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): November 4, 2025

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

Delaware (State or Other Jurisdiction of Incorporation)

001-35731		26-2123838
(Commission		(IRS Employer
File Number)		Identification No.)
6303 Waterford District Drive, Sui	ite 215	
Miami, Florida		33126
(Address of Principal Executive Of	fices)	(Zip Code)
(Registr	(888) 776-6804 rant's Telephone Number, Including Area C	ode)
Check the appropriate box below if the Form 8-K filing is intended to simultaneous	sly satisfy the filing obligation of the registr	ant under any of the following provisions:
$\hfill \square$ Written communications pursuant to Rule 425 under the Securities Act (17 CF	TR 230.425)	
$\hfill \Box$ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 2	240.14a-12)	
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Excl	hange Act (17 CFR 240.14d-2(b))	
$\hfill \Box$ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange \hfill	nange 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 Exchange Act of 1934 ($\S240.12b-2$ of this chapter).	defined in as defined in Rule 405 of the So	eccurities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities
If an emerging growth company, indicate by check mark if the registrant has elected	ad not to use the outended transition named	for complying with any pay or raying financial accounting standards provided
pursuant to Section 13(a) of the Exchange Act. □	ed not to use the extended transition period	tor comprying with any new or revised maneral accounting standards provided

Item 2.02 Results of Operations and Financial Condition

On November 4, 2025, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results and recent highlights for the three and nine months ended September 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 November 4, 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 November 4, 2025 (furnished herewith pursuant to Item 2.02)
99.2	Investor Presentation November 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: November 4, 2025 By: /s/ Michael Lawles

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



InspireMD Reports Third Quarter 2025 Financial Results

Successful initial CGuard Prime U.S. commercial launch drives record quarterly revenue

Miami, FL — November 4, 2025 – 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 third quarter and nine months ended September 30, 2025.

Recent Business Highlights:

- · Initiated U.S. commercial launch of the CGuard Prime carotid stent system
- Completed over 100 U.S. carotid procedures across leading hospitals
- Strengthened leadership team with the appointment of Peter A. Soukas, M.D., as Chief Medical Officer
- Appointed Dan Dearen to the Board of Directors as audit committee chairman bringing valuable experience to InspireMD

Marvin Slosman, CEO of InspireMD, commented: "Our business demonstrated strong growth across all geographies in the third quarter of 2025. Over the last few months, our team executed our planned U.S. commercial launch of our CGuard Prime carotid stent system, which delivered measurable revenue in our initial commercial quarter in the United States. We continue to see strong demand for our solutions globally, validating our mission as we work to transform the carotid intervention market with a stent first approach."

"Further, with the addition of \$58 million in gross proceeds to our balance sheet, as announced in July, we are able to continue adding top-tier talent and executing our commercial rollout with intention, purpose, and stamina. We are entering a new era of growth, and I am confident that this team and technology can deliver immense value over the years ahead."

Financial Results for the Third Quarter Ended September 30, 2025

For the third quarter of 2025, total revenue increased by 39%, to \$2.5 million as compared to \$1.8 million during the same period of last year.

U.S. revenue for the third quarter was \$497,000 and international revenue was \$2.0 million. This increase was predominantly attributable to CGuard Prime revenue in the U.S., increased penetration of international markets with CGuard, and the favorable impact of changes in foreign exchange rates.

Gross profit (revenue less cost of revenues) for the third quarter of 2025 was \$864,000 an increase of \$450,000 compared to \$414,000 for the third quarter of 2024. This increase in gross profit resulted from an increase in revenue and a favorable shift in sales mix towards higher margin revenue from the Company's U.S. commercial launch, partially offset by higher production variances and training costs.



Total operating expenses for the third quarter of 2025 were \$13.9 million an increase of 57% compared to \$8.9 million for the third quarter of 2024. This increase was primarily due to increases in headcount-related expenses as the Company continued to expand its U.S. personnel, particularly its commercial team, to drive the U.S. commercial launch of CGuard Prime. A second driver of the increase in operating expenses was occupancy and related infrastructure expense related to the establishment of the Company's U.S. headquarters.

Financial income, net for the third quarter of 2025 was \$343,000, a decrease of 40% compared to financial income of \$572,000 for the third quarter of 2024. This decrease was primarily due to a \$118,000 decrease in financial income from investments in marketable securities and money market funds and a \$104,000 increase in financial expenses related to changes in exchange rates.

Net loss for the third quarter of 2025 was \$12.7 million or \$0.17 per basic and diluted share, compared to a net loss of \$7.9 million or \$0.16 per basic and diluted share, for the same period in 2024.

As of September 30, 2025, cash and cash equivalents and marketable securities were \$63.4 million compared to \$34.6 million as of December 31, 2024.

Conference Call and Webcast Details

Management will host a conference call at 8:30 am ET today, November 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.

Tuesday, November 4th at 8:30 a.m. ET

Domestic: 1-800-579-2543
International: 1-785-424-1789
Conference ID: IMD3Q25

Webcast Link - Click Here

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet TM 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. 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 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.

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 September 30,		 Nine months ende September 30,				
		2025		2024	 2025		2024
Revenues	\$	2,523	\$	1,810	\$ 5,830	\$	5,060
Cost of revenues		1,659		1,396	 4,361		4,023
Gross Profit		864		414	 1,469		1,037
Operating Expenses:							
Research and development		3,635		3,915	11,528		9,941
Selling and marketing		4,392		1,472	11,314		4,154
General and administrative		5,888		3,489	 16,157	_	11,078
Total operating expenses		13,915	_	8,876	 38,999		25,173
Loss from operations		(13,051)		(8,462)	(37,530)		(24,136)
Financial income, net		343		572	 505		1,305
Net Loss	\$	(12,708)	\$	(7,890)	\$ (37,025)	\$	(22,831)
Net loss per share – basic and diluted	\$	(0.17)	\$	(0.16)	\$ (0.64)	\$	(0.58)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted		73,466,501		48,369,412	 58,245,368	_	39,413,004



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

	September 30, 2025		December 31, 2024	
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	63,403	\$	18,916
Marketable securities		-		15,721
Accounts receivable:				
Trade, net		1,961		1,572
Other		475		682
Prepaid expenses		945		1,060
Inventory	 	3,607		2,570
Total current assets		70,391		40,521
Non-current assets:				
Long term deposit		438		426
Property, plant and equipment, net		3,403		2,371
Operating lease right of use assets		2,915		2,360
Funds in respect of employee rights upon retirement		1,325		1,129
Total non-current assets		8,081		6,286
Total assets	\$	78,472	\$	46,807



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

	 September 30, 2025		December 31, 2024	
LIABILITIES AND EQUITY	 			
Current liabilities:				
Accounts payable and accruals:				
Trade	\$ 1,753	\$	1,254	
Other	 9,063		6,424	
Total current liabilities	 10,816		7,678	
Long-term liabilities:				
Operating lease liabilities net of current maturities	2,367		1,796	
Liability for employee rights upon retirement and others	 1,175		1,247	
Total long-term liabilities	 3,542		3,043	
Total liabilities	\$ 14,358	\$	10,721	
Equity:				
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at September 30, 2025, and December 31, 2024; 41,919,141 and 26,611,033 shares issued and outstanding on September 30, 2025, and December 31, 2024,				
respectively	4		3	
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at September 30, 2025, and December 31,			3	
2024; 1,718 shares issued and outstanding at September 30, 2025, and December 31, 2024, respectively	*		*	
Additional paid-in capital	354,641		289,589	
Accumulated deficit	 (290,531)		(253,506)	
Total equity	 64,114		36,086	
Total liabilities and equity	\$ 78,472	\$	46,807	

(1) All September 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 November 10, 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.





Disclaimers

Forward-looking statements

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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





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



- 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

INSPIRE

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

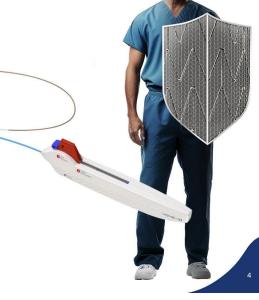
Ongoing U.S. Commercial Launch, With a Trained and Seasoned Salesforce Driving Adoption

A New Level of Stroke Prevention is Here

 With over 65,000 patients treated worldwide, we're ready to elevate embolic prevention for U.S. physicians and their patients

Tested. Trusted. Ready.

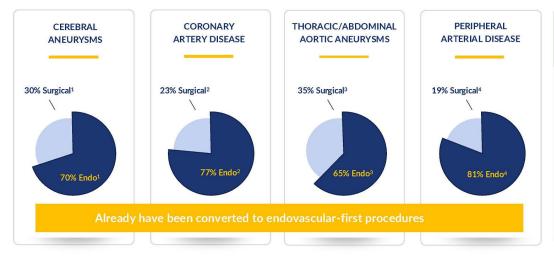
 Our U.S. entry brings a rigorously tested solution to stroke prevention and positions us to become a true global carotid technology leader

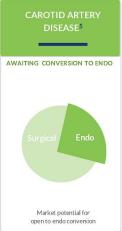


INSPIRE

Endovascular Revolution Has Arrived

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







LBekelis 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

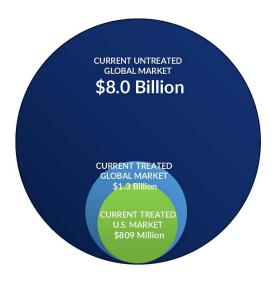
Zculler SD, Kugelmass AD, Brown PP., et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2083 and 2012. Circulation. 2015;131(4):362-70

Beck AW, Sednayan A, Moa J. et al. Variations in Abdominal Acrit che Neurysm Care. A Report From the international Consorties. Circulation. 2016;134(2):1348-1358

Guerra, 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 Recentgool. 2020 May214(5):962-966.

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





People diagnosed with High Grade Carotid Stenosis (HGCS)

~400,000

Global procedures (CEA/CAS/TCAR) annually to treat HGCS

~155,000

US Procedures (CEA/CAS/TCAR) annually

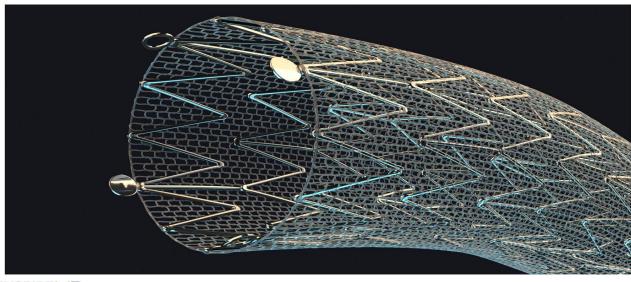
Market Growth Driver

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



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



INSPIRE MD

Transforming the Carotid Intervention Market

(3)

CGuard®Carotid Stent Platform

Proprietary MicroNet[™] Technology

Highly differentiated platform for treatment of carotid artery disease and stroke prevention



Unmatched Clinical Outcomes

Short and Long-Term Results

Ten clinical trials completed with >2,000 patients presented or published including US IDE trial



Deep Pipeline and Strategic Roadmap

MicroNet[™] technology pipeline; SwitchGuard NPS for TCAR; acute stroke with tandem lesions



CMS Coverage Expanded

Standard Risk and Asymptomatic Reimbursement

Enables stent-first approach to carotid revascularization



Significant Market Potential

Current Treated Market: \$1.3 Billion

(Patients treated with CEA + CAS globally), with significant growth potential



Expanding Commercial Footprint

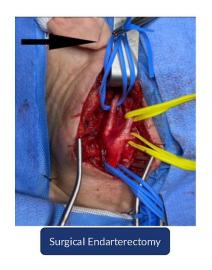
Double-digit market share in >30 served countries (>30% in Italy)

Nearly 70,000 stents sold to date

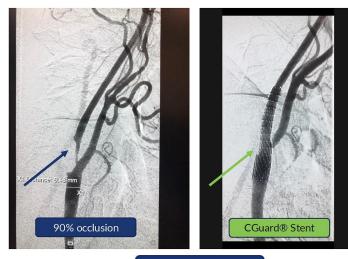
CGuard Prime Received FDA Approval in June 2025, Launched Commercially in July 2025



A Picture is Worth a Thousand Words...



VS

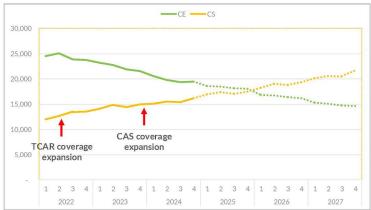


Stenting



Carotid Stenting (CAS + TCAR) is on the Rise

- DRG/CPT data by Facility and HCP
- Trailing 12 Quarters through Q4 2024
- ~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



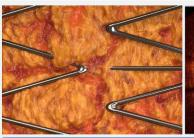
Market Shift

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



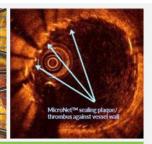
The CGuard® Difference: The Impact of MicroNetTM Technology¹

Approximately 2/3 of neurovascular events (stroke, TIA) occur after carotid interventions take place². Prevention depends on the protection from the stent implanted









Conventional Open Cell Stent (1St GEN):

Larger cell sizes allow increased plaque protrusion risk

CGuard Stent System (2nd GEN):

Stents are covered in MicroNet to minimize plague prolapse

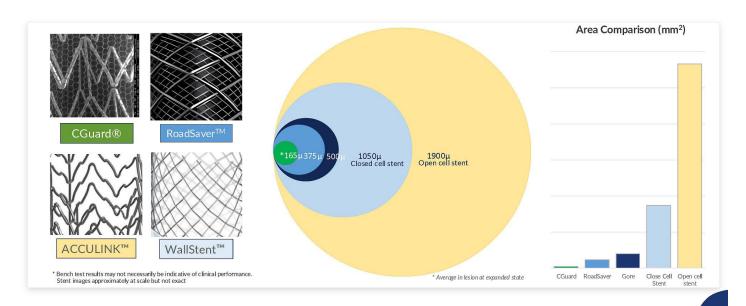
MicroNet: Advanced Protection Technology

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



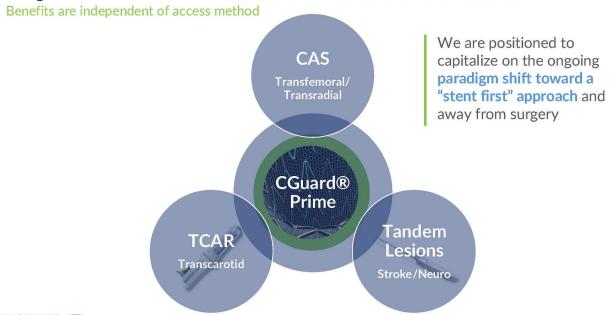
1.2 Tomoyuki Umemoto. MD. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. Eurointerventional 2017;1348-1355 (published online) Image: Prof. Valdés Chávarri

Stent Cell Sizes (Mechanism of Action)



INSPIRE

Long-Term Stent Performance is the Cornerstone of Our Business



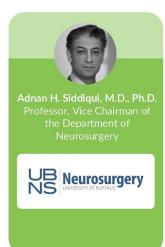
INSPIRE MD

Scientific Advisory Board (Multidisciplinary KOLs)









INSPIRE

Unmatched Foundational Data and Evidence

INSPIRE MD

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.



* 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



- Demonstrates the <u>lowest 30-day DSMI rates</u> 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

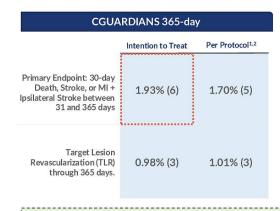


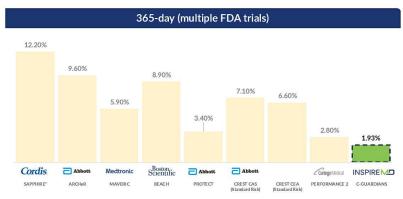
- Kaplan-Meier estimate for all 1-year endpoints
 Per Protocol Analysis excludes 15 patients with Major Protocol Deviations

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 App;67(4):503-12. lyer SS, et al, J Am Coll Cardiol. 2008 Jan 29;51(4):427-34. Matsumura JS, et al, J Vasc Surg. 2012 App;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. W. Gray VIVA 2023

C-GUARDIANS: 1 Year Outcomes

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





- Demonstrates the <u>lowest primary endpoint event rates</u> 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



- 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, CI 2006 Apr;67(4):503-12. Iyer SS, et al, J Am Coll Cardiol. 2008 Jan 29:51(4):e27-34. Matsumuna JS, et al, J Vasc Surg. 2012 Apr;54(4):68-97-68. 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)



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

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

- Improvements from secondgeneration 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)

Event	FGS	SGS	Terumo RoadSaver/ Casper	Gore (not marketed)	INSPIRE 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)

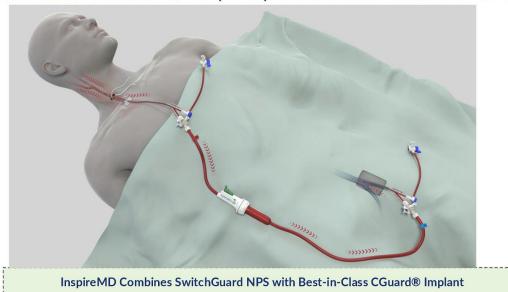


1) Clinical Outcomes of Second - versus First-Generation Carotid Stents: A Systematic Review and Meta-Analysis, J. Clin. Med. 2022, 11



INSPIRE MD

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

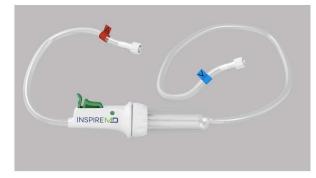


INSPIRE

1. Transient flow reversal combined with sustained embolic prevention in transcervical revascularization of symptomatic and highly-emboligenic carotid stenoses for optimized endovascula

Developing Comprehensive TCAR Solution









TCAR Market Opportunity

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

 $\textbf{~30,000} \ \mathsf{TCAR} \ \mathsf{procedures} \ \textbf{(~\$210M)} \ \mathsf{performed} \ \mathsf{in} \ \mathsf{the} \ \mathsf{U.S.} \ \mathsf{in} \ \mathsf{2024, double-digit} \ \mathsf{growth} \ \mathsf{projected}^{1,2}$



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

Commercial and Corporate

INSPIRE MD

Commercial Traction Progress in the U.S.

Salesforce

High-powered U.S. commercial team with CAS, TCAR, and Neurovascular expertise, proven success launching new products and navigating approvals

Continue to attract and recruit outstanding field sales talent

Targeting

Leverage claims database to:

- Map carotid stent procedures to the physician level
- Identify highest-opportunity markets to guide hiring decisions
- Target priority physicians and accounts with precision

Demand

Strong physician interest paired with a seasoned field team have driven significant progress with double-digit physicians having performed cases in the U.S.

INSPIRE

Roadmap / Milestones

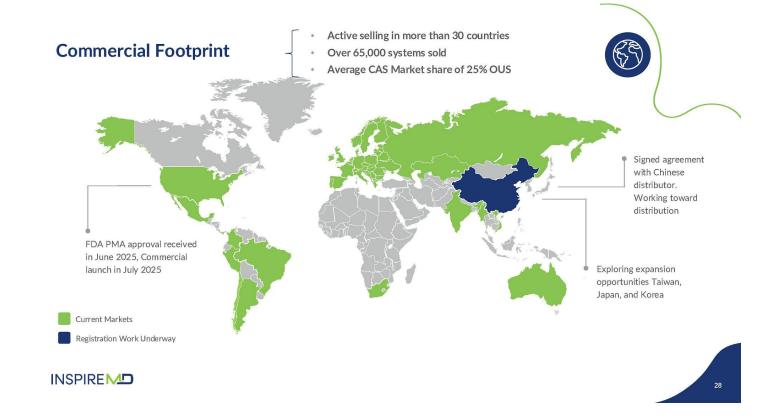


Key Value Drivers

2025 **CGuard® Prime CAS Approval CGuard Prime CAS Market Expansion** Potential SwitchGuard NPS Clearance / Launch for CAS Launch (Full TCAR Tool Kit) CGuard Prime indicated stent with **U.S Operational Expansion** Potential CGuard Prime TCAR Approval SwitchGaurd Neuro Protection for TCAR Build out of U.S. HQ, Operational and **CGuard Prime indicated stent for TCAR** Commercial Teams Further Commercial Expansion in the U.S. CGuard Prime FDA & CE Mark Approval Potential Global Expansion (Asia) **Acute Stroke EFS- Tandem Lesions Potential Portfolio Expansion**

INSPIRE

2/



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.



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

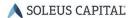
July 2025 PIPE Financing of \$40.1 million

May 2023 Financing of up to \$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. <u>Complete, July 2024</u>: 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.























Summary Financials November 3, 2025

NASDAQ Capital Markets	NSPR
Stock Price	\$2.29
Average 3 Month Volume	93K
Shares Outstanding	42.2M
Shares Outstanding with Prefunded Warrants	86.2M
Market Capitalization with Prefunded Warrants	\$197.5M
Cash Balance - Sep 30, 2025	\$63.4M
Debt	\$0M



