InspireMD Reports Third Quarter 2026 Financial Results

November 12, 2026

- Received FDA approval of CGuard® Prime for Transcarotid Arterial Revascularization (TCAR) procedures, expected to approximately double the U.S. addressable market -

- Company to host investor conference call today, November 12th, at 4:30pm ET -

MIAMI, Nov. 12, 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 three and nine months ended September 30, 2026.

Recent Business Highlights:

- Received U.S. Food and Drug Administration ("FDA") approval of the CGuard ® Prime TransCarotid Stent System ("CGuard Prime for TCAR") for use in transcarotid arterial revascularization ("TCAR") procedures, marking the return of the CGuard Prime platform to the U.S. market. The approval for the TCAR indication expands the Company's addressable market opportunity by over 35,000 procedures annually and is supported by CGUARDIANS II pivotal trial data, which demonstrated 100% acute device success and zero death, stroke, myocardial infarction or stent thrombosis reported at 30 days. InspireMD expects to commence U.S. sales promptly in the fourth quarter of 2026.
- Generated continued strong international performance with revenue of $2.2 million in the third quarter of 2026, compared with $2.0 million in the third quarter of 2025, an increase of 9% year over year.
- Announced two upcoming scheduled talks featuring the CGuard and the CGuard Prime platforms at VEITH symposium 2026, to be held November 17-21, 2026, in New York.
- Successfully implemented design changes to the delivery system of the CGuard Prime Carotid Stent System ("CGuard Prime for CAS"), which is approved for use in carotid artery stenting ("CAS") procedures. The enhanced CGuard Prime for CAS is currently undergoing final validation and performance testing in support of a premarket approval ("PMA") supplement that the Company expects to submit to the FDA in December 2026, with potential re-launch expected during the first half of 2027.
- Announced the appointment of commercial leader Kathleen Kennedy as Senior Vice President of Global Sales and Marketing in advance of anticipated U.S. launch of the CGuard Prime for TCAR and the expected relaunch of CGuard Prime for CAS.
- Continued enrollment in the Company's CGUARDIANS III pivotal trial of its SwitchGuard neuroprotection system, for use with its CGuard Prime for TCAR procedures.
- Continued to advance the original CGuard carotid stent system for CAS procedures through the FDA regulatory review process.

"FDA approval of CGuard Prime for TCAR procedures represents a transformative milestone for InspireMD, enabling the launch of our next-generation carotid implant that incorporates the latest carotid technology into a rapidly growing TCAR market," stated Marvin Slosman, Chief Executive Officer of InspireMD. "We believe CGuard Prime for TCAR, supported by the results of our CGUARDIANS II pivotal trial, supports our mission to most effectively 'treat the lesion' with our advanced carotid implant, and, with its best-in-class evidence, paves the way for our return to the U.S. commercial market, strengthens our competitive position and advances our vision of establishing CGuard Prime as a leading platform for carotid intervention."

"Building on this milestone, we remain focused on expanding our product portfolio and pipeline across both TCAR and CAS procedures. We continue to advance enhancements to our CGuard Prime for CAS delivery system, with submission of a PMA supplement to the FDA anticipated before year-end, while progressing our CGUARDIANS III pivotal trial evaluating our proprietary SwitchGuard neuroprotection system for TCAR procedures. We are also anticipating the introduction of a proprietary micro puncture kit, designed to support vascular access, a critical step in procedural success. Together, these initiatives reflect our commitment to building a comprehensive carotid intervention platform, with the goal of providing physicians with a broad range of solutions to address the diverse needs of patients undergoing carotid revascularization."

Financial Results for the Third Quarter Ended September 30, 2026

For the third quarter of 2026, total revenue was $2,242,000, a decrease of $281,000, or 11.1%, compared to $2,523,000 for the third quarter of 2025.

International revenue was $2,210,000, an increase of $184,000, or 9.1%, compared to $2,026,000 for the third quarter of 2025. U.S. revenue for the third quarter of 2026 was $32,000, compared to $497,000 for the third quarter of 2025. The U.S. sales

comparison reflects the impact of the voluntary recall of the delivery system of the CGuard Prime for CAS in May 2026.

Gross profit (revenue less cost of revenue) for the third quarter of 2026 was $240,000, or 10.7% of revenue, compared to gross profit of $864,000, or 34.2% of revenue, for the third quarter of 2025. This decline reflects the impact of the U.S. recall action during the third quarter of 2026 and the mix within international revenue to countries with a lower average sales price. Cost of revenues was $2,002,000 compared with $1,659,000 in the prior-year period.

Total operating expenses for the third quarter of 2026 were $10,193,000, a decrease of $3,722,000, or 26.7%, compared to $13,915,000 for the third quarter of 2025. Third-quarter 2026 operating expenses included $1,074,000 in restructuring expenses and related termination costs associated with the Company's workforce reduction. Research and development expenses were $3,273,000, compared to $3,635,000, selling and marketing expenses were $2,394,000, compared to $4,392,000, and general and administrative expenses were $3,452,000, compared to $5,888,000.

Financial income, net, for the third quarter of 2026 was $191,000, compared to financial income, net, of $343,000 for the third quarter of 2025.

Net loss for the third quarter of 2026 totaled $9,762,000, or $0.12 per basic and diluted share, compared to a net loss of $12,708,000, or $0.17 per basic and diluted share, for the same period in 2025.

As of September 30, 2026, cash and cash equivalents and marketable securities totaled $19,246,000, compared to $54,211,000 as of December 31, 2025.

Financial Results for the Nine Months Ended September 30, 2026

For the first nine months of 2026, total revenue increased by $1,581,000, or 27.1%, to $7,411,000, from $5,830,000 for the same period of 2025. U.S. revenue was $859,000, compared with $551,000 in the prior-year period, while international revenue was $6,552,000, an increase of $1,273,000, or 24.1%, from $5,279,000 for the first nine months of 2025.

Gross profit (revenue less cost of revenue) for the nine months ended September 30, 2026 was $153,000, or 2.1% of revenue, compared to gross profit of $1,469,000, or 25.2% of revenue, for the same period of 2025. This decline reflects the impact of the mix of revenue in the nine months ended September 30, 2026 due to the U.S. recall action and the mix within international revenue to countries with a lower average sales price. Cost of revenue was $7,258,000 compared with $4,361,000 for the prior year period.

Total operating expenses for the nine months ended September 30, 2026 were $38,529,000, a decrease of $470,000, or 1.2%, compared to $38,999,000 for the nine months ended September 30, 2025. These expenses included $1,074,000 of restructuring and other expenses in 2026. Research and development expenses were $12,331,000, compared to $11,528,000, selling and marketing expenses were $12,795,000, compared to $11,314,000, and general and administrative expenses were $12,329,000, compared to $16,157,000.

Financial income, net, for the nine months ended September 30, 2026 was $601,000, compared to $505,000 for the same period of 2025.

Net loss for the nine months ended September 30, 2026 totaled $37,775,000, or $0.45 per basic and diluted share, compared to a net loss of $37,025,000, or $0.64 per basic and diluted share, for the same period in 2025.

Conference Call and Webcast Details

Management will host a conference call at 4:30 pm ET today, November 12th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Parties interested in participating by phone should register using this online form. After registering for the webcast, dial-in details will be provided in an auto-generated e-mail containing a link to the conference phone number along with a personal pin.

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. Interested participants are encouraged to register more than 15 minutes before the start of the call.

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 the commencement and timing of U.S. sales of CGuard Prime for TCAR; the size of the addressable market opportunity for CGuard Prime for TCAR; the Company's planned submission of a PMA supplement to the FDA for the enhanced CGuard Prime for CAS and the timing of the potential relaunch thereof; the continued enrollment and advancement of the CGUARDIANS III pivotal trial evaluating the Company's SwitchGuard neuroprotection system; the advancement of the original CGuard carotid stent system through the FDA regulatory review process; the anticipated introduction of the Company's proprietary micro puncture kit; the Company's ability to compete effectively in the carotid intervention market and increase adoption of its products; the Company's ability to establish CGuard Prime as a leading platform for carotid intervention; and the Company's strategic priorities, growth plans and future business prospects. 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 our 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.

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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 September 30,	Nine months ended September 30,

	2026	2025	2026	2025
REVENUES	$ 2,242	$ 2,523	$ 7,411	$ 5,830
COST OF REVENUES	2,002	1,659	7,258	4,361
GROSS PROFIT	240	864	153	1,469
OPERATING EXPENSES:				
Research and development	3,273	3,635	12,331	11,528
Selling and marketing	2,394	4,392	12,795	11,314
General and administrative	3,452	5,888	12,329	16,157
Restructuring and other	1,074	-	1,074	-
Total operating expenses	10,193	13,915	38,529	38,999
LOSS FROM OPERATIONS	(9,953)	(13,051)	(38,376)	(37,530)
FINANCIAL INCOME, net:	191	343	601	505
NET LOSS	$ (9,762)	$ (12,708)	$ (37,775)	$ (37,025)
NET LOSS PER SHARE - basic and diluted	$ (0.12)	$ (0.17)	$ (0.45)	$ (0.64)
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	85,616,203	73,466,501	84,701,615	58,245,368

CONDENSED CONSOLIDATED BALANCE SHEETS [(2)]

(Unaudited)

(U.S. dollars in thousands, except share and per share data)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,246	$ 8,939
Marketable securities	-	45,272
Accounts receivable:		
Trade, net	1,895	2,168
Other	444	400
Prepaid expenses	1,077	1,296
Inventory	2,991	3,396
TOTAL CURRENT ASSETS	25,653	61,471
NON-CURRENT ASSETS:		
Long term deposit	455	442
Property, plant and equipment, net	3,947	3,584
Operating lease right of use assets	2,254	2,758
Fund in respect of employee rights upon retirement	1,259	1,149
TOTAL NON-CURRENT ASSETS	7,915	7,933
TOTAL ASSETS	$ 33,568	$ 69,404

	September 30, 2026	December 31, 2025
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	1,562	1,255

Other	7,007	9,457
TOTAL CURRENT LIABILITIES	8,569	10,712
LONG-TERM LIABILITIES-		
Operating lease liabilities net of current maturities	1,711	2,224
Liability for employee rights upon retirement and others	1,536	1,267
TOTAL LONG-TERM LIABILITIES	3,247	3,491
TOTAL LIABILITIES	11,816	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 September 30, 2026 and December 31, 2025; 47,119,438 and 43,532,281 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	5	4
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2026 and December 31, 2025; 1,718 shares issued and outstanding at September 30, 2026 and December 31 2025	*	*
Additional paid-in capital	361,814	357,489
Accumulated deficit	(340,067)	(302,292)
Total equity	21,752	55,201
Total liabilities and equity	$ 33,568	$ 69,404

(1) All 2026 financial information is derived from the Company's unaudited financial statements for the three and nine months ended September 30, 2026, included 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 unaudited financial statements for the three and nine months ended September 30, 2025, included in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All September 30, 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.