prepared in accordance GAAP, including adjusted gross profit. The Company believes that the use of non-GAAP accounting measures is useful to its investors as an additional tool to enhance the overall understanding of past financial performance and future prospects, and allow for greater transparency with respect to key measures used by management in its financial and operational decision making. The Company defines adjusted gross profit as gross profit excluding the impact of the reserve for inventory impairment recognized during the period.

The non-GAAP financial data are not measures of the Company's financial performance under GAAP and should not be considered as alternatives to gross margin or any other performance measures derived in accordance with GAAP. Non-GAAP financial measures may not provide information that is directly comparable to that provided by other companies in other industries or within InspireMD's industry, as other companies may calculate non-GAAP financial results differently, particularly related to non-recurring, unusual items. In addition, there are limitations in using non-GAAP financial measures because the non-GAAP financial measures are not prepared in accordance with GAAP, may be different from non-GAAP financial measures used by other companies and exclude expenses that may have a material impact on the Company's reported financial results. Further, the reserve for inventory impairment recognized during the period is a significant item that affects gross profit and may obscure the Company's underlying operating performance and comparability between periods.

The presentation of non-GAAP financial information is not meant to be considered in isolation, as a substitute for, or superior to the directly comparable financial measures prepared in accordance with GAAP. In addition, non-GAAP measures should not be construed as an inference that the Company's future results will be unaffected by unusual or non-recurring items. InspireMD urges investors to review the financial results calculated in accordance with GAAP and the reconciliation of the Company's non-GAAP financial measures to the comparable GAAP financial measures included below, and not to rely on any single financial measure to evaluate the Company's business.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS[(1)]
(Unaudited)
(U.S. dollars in thousands, except share and per share data)

	Three months ended March 31,	
	2026	**2025**
Revenues	$ 3,398	$ 1,529
Cost of revenues	2,711	1,237
Gross Profit	687	292
Operating Expenses:		
Research and development	4,763	4,059
Selling and marketing	5,180	2,750
General and administrative	4,722	4,943

Total operating expenses	14,665	11,752
Loss from operations	(13,978)	(11,460)
Financial Income, net	289	294
Net Loss	$ (13,689)	$ (11,166)
Net loss per share – basic and diluted	$ (0.16)	$ (0.22)
Weighted average number of common stock used in computing net loss per share – basic and diluted	83,801,839	49,993,509

CONDENSED CONSOLIDATED BALANCE SHEETS (2)

(Unaudited)

(U.S. dollars in thousands other than share and per share data)

ASSETS	**March 31, 2026**	**December 31, 2025**
Current Assets:		
Cash and cash equivalents	$ 11,362	$ 8,939
Marketable securities	30,208	45,272
Accounts receivable:		
Trade, net	2,381	2,168
Other	407	400
Prepaid expenses	1,200	1,296
Inventory	3,036	3,396
Total current assets	48,594	61,471
Non-current assets:		
Long term deposit	446	442
Property, plant and equipment, net	3,651	3,584
Operating lease right of use assets	2,595	2,758
Funds in respect of employee rights upon retirement	1,185	1,149
Total non-current assets	7,877	7,933
Total assets	$ 56,471	$ 69,404

LIABILITIES AND EQUITY	**March 31, 2026**	**December 31, 2025**
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,954	$ 1,255
Other	7,489	9,457
Total current liabilities	9,443	10,712
Long-term liabilities:		
Operating lease liabilities net of current maturities	2,042	2,224
Liability for employee rights upon retirement and others	1,369	1,267
Total long-term liabilities	3,411	3,491

Total liabilities	$ 12,854	$ 14,203
COMMITMENTS AND CONTINGENT LIABILITIES		
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2026 and December 31, 2025; 46,838,963 and 43,532,281 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	4	4
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2026 and December 31, 2025; 1,718 shares issued and outstanding at March 31, 2026 and December 31, 2025	*	*
Additional paid-in capital	359,594	357,489
Accumulated deficit	(315,981)	(302,292)
Total equity	43,617	55,201
Total liabilities and equity	$ 56,471	$ 69,404

(1) All 2026 financial information is derived from the Company's 2026 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; all 2025 financial information is derived from the Company's 2025 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All March 31, 2026 financial information is derived from the Company's 2026 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2025 financial information is derived from the Company's 2025 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2025 filed with the Securities and Exchange Commission.

Adjusted Gross Profit
The following table reconciles Adjusted Gross Profit to Gross Profit, which we consider to be the most directly comparable GAAP financial measure

	Three Months Ended			
	March 31, 2026		March 31, 2025	
Dollars in thousands	$	% of revenues	$	% of revenues
Gross profit	$ 687	20.2%	$ 292	19.1%
Adjustments:				
Inventory impairment charge	$ 473		-	-
Adjusted gross profit	$ 1,160	34.1%	$ 292	19.1%