UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): **August 5, 2025**

InspireMD, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-35731	**26-2123838**
(Commission File Number)	(IRS 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)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	The Nasdaq Capital Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition

On August 5, 2025, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results and recent highlights for the three and six months ended June 30, 2025. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K that is furnished pursuant to this Item 2.02 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On August 5, 2025, the Company made available an updated investor presentation. A copy of the presentation is attached hereto as Exhibit 99.2 and incorporated by reference in this Item 7.01. A copy of the presentation is also available on the Company's website https://www.inspiremd.com/en/investors/.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01 shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated August 5, 2025 (furnished herewith pursuant to Item 2.02)
99.2	Investor Presentation August 2025 (furnished herewith pursuant to Item 7.01)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

INSPIREMD, INC.

Date: August 5, 2025

By: */s/ Michael Lawless*
Name: Michael Lawless
Title: Chief Financial Officer

Exhibit 99.1

InspireMD Reports Second Quarter 2025 Financial Results

Management to host investor conference call today, August 5th, at 8:30am ET

Miami, FL — August 5, 2025 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard® Prime carotid stent system for the prevention of stroke, today announced financial and operating results for the second quarter and six months ended June 30, 2025.

Recent Business Highlights:

- Received premarket application (PMA) approval from the U.S. Food and Drug Administration (FDA) for the CGuard Prime carotid stent system
- Commenced commercial launch of the CGuard Prime carotid stent system in the U.S. Market
- Raised $58 million in gross proceeds from an equity private placement and the exercise of existing warrants to advance growth initiatives
- Received CE Mark approval under the European Medical Device Regulation (MDR) for CGuard Prime EPS, with plans to launch in third quarter
- Strengthened leadership team with the appointment of Mike Lawless as Chief Financial Officer
- Added Raymond W. Cohen to Board of Directors

Marvin Slosman, CEO of InspireMD, commented: "Over the last few months, our team has executed the most significant set of milestones in InspireMD's history, as we obtained approval for our proprietary CGuard Prime carotid stent system in the U.S. and began its commercial rollout. These transformational milestones were years in the making and validate our vision and execution. Backed by a fully trained, world-class commercial team, we are now focused on scaling with discipline and precision to unlock the full potential of our platform."

"Our forward momentum is further supported by the recent addition of $58 million in gross proceeds to our balance sheet, evidencing clear confidence from investors who share our conviction in InspireMD's future. We are entering a new era of growth, and we are laser-focused on establishing our breakthrough technology as the standard of care in the treatment of carotid artery disease and the prevention of stroke. We look forward to bringing meaningful impact to physicians and patients across the U.S."

Financial Results for the Second Quarter Ended June 30, 2025

For the second quarter of 2025, total revenue increased by $39,000, or 2.3%, to $1,778,000, from $1,739,000 during the second quarter of 2024. This increase was driven by continued adoption of the Company's CGuard technology in existing markets and the positive impact of exchange rates offset by decreased revenue from Russia, and distributors managing CGuard inventory levels in anticipation of CGuard Prime approval in Europe.

Gross profit (revenue less cost of revenues) for the second quarter of 2025 decreased by $18,000, or 5.4%, to $313,000, from $331,000, during the second quarter of 2024.

Total operating expenses for the second quarter of 2025 were $13,332,000, an increase of $4,741,000, or 55.2% compared to $8,591,000 for the second quarter of 2024. This increase was primarily due to higher salaries and share-based compensation tied to U.S. sales force expansion ahead of FDA approval. Additional increases stemmed from CGuard Prime launch preparation, U.S. facility rent, and CFO severance fees.

Financial expense, net for the second quarter of 2025 was $132,000, a decrease of $483,000 compared to financial income of $351,000 for the second quarter of 2024. This decrease was primarily due to the impact of foreign exchange and less interest income from investments in marketable securities and money market funds.

Net loss for the second quarter of 2025 totaled $13,151,000 or $0.26 per basic and diluted share, compared to a net loss of $7,909,000, or $0.22 per basic and diluted share, for the same period in 2024.

As of June 30, 2025, cash and cash equivalents and marketable securities were $19,374,000 compared to $34,637,000 as of December 31, 2024.

Financial Results for the Six Months Ended June 30, 2025

For the six months ended June 30, 2025, revenue increased by $57,000, or 1.8%, to $3,307,000, from $3,250,000 for the six months ended June 30, 2024. This increase was driven by continued adoption of our CGuard technology in existing markets, offset by decreased revenue from Russia, the impact of exchange rates, and distributors managing CGuard inventory levels in anticipation of CGuard Prime approval in Europe.

For the six months ended June 30, 2025, gross profit (revenue less cost of revenues) decreased by 2.8%, or $18,000, to $605,000, compared to $623,000 for the same period in 2024.

Total operating expenses for the six months ended June 30, 2025, were $25,084,000, an increase of $8,787,000, or 53.9% compared to $16,297,000 for six months ended June 30, 2024. This increase was primarily due to higher salaries and share-based compensation tied to U.S. sales force expansion ahead of FDA approval. Additional increases stemmed from development and regulatory activities for SwitchGuard NPS, CGuard Prime launch preparation, U.S. facility rent, promotional activities and CFO severance fees.

Financial income, net for the six months ended June 30, 2025, was $162,000, a decrease of $571,000 compared to financial income of $733,000 for the six months ended June 30, 2024. This decrease was primarily due to a reduction in income from investments in marketable securities and money market funds, as well as an increase in financial expenses resulting from exchange rate fluctuations.

Net loss for the six months ended June 30, 2025, totaled $24,317,000 or $0.48 per basic and diluted share, compared to a net loss of $14,941,000, or $0.43 per basic and diluted share, for the same period in 2024.

Conference Call and Webcast Details

Management will host a conference call at 8:30 am ET today, August 5th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Tuesday, August 5th at 8:30 a.m. ET

Domestic:	1-800-579-2543
International:	1-785-424-1789
Conference ID:	IMD2Q25
Webcast:	Webcast Link – Click Here

https://viavid.webcasts.com/starthere.jsp?ei=1723041&tp_key=b02c396fff

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 InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation, including expectations regarding financial runway, U.S. commercial launch and expansion, and the exercise of any warrants. 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. 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 our history of recurring losses and negative cash flows from operating activities; substantial doubt about our ability to continue as a going concern; significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; market acceptance of our products; an inability to secure and maintain regulatory approvals for the sale of our products; negative clinical trial results or lengthy product delays in key markets; our ability to maintain compliance with the Nasdaq listing standards; our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products; our ability to adequately protect our intellectual property; 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; insufficient or inadequate reimbursement by governmental and other third-party payers for our products; 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; the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk. 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.

Investor Contacts:

Webb Campbell
Gilmartin Group LLC
Webb@gilmartinir.com
investor-relations@inspiremd.com

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

	Three months ended June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenues	$ 1,778	$ 1,739	$ 3,307	$ 3,250
Cost of revenues	1,465	1,408	2,702	2,627
Gross Profit	313	331	605	623
Operating Expenses:				
Research and development	3,834	3,401	7,893	6,026
Selling and marketing	4,172	1,445	6,922	2,682
General and administrative	5,326	3,745	10,269	7,589
Total operating expenses	13,332	8,591	25,084	16,297
Loss from operations	(13,019)	(8,260)	(24,479)	(15,674)
Financial income (expense), net	(132)	351	162	733
Net Loss	$ (13,151)	$ (7,909)	$ (24,317)	$ (14,941)
Net loss per share – basic and diluted	$ (0.26)	$ (0.22)	$ (0.48)	$ (0.43)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	51,003,900	35,877,926	50,508,660	35,060,450

CONDENSED CONSOLIDATED BALANCE SHEETS (1)
(Unaudited)
(U.S. dollars in thousands, except share and per share data)

	June 30, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 11,509	$ 18,916
Marketable securities	7,865	15,721
Accounts receivable:		
Trade, net	1,592	1,572
Other	496	682
Prepaid expenses	947	1,060
Inventory	3,054	2,570
Total current assets	25,463	40,521
Non-current assets:		
Long term deposit	433	426
Property, plant and equipment, net	3,101	2,371
Operating lease right of use assets	3,069	2,360
Funds in respect of employee rights upon retirement	1,276	1,129
Total non-current assets	7,879	6,286
Total assets	$ 33,342	$ 46,807

CONDENSED CONSOLIDATED BALANCE SHEETS (1)
(Unaudited)
(U.S. dollars in thousands, except share and per share data)

	June 30, 2025	December 31, 2024
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 1,518	$ 1,254
Other	7,550	6,424
Total current liabilities	9,068	7,678
Long-term liabilities:		
Operating lease liabilities net of current maturities	2,507	1,796
Liability for employee rights upon retirement and others	1,524	1,247
Total long-term liabilities	4,031	3,043
Total liabilities	$ 13,099	$ 10,721
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at June 30, 2025, and December 31, 2024; 32,552,888 and 26,611,033 shares issued and outstanding on June 30, 2025, and December 31, 2024, respectively	3	3
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at June 30, 2025, and December 31, 2024; 1,718 shares issued and outstanding at June 30, 2025, and December 31, 2024, respectively	*	*
Additional paid-in capital	298,063	289,589
Accumulated deficit	(277,823)	(253,506)
Total equity	20,243	36,086
Total liabilities and equity	$ 33,342	$ 46,807

(1) All June 30, 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 on August 4, 2025. All December 31, 2024, financial information is derived from the Company's 2024 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2024, filed with the Securities and Exchange Commission on March 12, 2025.

Exhibit 99.2

InspireMD Poised to Revolutionize the Carotid Intervention Market

INSPIREMD

Nasdaq: NSPR

Disclaimers

Forward Looking Statement

This presentation contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. For example, the Company is using forward-looking statements when it discusses the potential commercialization and market opportunities for its products and product candidates, its cash runway, and its anticipated future milestone Company events. 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 (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payors for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) 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. 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Executive Leadership Team

Deep industry experience and subject matter expertise

Marvin Slosman
Chief Executive Officer

- 30+ years of medical device experience, NSPR since 2019
- Previous CEO/President of ITAMAR Medical, Ovalum Vascular, Phormax Medical
- Prior experience at JNJ, GE Healthcare and Baxter
- BS from University of Alabama, MBA from University of Chicago

Shane Gleason
Chief Commercial Officer

- 20+ years of cardiovascular medical device experience, NSPR since 2023
- Previous CCO of Nuvaira; VP Sales of TriVascular, Cordis and Surmodics
- Prior experience at Abbott and Edwards Lifesciences
- BS in Engineering Science and Mechanics from Virginia Tech, MBA from University of Maryland

Mike Lawless
Chief Financial Officer

- 20+ years of financial leadership management, NSPR since 2025
- Previous CFO of Lifeward Ltd.
- Prior leadership experience at Brooks Automation, PerkinElmer, MFS Investment Management
- BS in Economics from Swarthmore College, MBA from Tuck School of Business at Dartmouth College

Andrea Tommosoli
Chief Operating Officer

- 20+ years of medical technology experience, NSPR since 2020
- Previous international leadership experience at Integra LifeSciences, St Jude (Abbott)
- BA in Nuclear Engineering from Bologna University, MBA from HEC Paris

Now Approved in the U.S. CGuard® Prime Carotid Stent System

Ongoing U.S. Commercial Launch, With a Trained and Seasoned Salesforce at the Ready

A New Level of Stroke Prevention is Here

- With 60,000+ patients treated worldwide, we're ready to elevate embolic prevention for U.S. physicians and their patients

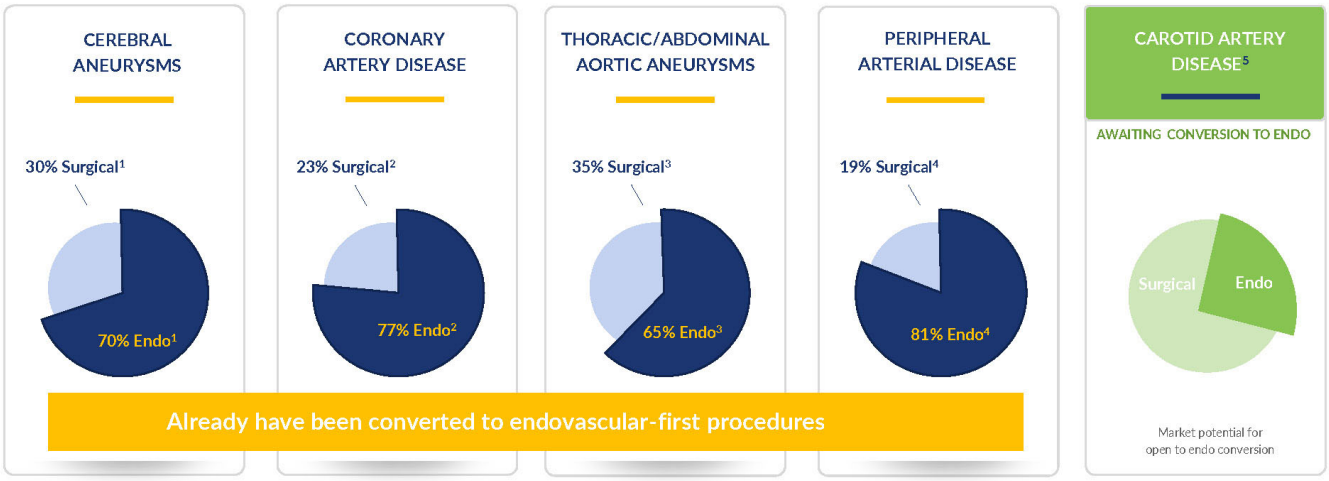
Tested. Trusted. Ready.

- Our U.S. entry brings a rigorously tested solution to stroke prevention and positions us to become a true global carotid technology leader

INSPIRE MD

Endovascular Revolution Has Arrived

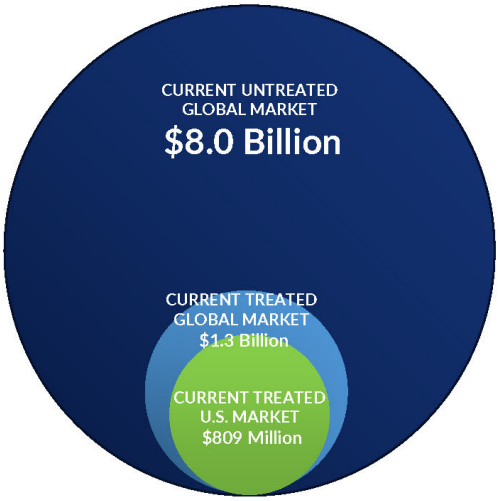
MicroNet™ covered CGuard® stent platform could become the new gold standard



INSPIREMD

[1] Bekelis K, Gottlieb DJ, Su Y, et al. Comparison of clipping and coiling in elderly patients with unruptured cerebral aneurysms. J Neurosurg. 2017;126(3):811–818
[2] Culler SD, Kugelmass AD, Brown PP, , et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 and 2012. Circulation. 2015;131(4):362-70
[3] Beck AW, Sedrakyan A, Mao J, et al. Variations in Abdominal Aortic Aneurysm Care: A Report From the International Consortium of Vascular Registries. Circulation. 2016;134(24):1948-1958
[4] Guez, D., Hansberry, D. R., Gonsalves, C. F., Eschelman, D. J., Parker, L., Rao, V. M., & Levin, D. C. Recent Trends in Endovascular and Surgical Treatment of Peripheral Arterial Disease in the Medicare Population. AJR Am J Roentgenol. 2020 May;214(5):962-966.
[5] Procedures For Selected Nations, 2017 – 2025 presented to InspireMD, Inc. by Health Research International Personal Medical Systems, Inc. Sept. 13, 2021

$8B Global Market Potential



~2.8 million
People diagnosed with High Grade Carotid Stenosis (HGCS)

~400,000
Global procedures (CEA/CAS/TCAR) annually to treat HGCS [1]

~155,000
US Procedures (CEA/CAS/TCAR) annually

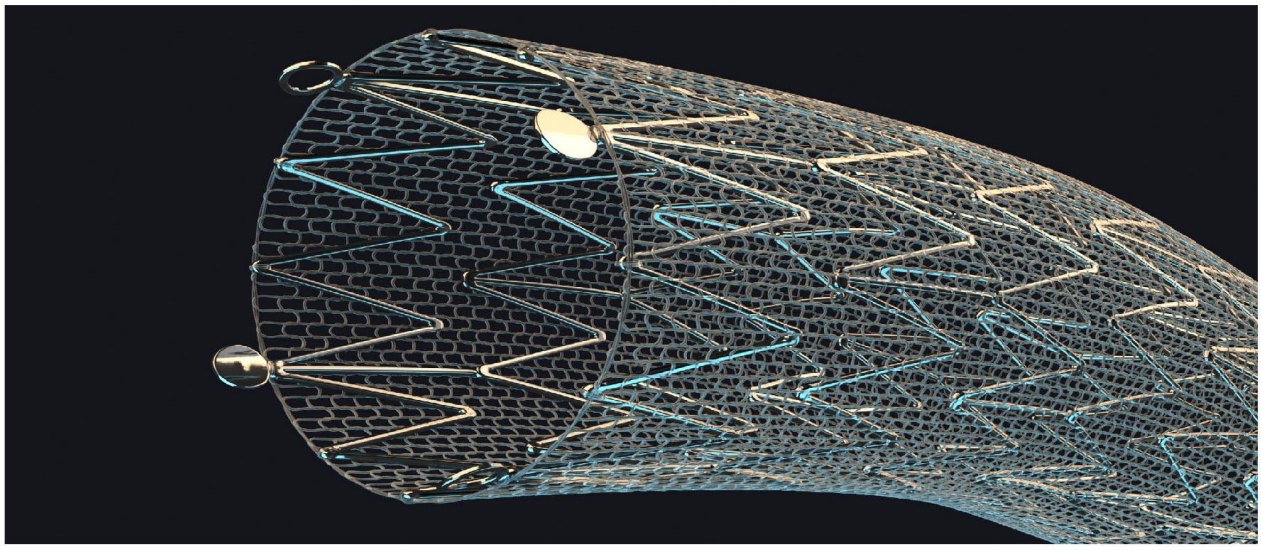
Market Growth Driver
Reimbursement for the treatment of asymptomatic and standard surgical risk patients increases CAS potential, expected to increase screening and diagnosis

INSPIREMD

1. 2021 Health Research International Market Report; internal estimates

Developer of CGuard® Prime Carotid Stent Platform

Dedicated to advancing the prevention of stroke and treatment of carotid artery disease



INSPIREMD

Transforming the Carotid Intervention Market

CGuard®Carotid Stent Platform
Proprietary MicroNet™ Technology
Highly differentiated platform for treatment of carotid artery disease and stroke prevention

CMS Coverage Expanded
Standard Risk and Asymptomatic Reimbursement
Enables stent-first approach to carotid revascularization

Unmatched Clinical Outcomes
Short and Long-Term Results
Ten clinical trials completed with >**2,000** patients presented or published including US IDE trial

Significant Market Potential
Current Treated Market: $1.3 Billion
(Patients treated with CEA + CAS globally), with significant growth potential

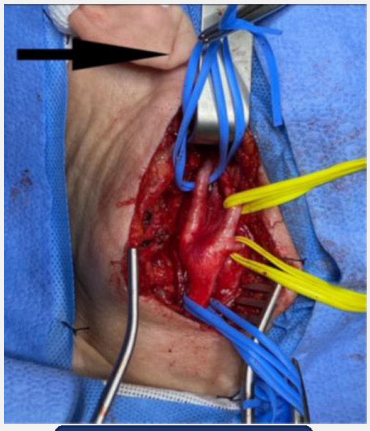
Deep Pipeline and Strategic Roadmap
MicroNet™ technology pipeline; SwitchGuard NPS for TCAR; acute stroke with tandem lesions

Expanding Commercial Footprint
Double-digit market share in **>30** served countries (>30% in Italy)

Over **65,000** stents sold to date

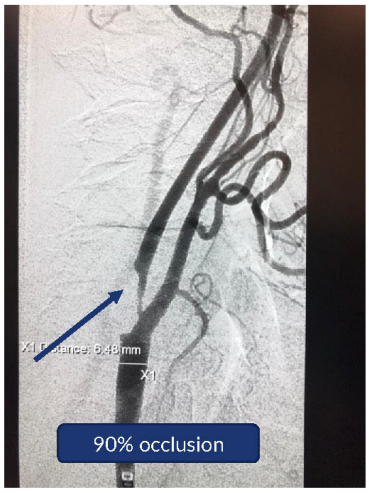
CGuard Prime Received FDA Approval in June 2025

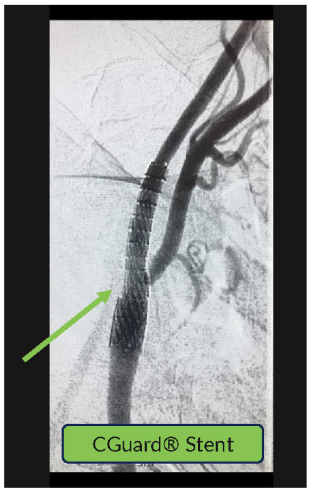
A Picture is Worth a Thousand Words…



Surgical Endarterectomy

VS

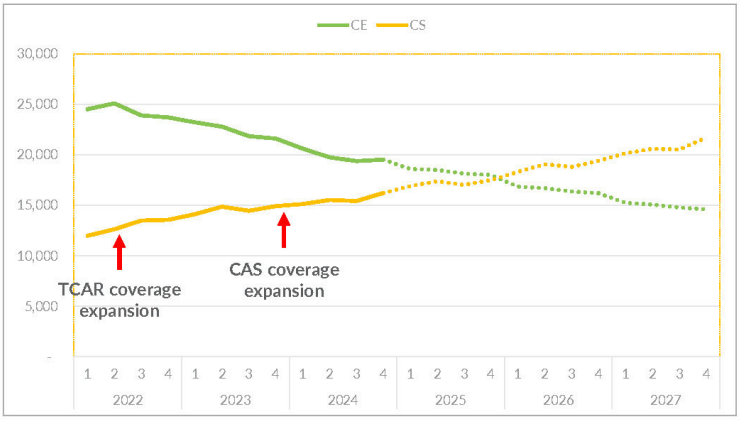




Stenting

Carotid Stenting (CAS + TCAR) is on the Rise

- DRG/CPT data by Facility and HCP
- Trailing 12 Quarters through Q4 2024 (one quarter in arrears)
- ~147K annual carotid intervention claims
  - Represents ~90% of procedures (does not include Kaiser, Gov't/DoD)
  - **10.6% stent (CAS + TCAR) CAGR over prior three years** (TCAR reimbursement expansion 2022, CAS 2023)

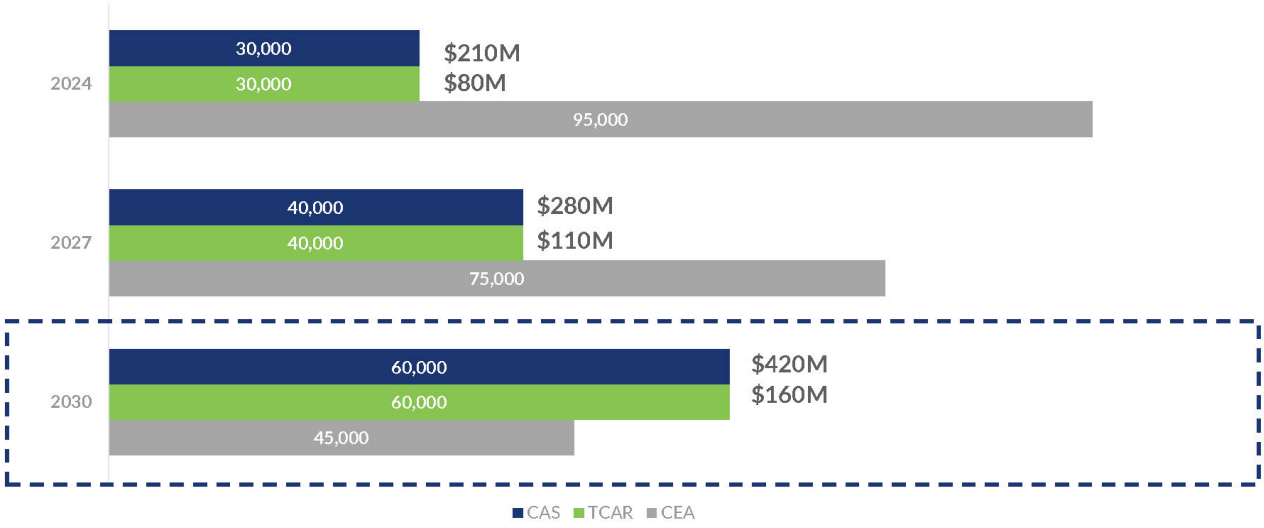


Diagnosis	2024 Patient Encounters
Carotid Endarterectomy DRG 3 DRG Codes	79,239
Carotid Artery Stent DRG 3 DRG Codes	62,273

INSPIREMD Data provided by acuity MD

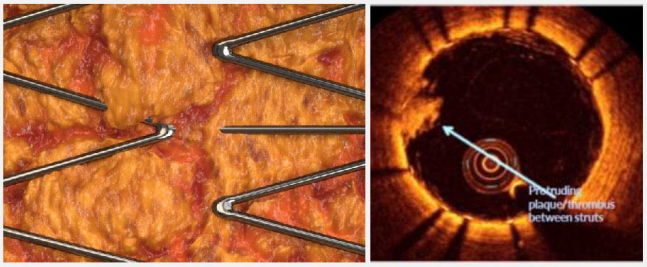
Market Shift

The market has already begun the shift from surgery to stents (procedures and revenue opportunity)



The CGuard® Difference: The Impact of MicroNet™ Technology[1]

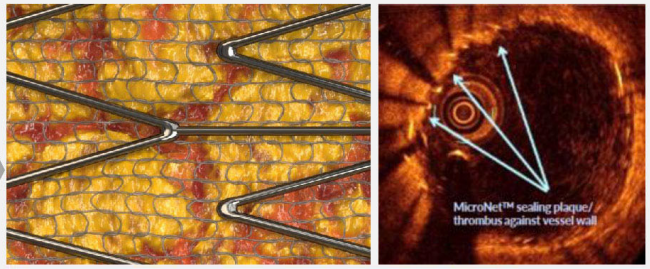
Approximately 2/3 of neurovascular events (stroke, TIA) occur after carotid interventions take place[2]. Prevention depends on the protection from the stent implanted



Conventional Open Cell Stent (1st GEN):

Larger cell sizes allow increased plaque protrusion risk

VS.



CGuard Stent System (2nd GEN):

Stents are covered in MicroNet to minimize plaque prolapse

MicroNet: Advanced Protection Technology

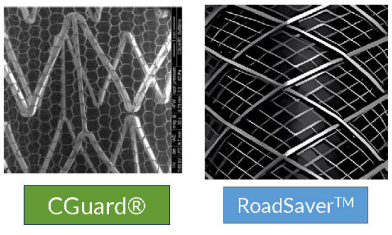
MicroNet captures and locks thrombus & plaque materials against the arterial wall, deterring debris from entering the bloodstream by acting as a mechanical barrier to prevent plaque prolapse

Image: Prof. Valdés Chávarri

INSPIRE MD

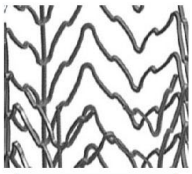
[1,2] Tomoyuki Umemoto, MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1348-1355 (published online)

Stent Cell Sizes (Mechanism of Action)



CGuard®

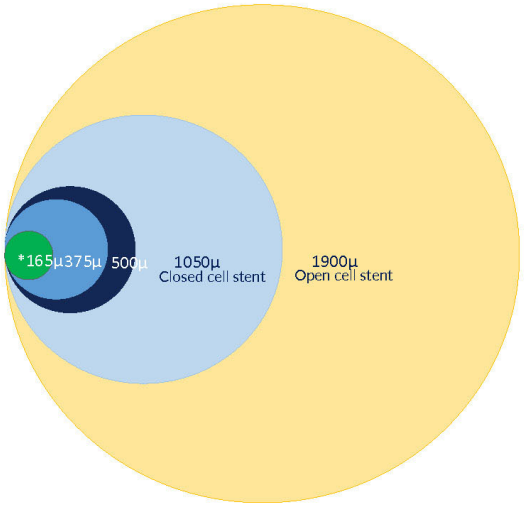
RoadSaver™



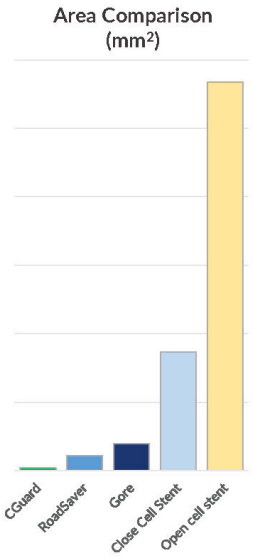
ACCULINK™

WallStent™

* Bench test results may not necessarily be indicative of clinical performance.
Stent images approximately at scale but not exact

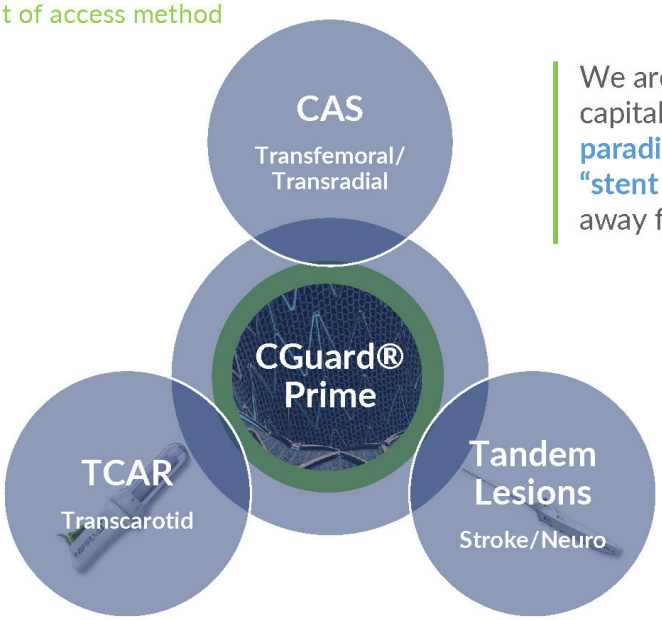


* Average in lesion at expanded state



Long-Term Stent Performance is the Cornerstone of Our Business

Benefits are independent of access method



We are positioned to capitalize on the ongoing **paradigm shift toward a "stent first" approach** and away from surgery

INSPIREMD

Scientific Advisory Board (Multidisciplinary KOLs)

Sean Lyden, M.D.
Vascular Surgeon

Cleveland Clinic

Chris Metzger, M.D.
Medical Director
Cardiologist

OhioHealth

Kenneth Rosenfield, M.D.
Interventional Cardiologist

Mass General Brigham

Adnan H. Siddiqui, M.D., Ph.D.
Professor, Vice Chairman of the Department of Neurosurgery

UBNS Neurosurgery
UNIVERSITY AT BUFFALO

Unmatched Foundational Data and Evidence

PMA Trial Design (C-GUARDIANS)

Prospective, multicenter international single-arm clinical trial

Pivotal Study Objective

Evaluate the safety and efficacy of the CGuard® Carotid Stent System in the treatment of carotid artery stenosis

Study Metrics

316 Patients – Enrollment completed (23 months)

24 Centers (19 in the United States and 5 in Europe)

Principal Investigators

Chris Metzger, M.D. (Ballad Health, Kingsport, TN)

Piotr Musialek, M.D. (John Paul II Hospital, Krakow, Poland)

Primary Endpoints

Composite of DSMI through 30 days or ipsilateral stroke 31 - 365 days post-index procedure

Calculation will be the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication. The rate will be compared to a performance goal of 11.6% developed from published CAS literature.

INSPIREMD

* Schofer, J. et al. JACC Cardiovasc. Interv. 2015; Speziale, F. et al. EuroIntervention. 2018; Sirignano, P et al. Cardiovascular Interv. 2020; Musialek et al. EuroIntervention. 2020; Karpenko, A. et al. JACC Cardiovasc. Interv. 2021.

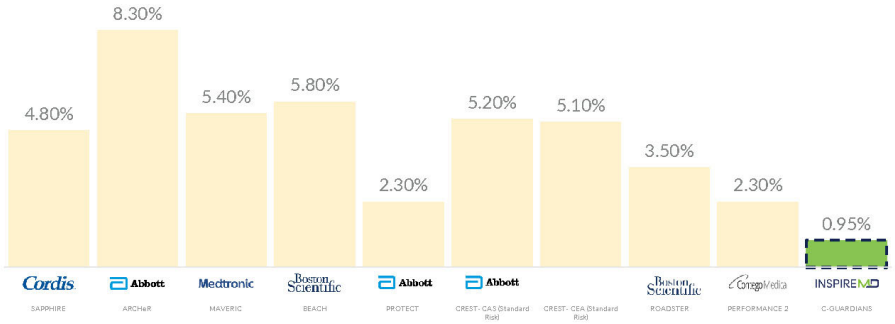
C-GUARDIANS: 30-Day Safety Outcomes

30-Day Death/Stroke/MI (DSMI) rates, compared to other carotid trials

CGUARDIANS 30-day outcomes

	Intention to Treat	Per Protocol[1,2]
30-day DSMI	0.95% (3)	0.63% (2)
Death	0.32% (1)	0.0% (0)
Stroke	0.95% (3)	0.63% (2)
MI	0.00% (0)	0.0% (0)

30-day DSMI (multiple FDA trials)



- Demonstrates the lowest 30-day DSMI rates of any FDA approval/clearance trial for carotid intervention (CAS or TCAR)
- Trial includes independent event adjudication
- 0.95% event rate consistent with 1.03% 30-day event rate from >1350 patients in peer-reviewed, published studies of real-world use, supporting the CGuard Stent as a front-line therapeutic option for carotid revascularization

INSPIREMD

1. Kaplan-Meier estimate for all 1-year endpoints
2. Per Protocol Analysis excludes 15 patients with Major Protocol Deviations

Yadav JS, et al, N Engl J Med 2004;351:1493-501. Gray WA, et al, J Vasc Surg. 2006 Aug;44(2):258-68. Higashida RT, et al, Stroke. 2010 Feb;41(2):e102-9. White CJ, et al, CCI 2006 Apr;67(4):503-12. Iyer SS, et al, J Am Coll Cardiol. 2008 Jan 29;51(4):427-34. Matsumura JS, et al, J Vasc Surg. 2012 Apr;55(4):968-976.e5. SSED Premarket Approval Application (PMA) Number: P040012/SO34. Kwolek CJ, et al, J Vasc Surg. 2015 Nov;62(5):1227-34. W. Gray VIVA 2023

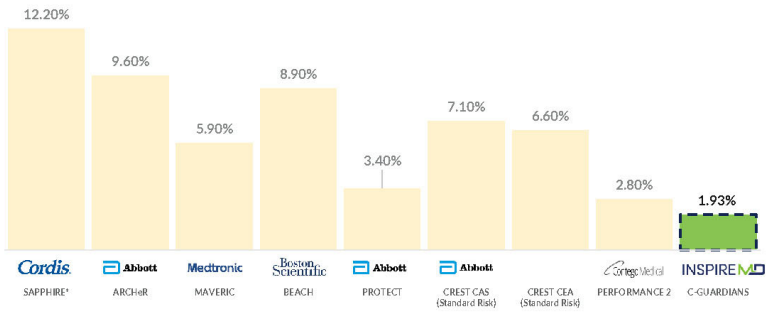
C-GUARDIANS: 1 Year Outcomes

365-Day Death/Stroke/MI (DSMI) rates, compared to other carotid trials

CGUARDIANS 365-day

	Intention to Treat	Per Protocol[1,2]
Primary Endpoint: 30-day Death, Stroke, or MI + Ipsilateral Stroke between 31 and 365 days	1.93% (6)	1.70% (5)
Target Lesion Revascularization (TLR) through 365 days.	0.98% (3)	1.01% (3)

365-day (multiple FDA trials)



- Demonstrates the lowest primary endpoint event rates of any FDA approval/clearance trial for CAS
- Trial includes independent event adjudication
- 1.93% event rate consistent with 1.99% 1-year event rate from >1100 patients in peer-reviewed, published studies of real-world use, supporting the CGuard Stent as a front-line therapeutic option for carotid revascularization

INSPIRE MD

1. Kaplan-Meier estimate for all 1-year endpoints
2. Per Protocol Analysis excludes 15 patients with Major Protocol Deviations
3. SAPPHIRE one-year primary endpoint also included Death/MI from 31-365 days

Yadav JS, et al, N Engl J Med 2004;351:1493-501. Gray WA, et al, J Vasc Surg. 2006 Aug;44(2):258-68. Higashida RT, et al, Stroke. 2010 Feb;41(2):e102-9. White CJ, et al, CCI 2006 Apr;67(4):503-12. Iyer SS, et al, J Am Coll Cardiol. 2008 Jan 29;51(4):427-34. Matsumura JS, et al, J Vasc Surg. 2012 Apr;55(4):968-976.e5. SSED Premarket Approval Application (PMA) Number: P040012/S034. Kwolek CJ, et al, J Vasc Surg. 2015 Nov;62(5):1227-34. Langhof, LINC 2024

OUS Clinical Data Supporting CGuard® Periprocedural Safety

CGuard commercially available in Europe since 2015 (CE Mark)

Study	Year	N	DS 30-Day % (n)	DSMI 30-Day % (n)
CARENET	2015	30	0.0%(0)	0.0%(0)
PARADIGM	2016	101	0.0%(0)	0.0%(0)
CASANA	2017	82	1.22%(1)	1.22%(1)
WISSGOTT I	2017	30	0.0%(0)	0.0%(0)
IRONGUARD I	2018	200	2.50%(5)	2.50%(5)
WISSGOTT II	2019	30	0.0%(0)	0.0%(0)
IRONGUARD 2	2020	733	0.5%(4)	1.09%(8)
GREEK Study	2021	103	0.0%(0)	0.0%(0)
SIBERIA	2021	50	0.0%(0)	0.0%(0)
Total		**1,359**	**0.80%(11)**	**1.03%(14)**

INSPIREMD

1. Schofer, J. et al. JACC Cardiovasc. Interv. 2015; 2) Casana, R. et al. Eur. J. Vasc. Endovasc. 2017; 3) Musialek, P. et al. Interv. Cardiol. 2016
4. Wissgott, C. et al. Int. Soc. Endovasc. Spec. 2017; 5) Speziale, F. et al. EuroIntervention 2018; 6) Wissgott, C. et al. J Endovasc Ther. 2019
7. Sirignano, P et al. Cardiovascular Interventions 2020;8) Tigkiropoulos, K. et al. Journal of EndoTherapy 2021; 9) Karpenko, A. et al JACC Cardiovasc. Interv. 2021

CARMEN Meta-Analysis (112 Studies, 68K Patients)[1]

- Improvements from second-generation stents (SGS) relative to first-generation stents (FGS), but important differences exist amongst the SGS
- CGuard®'s MicroNet™ **drives improvement both in event reduction** (due to improved scaffolding) and **restenosis reduction** (due to less metal burden)

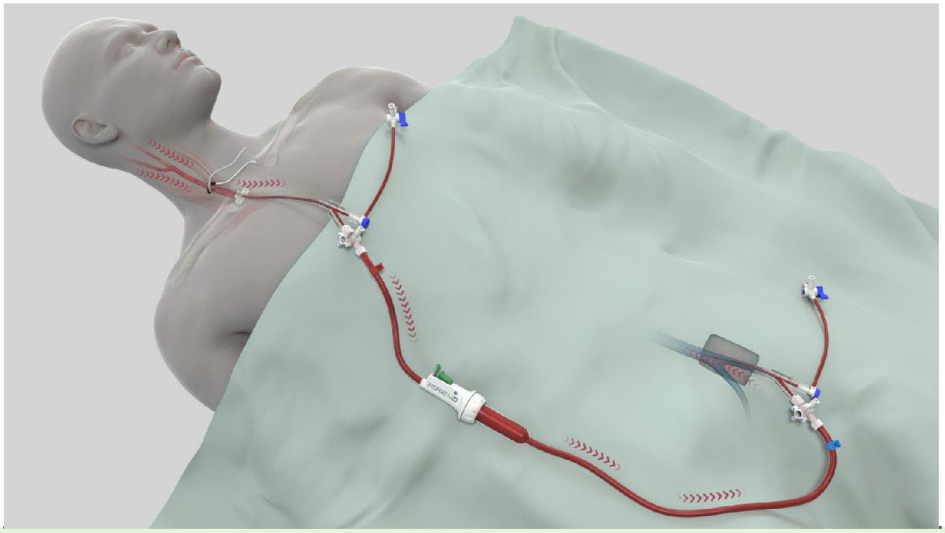
30-day and 12-month event rates by stent type (random-effect model)

Event	FGS	SGS	Terumo RoadSaver/ Casper	Gore (not marketed)	INSPIREMD CGuard
30-day Stroke [%] (95% CI)	3.01 (2.63-3.38)	0.60 (0.28-0.92)	0.50 (0.0-1.15)	2.89 (1.03-4.76)	0.54 (0.17-0.92)
30-day Death / Stroke / MI [%] (95% CI)	4.11 (3.65-4.56)	1.30 (0.64-1.96)	1.33 (0.0-2.66)	4.82 (2.44-7.2)	1.08 (0.55-1.60)
12-month Ipsilateral Stroke [%] (95% CI)	3.51 (2.52-4.50)	0.7 (0.0-1.47)	0.26 (0.0-1.27)	3.1 (1.11-5.1)	0.38 (0.0-0.9)
12-month Restenosis [%] (95% CI)	3.97 (0.28-5.14)	3.38 (1.39-5.37)	7.16 (4.45-9.86)	4.83 (2.36-7.29)	0.34 (0.0-0.82)
12-month Ipsilateral Stroke / Restenosis [%] (95% CI)	8.15 (6.34-9.93)	5.12 (2.14-8.10)	7.86 (5.04-10.68)	7.93 (4.82-11.04)	0.73 (0.0-1.44)

1) Clinical Outcomes of Second- versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis, J. Clin. Med. 2022, 11

TCAR

Transcarotid Arterial Revascularization (TCAR): Direct Carotid Access with Reverse Flow



InspireMD Combines SwitchGuard NPS with Best-in-Class CGuard® Implant

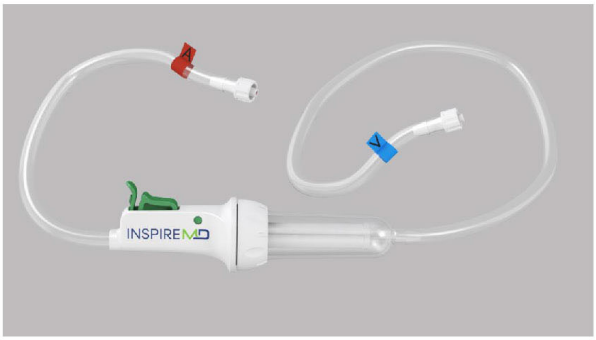
INSPIREMD

1. Transient flow reversal combined with sustained embolic prevention in transcervical revascularization of symptomatic and highly-emboligenic carotid stenoses for optimized endovascular lumen reconstruction and improved peri- and post-procedural outcomes, Advances in Interventional Cardiology 2020;16, 4 (62):495-506

Developing Comprehensive TCAR Solution

80cm

CGUARD® PRIME



SWITCH GUARD

TCAR Market Opportunity

~3,000 TCAR-trained physicians in the U.S.[1]

~30,000 TCAR procedures **(~$210M)** performed in the U.S. in 2024, double-digit growth projected[1,2]

1 Piper-Sandler model, 05/01/24
2 Piper-Sandler model, 05/01/24

Commercial and Corporate

Roadmap / Milestones

Key Value Drivers

2025

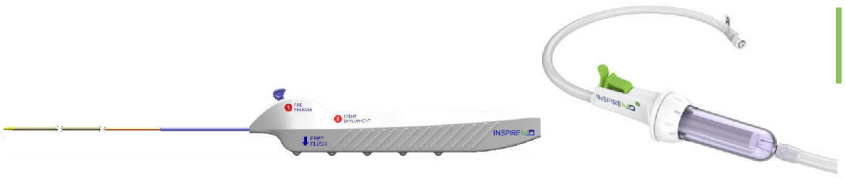
- **CGuard® Prime CAS Approval**
  Launch for CAS
- **U.S Operational Expansion**
  Build out of U.S. HQ, Operational and Commercial
- **Acute Stroke EFS- Tandem Lesions**
- **CGuard Prime FDA & CE Mark Approval**

2026

- **CGuard Prime CAS Market Expansion**
- **CGuard Prime TCAR Approval**
  CGuard Prime indicated stent for TCAR

2027

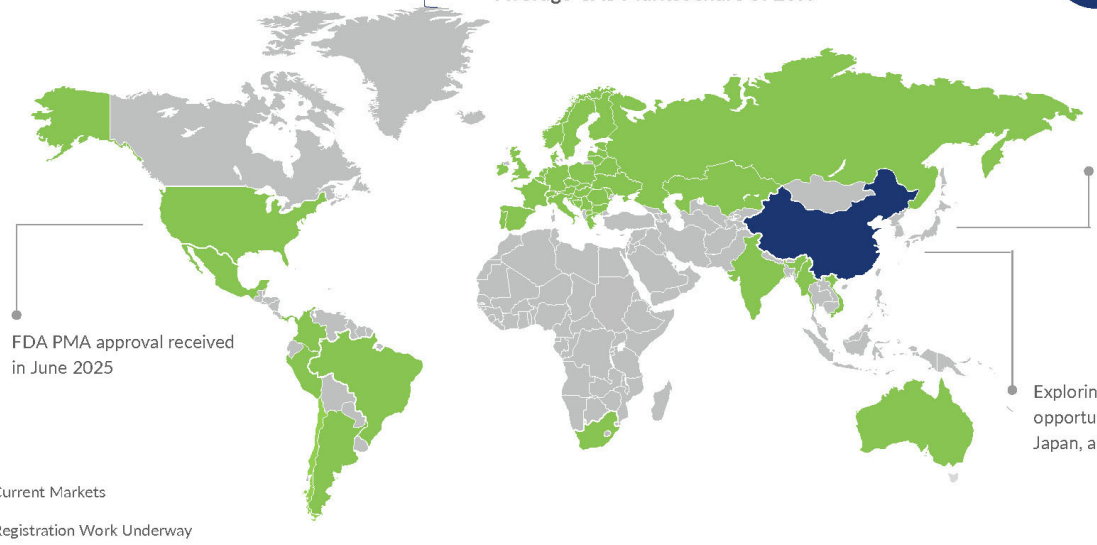
- **SwitchGuard NPS Clearance / Launch (Full TCAR Tool Kit)**
  CGuard Prime indicated stent with SwitchGaurd Neuro Protection for TCAR
- **Further Commercial Expansion in the U.S.**
- **Potential Global Expansion (Asia)**
- **Potential Portfolio Expansion**



INSPIREMD

Commercial Footprint

- Active selling in more than 30 countries
- Over 65,000 systems sold
- Average CAS Market share of 25%



FDA PMA approval received in June 2025

Signed agreement with Chinese distributor. Working toward distribution

Exploring expansion opportunities Taiwan, Japan, and Korea

Current Markets

Registration Work Underway

INSPIREMD

Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Pending
USA	20	7
Rest of World	54	21

InspireMD will continue to strengthen and broaden its patent protection globally to enable future pipeline products

IP Counsel: Kligler and Associates, P.A.

INSPIREMD

Transformational July 2025 PIPE and May 2023 Financing Up To $153.7 Million

To advance the company towards successful U.S. commercialization and path to profitability

July 2025 PIPE Financing of $40.1 million

May 2023 Financing of $113.6 million

- **$42.2 million** upfront funding
- **$71.4 million** tied to the achievement of four milestones (**$17.9 million** each) each expiring upon the earlier of 5 years or 20 trading days following the achievement of the following milestones:

1. **Complete, July 2024:** Release of primary and secondary end points related to one year follow up study results from the C-Guardians pivotal trial;
2. **Complete, July 2025:** Receipt of Premarket Approval (PMA) from the FDA for the CGuard® Prime Carotid Stent System (135 cm);
3. Receipt of FDA approval for the SwitchGuard trans carotid system and CGuard Prime 80 cm; and
4. Completion of four quarters of commercial sales of the CGuard in the U.S.

Strong validation from leading fundamental healthcare investors, with additional participation by select NSPR Board members.

ROSALIND
SOLEUS CAPITAL
NANTAHALA CAPITAL MANAGEMENT, LLC
VELAN CAPITAL
MARSHALL WACE
OrbiMed Healthcare Fund Management
PARKMAN HEALTHCARE PARTNERS
Ghisallo
TEKLA Capital Management LLC

INSPIREMD

Summary Financials

August 4, 2025

NASDAQ Capital Markets	NSPR
Stock Price	$2.67
Average 3 Month Volume	170K
Shares Outstanding	41.7M
Shares Outstanding with Prefunded Warrants	85.8M
Market Capitalization with Prefunded Warrants	$229.0M
Cash Balance - Aug 4, 2025	$72.6M
Debt	$0M


INSPIREMD
Nasdaq: NSPR