



InspireMD Initiates Voluntary U.S. Recall of CGuard® Prime 135 cm Carotid Stent Delivery System

May 1, 2026

- Strong clinical demand continues in Q1 2026 with global year-over-year unit sales growth of 53% and quarter-over-quarter U.S. unit sales growth of 34% -

- FDA approval anticipated with U.S. market availability of original CGuard delivery system in the third quarter of 2026 -

- Continuing to anticipate FDA approval of CGuard Prime 80 cm for TCAR procedures during 2H 2026 -

MIAMI, May 01, 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 that, in consultation with the U.S. Food and Drug Administration ("FDA"), the Company has initiated a voluntary recall in the U.S. for its CGuard® Prime 135 cm carotid stent delivery system.

The Company acted after determining during a controlled launch that the technical success of the delivery system during carotid artery stenting ("CAS") procedures has not met performance expectations. This action is voluntary with no implications for the safety of patients who have previously received the CGuard stent.

This voluntary action pertains specifically to the CGuard Prime 135 delivery system, and does not include the CGuard stent implant, which continues to generate unmatched clinical outcomes, including the lowest major adverse event rates and most durable stroke prevention among CAS carotid interventions.

InspireMD anticipates FDA approval for its original CGuard stent delivery system for CAS procedures in the U.S. in the third quarter of 2026. The delivery system has been successfully used in over 70,000 cases worldwide, including the majority of clinical study cases in the CGUARDIANS clinical trial.

The Company is also implementing design improvements to the CGuard Prime stent delivery system and anticipates FDA approval in the first half of 2027.

"Our continued strong unit sales growth worldwide in the first quarter 2026 reflects significant demand for this novel stent technology with our best-in-class CGuard implant," stated Marvin Slosman, Chief Executive Officer.

"However, the controlled launch of CGuard Prime in the U.S. has revealed opportunities to improve the technical performance of the delivery system," continued Mr. Slosman. "As a result, we have taken the proactive step to pause commercialization of the CGuard Prime delivery system to implement the necessary enhancements. This voluntary action reflects our unwavering commitment to providing our customers with the highest quality carotid stent platform on the market, while minimizing market disruptions and achieving the optimal physician satisfaction and patient safety for which we are known."

TCAR Initiatives On-Track

InspireMD anticipates FDA approval later this year for its CGuard Prime 80 cm carotid stent delivery system for transcrotid artery revascularization ("TCAR") procedures, designed to be compatible with neuroprotection systems that are already in use. With approximately 35,000 TCAR procedures annually in the United States, an approved TCAR indication could potentially double the size of the addressable market for the CGuard stent implant. The technical performance of the CGuard Prime 80 cm version meets all technical expectations. Additionally, the Company anticipates potential FDA clearance of its SwitchGuard neuroprotection system for TCAR procedures in the second half of 2027.

2026 Financial Guidance

Concurrent with today's announcement, the Company is withdrawing its prior full year 2026 revenue guidance. Management believes this is the most prudent step given the impact of the temporary discontinuation of commercial activity in the U.S. pending the anticipated FDA approval of its original CGuard stent delivery system in the third quarter of 2026.

Management intends to provide a full company update on this and other recent developments during its conference call for the results of the first quarter of 2026 on May 4th.

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 our 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 the Company 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 expectations regarding potential FDA approvals for original CGuard and the CGuard Prime 80 cm stent for TCAR procedures, and expectations regarding enhancements to the CGuard Prime 135 cm delivery system and recommencement of sales. 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.

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