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 1, 2023**

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.)
4 Menorat Hamaor St. Tel Aviv, Israel (Address of Principal Executive Offices)	**6744832** (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 7.01 Regulation FD Disclosure.

On November 1, 2023, InspireMD, Inc. (the "Company") issued a press release titled "InspireMD Presents Positive 30-Day Follow-Up Results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) Clinical Trial at VIVA23". A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. A copy of the presentation that the Company presented at the Vascular InterVentional Advances meeting ("VIVA23") is attached hereto as Exhibit 99.2 and incorporated by reference in this Item 7.01.

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, including Exhibit 99.1 and Exhibit 99.2, 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 8.01 Other Events.

On November 1, 2023, the Company presented 30-day results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial at VIVA23.

From July 2021 to June 2023, 316 patients were prospectively enrolled in a single-arm carotid artery stenting study performed at 24 sites in the United States and the European Union. The primary endpoint in the clinical trial was a composite of: (1) incidence of major adverse events including death (all-cause mortality), any stroke, or myocardial infarction ("DSMI") through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure. Stenting with the C-Guard carotid stent system in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%, measured from the date of the procedure through 30 days follow-up post-procedure.

The Company anticipates reporting primary endpoint results from C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial in the second half of 2024 that may support a premarket approval application with the U.S. Food and Drug Administration.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release, dated November 1, 2023 (furnished herewith pursuant to Item 7.01)
99.2	InspireMD VIVA23 Presentation, November 2023
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 1, 2023

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

Exhibit 99.1

InspireMD Presents Positive 30-Day Follow-Up Results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) Clinical Trial at VIVA23

Data demonstrate a low major adverse event rate of 0.95% through 30 days post-procedure.

Tel Aviv, Israel, and Miami, Florida — November 1, 2023 – InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Embolic Prevention Stent System (EPS) for the prevention of stroke, today presented 30-day results from the C-GUARDIANS U.S. Investigational Device Exemption (IDE) clinical trial at the Vascular InterVentional Advances (VIVA) meeting, which is being held October 30 through November 2 in Las Vegas, NV. The presentation, which was accepted as a late-breaking abstract, was delivered by Dr. Chris Metzger, System Vascular Chief at OhioHealth in Columbus, OH and principal investigator of the C-GUARDIANS trial.

C-GUARDIANS is a pivotal trial designed to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting (CAS) and at a high risk for carotid endarterectomy (CEA).

Presentation Highlights:

- From July 2021 to June 2023, 316 patients were prospectively enrolled in this single-arm carotid artery stenting study performed at 24 sites in the US and the EU.
- The primary endpoint is a composite of: (1) incidence of major adverse events including death (all-cause mortality), any stroke, or myocardial infarction (DSMI) through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure.
- Stenting with the C-Guard carotid stent system in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%, from procedure through 30 days follow-up.

Marvin Slosman, chief executive officer of InspireMD, stated, "The follow-up data from C-GUARDIANS once again supports the safety of the C-Guard EPS stent, with its novel MicroNet™ technology, as reflected in the low rate of major adverse events observed through 30 days. We believe the neuroprotective qualities of C-Guard set it apart from competing stents on the market and should help accelerate the ongoing shift in carotid revascularizations from 'surgery first' to an endovascular 'stent first' approach. We look forward to reporting 12-month results as we continue to advance CGuard EPS toward potential FDA approval in the first half of 2025."

InspireMD anticipates reporting primary endpoint results from C-GUARDIANS in the second half of 2024 that may support a Premarket Approval (PMA) application.

About C-GUARDIANS

The C-GUARDIANS clinical trial is evaluating the safety and efficacy of the CGuard™ Carotid Stent System for the treatment of carotid artery stenosis. The study, which completed enrollment in June r023l enrolled 316 patients across 24 trial sites in the U.S. and Europe.

The trial includes both symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS). The primary endpoint includes the composite of the incidence of the following major adverse events: death (all-cause mortality), any stroke, or myocardial infarction (DSMI) through 30-days post-index procedure or ipsilateral stroke from 31-365-day follow-up, based on Clinical Events Committee (CEC) adjudication. The trial will be considered a success if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is less than the performance goal of 11.6%.

The company anticipates primary endpoint results from the study in H2 2024.

About VIVA

VIVA (Vascular InterVentional Advances) is a global educational event for specialists caring for patients with vascular disease. VIVA brings together attendees and faculty specializing in vascular surgery, interventional cardiology, interventional radiology, vascular medicine, neurointervention/neurosurgery, and cardiothoracic surgery, offering a uniquely comprehensive educational experience with access to some of the best minds in endovascular care.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® 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 the 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 the future. 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. Examples of such statements include, but are not limited to, statements relating to the C-GUARDIANS U.S. IDE clinical trial, including 30-day results from such trial, as well as the timing and outcome of any subsequent results, PMA or potential launch. 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, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern; 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.

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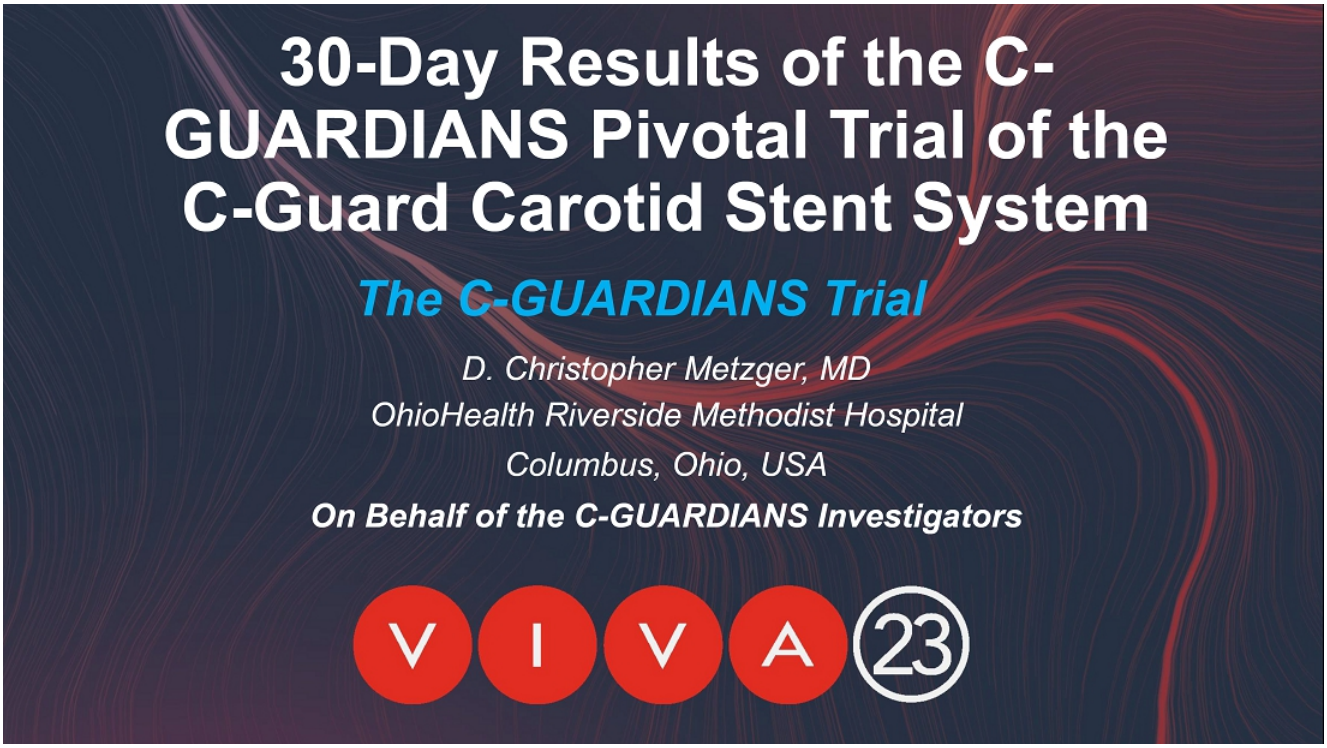
Exhibit 99.2


30-Day Results of the C-GUARDIANS Pivotal Trial of the C-Guard Carotid Stent System
The C-GUARDIANS Trial
D. Christopher Metzger, MD
OhioHealth Riverside Methodist Hospital
Columbus, Ohio, USA
On Behalf of the C-GUARDIANS Investigators
VIVA 23

Disclosure Statement of Financial Interest

Symposia Honoraria & Proctor Fees:
- Abbott, Endologix

Symposia Honoraria:
- Boston Scientific, Medtronic, Penumbra, Shockwave

VIVA Board Member

National PI/Co-PI:
- C-GUARDIANS, CONFIDENCE, SAPPHIRE WW, CANOPY, PERFORMANCE 3

Stock Options: INSPIREMD

Research Grants, Stocks, Equity: None

Background

- Goal is carotid artery stenting (CAS) performed at *low* risk of peri-procedural stroke
- More recent CAS trials have shown significant improvement in results, with 30-day stroke and death rates of ~2-3.5%*
- US : CMS requires use of embolic protection devices, which decrease but do not completely obviate procedural and peri-procedural embolic events
- Stents with additional “neuro-protective properties” may further decrease peri-procedural stroke events

*PROTECT, ARMOUR, EMBOLDEN , CREST 2 Registry (Matsumura, J et al JVS 2012; White, C. et al JACC 2022)

POST-CAS Strokes: Advantage for a Micro-Mesh Stent Design?

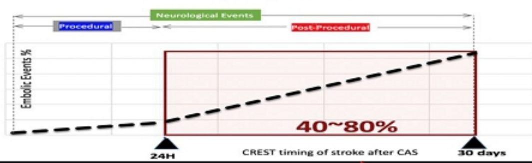
Approximately 2/3 of Events Occur AFTER the CAS Procedure

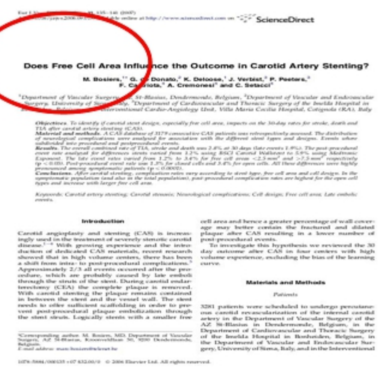
Does Free Cell Area Influence the Outcome in Carotid Artery Stenting? 139

Table 6. Overview of event rates related to the different free cell area

	Total population			Symptomatic population			Asymptomatic population		
	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events
Free cell area									
<2,5 mm^2	2107	48	26	882	20	11	1225	28	15
2,5–5 mm^2	135	3	3	52	1	1	83	2	2
5–7,5 mm^2	327	16	11	155	10	8	172	6	3
>7,5 mm^2	610	23	21	228	17	16	382	6	5
Total	3179	90	61	1317	48	36	1862	42	25
Free cell area									
<2,5 mm^2		2.3%	1.2%		2.3%	1.2%		2.3%	1.2%
2,5–5 mm^2		2.2%	2.2%		1.9%	1.9%		2.4%	2.4%
5–7,5 mm^2		4.9%	3.4%		6.5%	5.2%		3.5%	1.7%
>7,5 mm^2		3.8%	3.4%		7.5%	7.0%		1.6%	1.3%
Total	3179	2.83%	1.9%	1317	3.6%	2.73%	1862	2.25%	1.3%

40-80% of CAS embolic events are post-procedural

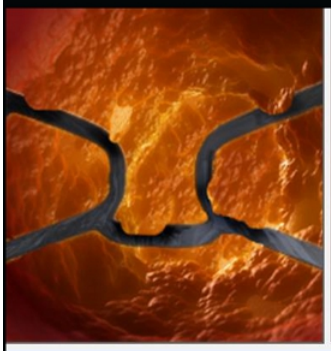


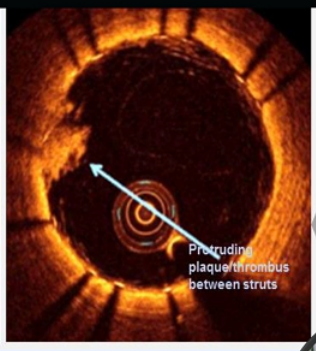


D. Christopher Metzger, MD

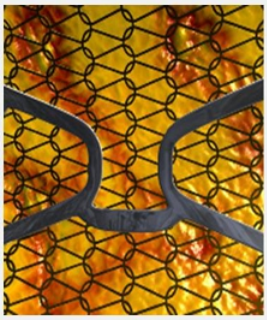
VIVA 23

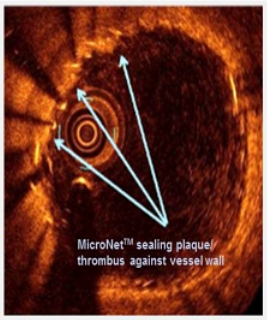
Stroke Prevention Strategy: MicroNet Technology





VS.





Conventional Open Cell Stent (1St GEN):

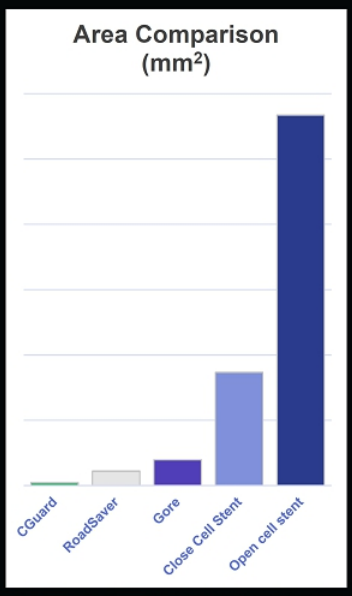
Bare or dual layer approach, with plaque protrusion risk

CGuard Stent System (3rd GEN):

Stents are covered in MicroNet

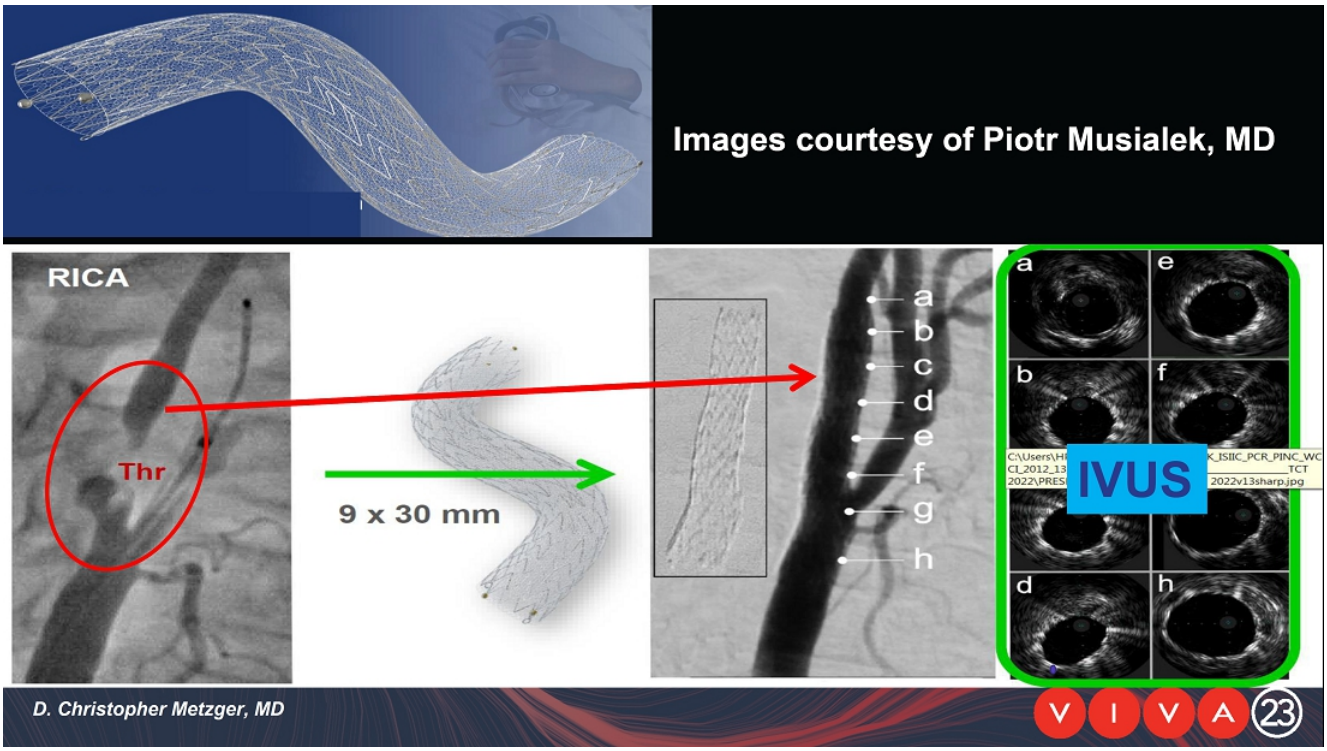
Important Note: The C-GUARD stent is an *investigational device ONLY* in the US

“Pore Size” Comparisons of Carotid Stents



Theoretic Advantages of CGuard Stent

- Maximized *conformability* suitable for more carotid anatomies ("open –cell" stent with proprietary "Smart Fit" auto-taper technology)
- Coupled with maximized *scaffolding and plaque coverage* with smallest pore size and free cell area of available carotid stents
- Potential to minimize plaque protrusion/embolization *during* procedure at highest risk intervals (stent placement, post dilatation) *and* post - procedure


Images courtesy of Piotr Musialek, MD
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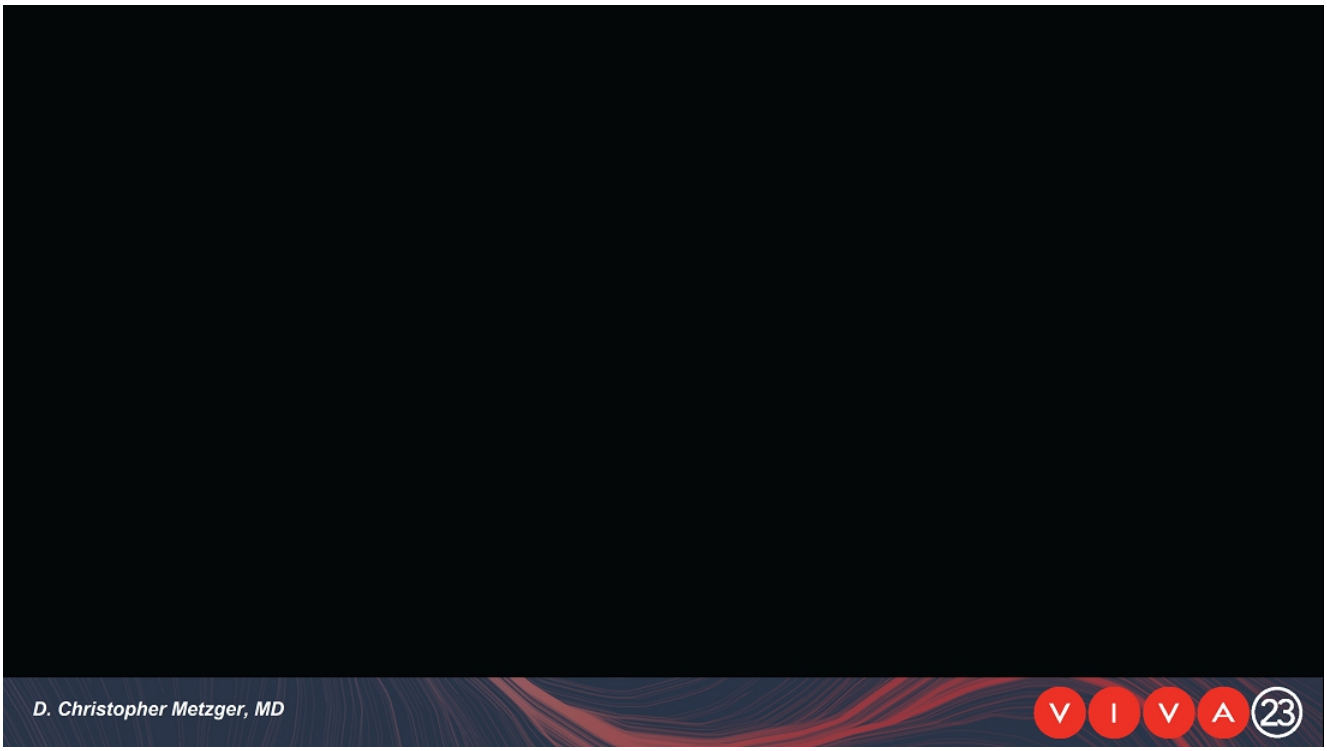
D. Christopher Metzger, MD
VIVA 23

C-GUARDIANS US Pivotal IDE Trial

Disclaimers:

- CE Mark Approved Europe 2015
- INVESTIGATIONAL Only in US
  - In C-GUARDIANS IDE Trial (enrollment completed), and allowed as part of ongoing CREST 2 trial
- *Results presented today are 30- day results, although the primary endpoint for the trial is a 1-year composite endpoint*
  - FDA approved this 30- day result presentation


D. Christopher Metzger, MD
VIVA 23

Other Key Study Personnel

25 investigative sites in the US and Europe

- Ascension Seton Heart (UT Austin)
- Asklepios Hospital St Georg
- Avera Heart Hospital (NC Heart)
- Ballad Wellmont Holston Valley
- Baylor Plano
- Brookwood Baptist
- Cleveland Clinic
- Columbia Medical Center
- Imland Klinik Rendsburg
- John Paul II Hospital
- Mercy Heart & Vascular
- Miriam Hospital
- Novant Health/Forsyth MC
- Ochsner
- Prairie Research
- Prisma Health
- Silesian Medical University
- St. John's
- SUNY Stony Brook UMC
- Tennova Healthcare
- UNC Heart & Vascular
- University of Buffalo
- University of Florida
- University of Leipzig
- UPMC Pinnacle

CGuard Stent System is investigational only and not for sale in the USA.

Study Patients

- Patients ≤ 80 years of age at high risk for carotid endarterectomy
- Asymptomatic ≥ 80%, symptomatic ≥ 50% stenosis
  - Pre-specified 25% of population symptomatic per FDA
- All patients had pre-CAS carotid duplex and CTA/MRA
- All patients were approved by screening committee (2 approvals)
- All patients required to have embolic protection with Abbott Emboshield NAV 6, MoMa proximal embolic protection, or both
- All neurologic and cardiac events adjudicated by CEC

Study Visits and Evaluations

D. Christopher Metzger, MD

Patient Demographics

Characteristic	ITT (N = 316)
Age (mean ± SD)	69.0 ± 6.6
% Symptomatic	24.3%
% Male	63.9%
Diabetes Mellitus	41.8%
Hypertension	92.6%
Dyslipidemia	90%
CAD	52.1%
COPD	23.8%
Current Smoker	26.4%
PVD	28.6%

Embolic Protection Utilized

Emboshield NAV 6 Distal embolic protection	**261**
MoMA Proximal embolic protection	78
Both (Nav6 and MoMa)	24
None	1

C-GUARDIANS 30-day Results

* Hierarchical: patient count (each patient first occurrence of the most serious event).

Non-hierarchical: event count (multiple events in each patient are counted individually).

C-Guardians: 30-day Major Adverse Events

The CEC independently adjudicated all neurological, cardiac events:

- 1 major fatal stroke on post procedural day 10 after all DAPT stopped contrary to per protocol requirements.
- 1 major stroke. (NIHSS 2, post procedure). NIHSS 1, CDU patent 30 days, NIHSS 0 at 6 and 12 months
- 1 retinal infarct in a patient presenting with amaurosis fugax, adjudicated as a minor stroke. (NIHSS 1). NIHSS 0, CDU patent 30 days

C-Guardians: 30-day Major Adverse Events

Event rate in % (n)	ITT (N=316)	Per Protocol^
Death, Stroke or MI*	0.95% (3)	0.63% (2)
Death#	0.32% (1)	0.% (0)
Any stroke#	0.95% (3)	0.63% (2)
Major Stroke#	0.63% (2)	0.32% (1)
Minor Stroke#	0.32% (1)	0.32% (1)
MI#	0.0% (0)	0.0% (0)
Death or any stroke*	0.95% (3)	0.63% (2)
Death or major stroke*	0.63% (2)	0.32% (1)

* Hierarchical: patient count (each patient first occurrence of the most serious event).

Non-hierarchical: event count (multiple events in each patient are counted individually).

^ Per Protocol Analysis excludes 1 patient (did not take dual antiplatelet therapy; had a major stroke and died).

CGuard Stent system is investigational only and not for sale in the USA

Conclusions

- In the C-GUARDIANS IDE Pivotal trial of patients at high risk for carotid endarterectomy with obstructive carotid disease (25% symptomatic), treatment with carotid artery stenting with the CGuard carotid stent system with embolic protection had a low incidence of stroke, death, or MI post-procedure to 30 day follow up
- These results appear to confirm a potential “neuro-protective” effect of this stent
- We await the pre-specified 1- year primary composite endpoint results of this trial

Event Rate in % (n)	ITT	Per Protocol
Death/ Stroke/ MI	0.95%	0.63%
Death/ Stroke	0.95%	0.63%

Thank You for Your Attention!