



#### **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.

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## **Investment Highlights: Transformational Market Drivers**



# CGuard EPS Stent Platform utilizing Proprietary MicroNet™ Technology

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



#### **Expanding Commercial Footprint**

Double-digit market share in **30** served countries (34% in Italy) Over **40,000** stents sold to date



# Unmatched Clinical Outcomes Data (both Short- and Long-Term)

CGuard<sup>™</sup> EPS – (9) clinical trials completed >1,850 patients CGuard results 1.12% vs. Conventional Stents 5.2% and Surgery 4.5% (30 Day Death, Stroke, Myocardial Infarction)



#### **CMS Consideration of Standard Risk Reimbursement**

Decision, Expected October 2023

- Opens entirety of Carotid Revascularization segment to stenting
- Enables Trans Femoral stenting to broader patient cohort (155,000)

#### **US IDE Trial Advancing toward US approval**

FDA decision on approval of CGuard EPS anticipated in Q1 2025

\*milestones and study design noted in U.S. Market / Regulatory Pathway



#### **Market Potential**

Current treated market: \$1.3 billion (Dx & Treated with CEA + CAS)

Total untreated market: \$8 billion (Dx with HGCS not treated)

Standard risk reimbursement (US) increases CAS potential



#### **Deep Pipeline and Strategic Roadmap**

MicroNet™ technology pipeline advancing into multi generational development plans including: SwitchGuard for TCAR; Acute Stroke with tandem lesions

Transformational May 2023 financing up to \$113.6 million to advance the company towards potential US approval and launch of CGuard Prime EPS and other value-creating milestones



## Transformational May 2023 Financing Up To \$113.6 Million

To advance the company towards potential US approval and launch of CGuard EPS and other value-creating milestones

- \$42.2 million upfront funding
- \$71.4 million tied to the achievement of four milestone driven warrants (\$17.9 million each) each expiring upon the earlier of 5 years or 20 trading days following the achievement of the following milestones:
  - 1. Release of primary and secondary end points related to one year follow up study results from the C-Guardians pivotal trial;
  - 2. 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 United States.
- **Strong validation** from leading fundamental healthcare investors, with additional participation by select NSPR Board members.

## ROSALIND





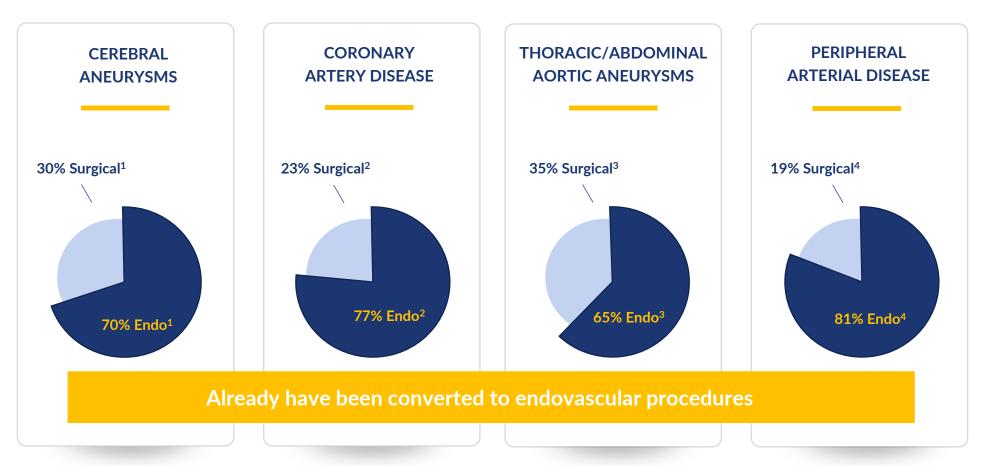


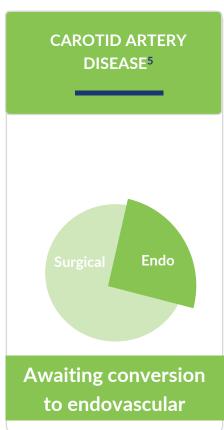






## **Endovascular Procedures: Landscape and InspireMD Potential**





<sup>4</sup> 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



Company and Products Overview

<sup>&</sup>lt;sup>1</sup> 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

<sup>2</sup> 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

<sup>&</sup>lt;sup>3</sup> 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

#### **Approaches to Treating Carotid Artery Disease**

155,000 Procedures Annually

Surgical Approach

Carotid Endarterectomy (CEA) (70%) TCAR (10%)

#### Risk of complications:

Myocardial infarction risk<sup>1</sup> (heart attack)

Cranial nerve injury risk<sup>1</sup> (vertigo, hearing loss, paralysis, etc)

Aesthetic concern



#### **Carotid Artery Stenting (CAS)**

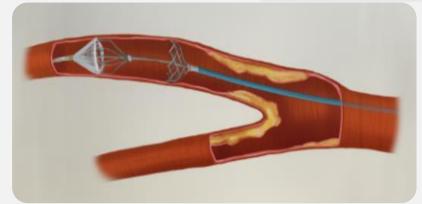
Conventional Approach (Bare Stent) 1st generation

#### (20%)

#### Risk of complications:

Procedural and post-procedural increase minor stroke risk<sup>1</sup>





<sup>&</sup>lt;sup>1</sup> Based on the **CREST** clinical trial data, in which only **conventional carotid stents** were used vs.**surgery**, CREST Trial: N Engl J Med 2010;363:11-23

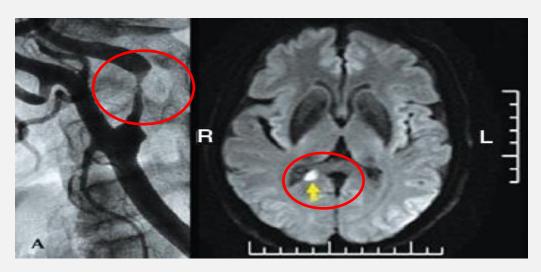


Company and Products Overview

# THE PROBLEM: Risk of Embolism Following Conventional Carotid Stenting (1st generation stents)

Approximately 2/3 of neurovascular events (stroke, TIA) occur after the procedure takes place.

#### **Pre-Procedure**

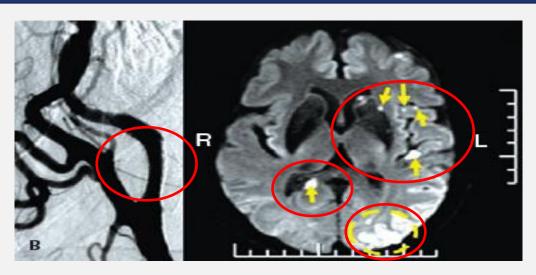


90% occlusion of the carotid artery

MRI of a pre-existing white matter infarction (obstruction)

#### **Post-Procedure**

with Conventional Stent



Successful opening of the carotid artery

MRI reveals new multiple micro-infarcts (obstructions) due to liberation of embolic particles

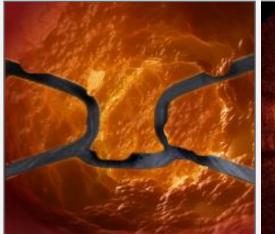
MRI reveals post-procedural cerebral embolization

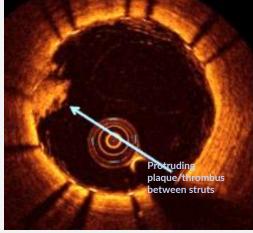
2. Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.,



## OUR SOLUTION: Proprietary MicroNet<sup>TM</sup> Technology<sup>1</sup>

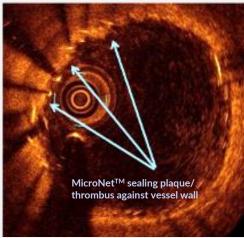
New mesh covered stent offers superior plaque coverage when compared to conventional stent approaches











Conventional Open Cell Stent (1<sup>St</sup> GEN):

Bare or dual layer approach, with plaque protrusion risk

CGuard Stent System (3<sup>rd</sup> GEN):

Stents are covered in MicroNet

#### An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

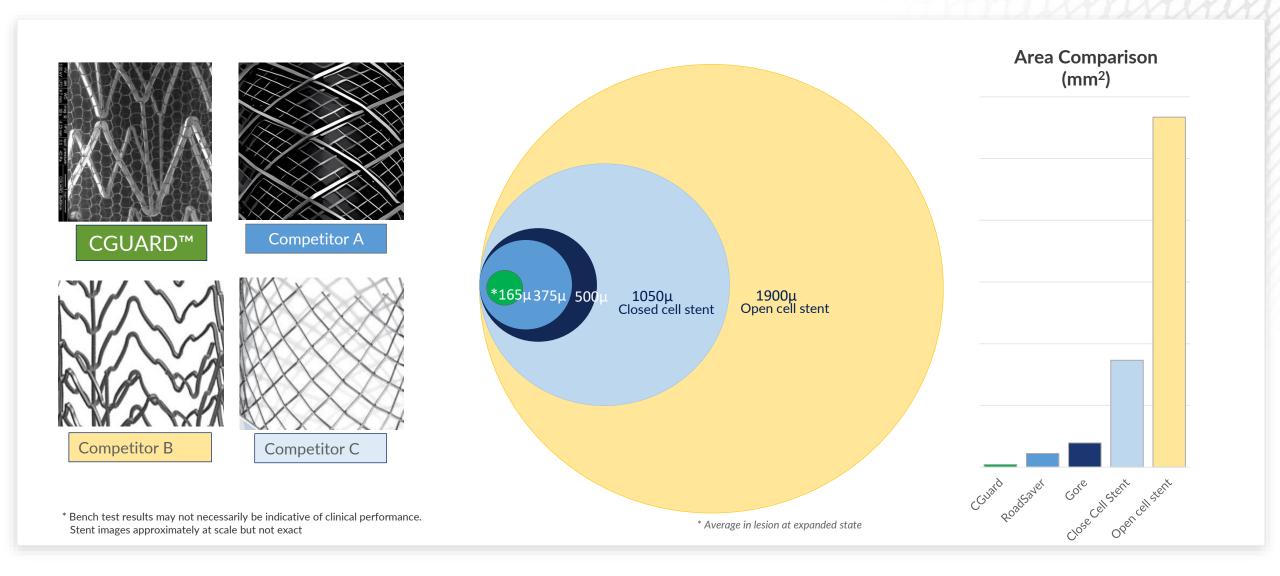
MicroNet captures and locks thrombus & plaque materials against the arterial wall, deterring debris from entering the bloodstream while also acting as a mechanical barrier to prevent plaque protrusion

<sup>1</sup> 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



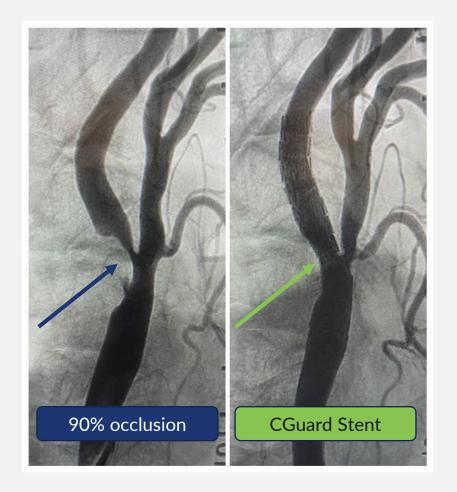
Company and Products Overview

## **Scaffolding- Stent Cell Diameters**





## A picture is worth a thousand words ...





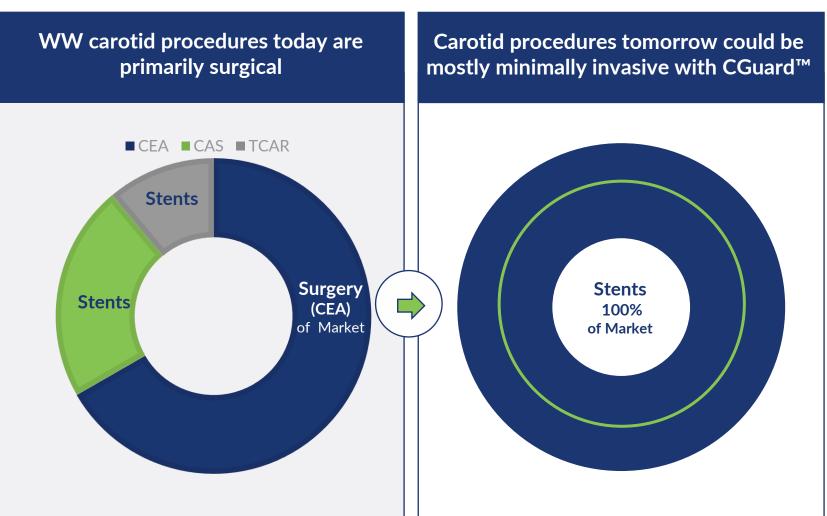




#### Potential Multi-Billion Dollar Market Opportunity



MicroNet<sup>TM</sup> covered CGuard<sup>TM</sup> stent platform could become the new gold standard



 ◆ Current <u>Treated</u> Global Market:
 → \$1.3 billion (1)
 407K Global procedures (CEA/CAS/TCAR) to treat HGCS (High

◆ Current <u>Treated</u> U.S. Market:
 → \$809 million
 155K procedures to treat HGCS

**Grade Carotid Stenosis**)

- ◆ Current <u>Untreated</u> Global Market:
   → \$8 billion
   ~2.8 million people diagnosed with HGCS
  - ~2.8 million people diagnosed with HGCS (Untreated)
- Standard Risk Reimbursement (US) increases CAS potential

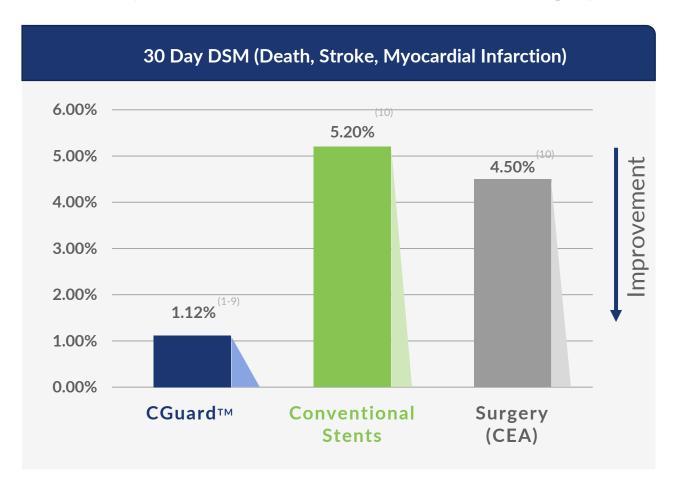
## **Unmatched Foundational Data**



## **CGuard™ EPS Yields Superior Clinical Outcomes**



When compared with Conventional Stents and Surgery (CEA), CGuard trends Superior



- No stent-related major strokes and 11 minor strokes to date with CGuard in 1,873 patients in 9 studies (0.6%)
- CGuard is a next-generation stent supported by a strong clinical data

<sup>1.</sup> IRONGUARD I EuroIntervention 2018 Nov 20. 14:1150-1152. 2. IRONGUARD II, LINC 2020 3. CASANA Eur J Vasc Endovasc Surg 2017 Dec. 54:681-687. 4. WISSGOTT I J Endovasc Ther 2019 08. 26:578-582. 5. WISSGOTT II J Endovasc Ther 2017 02. 24:130-137. 6. PARADIGM Extend, EuroIntervention 2016 Aug 05. 12:e658-70. Updated LINC 2020. 7. CARENET JACC Cardiovasc Interv 2015 Aug 17. 8:1229-1234. 8. Randomize Clinical Trial EuroPCR e-Course, June 25, 2020. 9. Tigkiropoulos J Endovasc Therapy Volume 28 Issue 4, Aug 2021 10. CREST N Engl J of Med 2010 July 1. 11-23.



Company and Products Overview

#### **Carotid Solution: Our Well Studied Mesh-Covered Technology**

More than

1,850

patients in
Clinical
Publications &
Studies



















## **Clinical Data Foundation: Evolution to Standard of Care**

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (known & anticipated)	Journal
2015	CARENET	Safety, Efficacy & Neuroprotection over other stents data		JACC
2016	PARADIGM	All comers population; Excellent clinical results	© CGuard evaluated as new	Eurointervention, LINC
2017	CASANA	Large surgical center, Clinical results over conventional stents historical data	approach 'to CAS	Eur J Endovasc Surg
2017	WISSGOTT	Clinical & mechanical assessment; Mechanical advantages vs competitive stents		J Endovasc Ther
2017	IRON-GUARD 1	Real world multicentric 30d results; Excellent clinical results in multicentric	©CGuard demonstrates	Eurointervention
2018	WISSGOTT 10MM	"One-Size-Fit-Ail" (OSFA); 10 mm CGuard OSFA demonstrates safety and efficacy	best performance in field	J Endovasc Ther
2019	IRON-GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric		Eurointervention
2020	IRON-GUARD 2	Large real world multicentric; Large Multicentric Best-In-Class clinical results		Cardiovasc Interv
2021	CGuard-TCAS	CGuard Trans-Cervical excellent results		Adv Interv Cardiol
2021	IRON-GUARD 2	12-month 733 pts clinical results		JACC
2021	Randomized Control Trial	Randomized Trial; CGuard demonstrates Neuroprotection vs Conventional stents	©CGuard demonstrates	JACC, LINC
2021	ONE SIZE-FIT-ALL	CGuard 150 pts 12m-FU	superiority to other stents	CIRSE
2021	Greek Registry	CGuard in Real live at 30d		J Endovasc Ther
2021	Meta-Analysis	CGuard superior to Other Stents at 1y-FU		J Clin Med
2021-24	PARADIGM Extend	CGuard in all-comers 550 pts 30d / 5y FU		LINC, DEKRA PMCF
2021	Meta-Analysis	CGuard superior to CEA at 1y-FU		Writing
2021	OCTOPVS	OCT comparison CGuard vs CEA; CGuard superior post-intervention OCT than CEA	CGuard demonstrates	Writing
2022	OPTIMA	IVUS assessnnent after CGuard: Anticipated Plaque exclusion detnonstrated	superiority to surgery	Writing
2022	FLOW-GUARD	Use of CGuard as flow diverter in very high-risk patients beyond carotids; Potential new CGuard indications		Writing



#### **Clinical Support Highlights / Call out**

2015-2022



#### **CARENET Trial**

First in Man StudyDemonstrated Safety,
Efficacy, &
Neuroprotection over
other stents data
Reduction of embolization
(50% fewer lesions / 80% less volume

with 0 events @ 30 days)



#### PARADIGM + Extend

Opened CARENET study inclusion criteria all comers.

Concluded the safety and clinical outcomes were applicable to all.

500 patients followed 5 years.

Defines standard for measured sustained protection and long-term outcomes



#### **Randomized Control Trial**

CGuard vs. Conventional
Stent (Abbott Acculink)
CGuard superiority in
Randomized study format
Confirms CARENET results with
statistical significance

CGuard™ EPS: Nine clinical trials completed with >1,850 patients followed



**CARMEN Meta-Analysis (112 Studies, 68K Patients)** 

Table 2A. 30-day and 12-month event rates by stent type (random-effect model).

- 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)

	FGS	SGS	Competitor #1	Competitor #2	CGuard
30-day Stroke [%] (95% CI)	<b>3.01</b> (2.63-3.38)	0.60 (0.28-0.92)	0.50 (0-1.15)	<b>2.89</b> (1.03-4.76)	<b>0.54</b> (0.17-0.92)
30-day Death/Stroke/MI [%] (95% CI)	<b>4.11</b> (3.65-4.56)	1.30 (0.64-1.96)	<b>1.33</b> (0-2.66)	<b>4.82</b> (2.44-7.2)	1.08 (0.55-1.60)
12-mo Ipsilateral Stroke [%] (95% CI)	<b>3.51</b> (2.52-4.50)	<b>0.7</b> (0-1.47)	<b>0.26</b> (0-1.27)	<b>3.1</b> (1.11-5.1)	<b>0.38</b> (0-0.9)
12-mo Restenosis [%] (95% CI)	<b>3.97</b> (0.28-5.14)	<b>3.38</b> (1.39-5.37)	<b>7.16</b> (4.45-9.86)	<b>4.83</b> (2.36-7.29)	<b>0.34</b> (0-0.82)
12-mo Ipsilateral Stroke/Restenosis [%] (95% CI)	<b>8.15</b> (6.34-9.96)	<b>5.12</b> (2.14-8.10)	<b>7.86</b> (5.04-10.68)	<b>7.93</b> (4.82-11.04)	<b>0.73</b> (0-1.44)

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



# **US IDE Trial**



## **PMA Trial Design**

#### FDA Trial Performance Goal – 11.6% vs European Clinical Trials' Performance 1.32% (w/ 1 Yr)

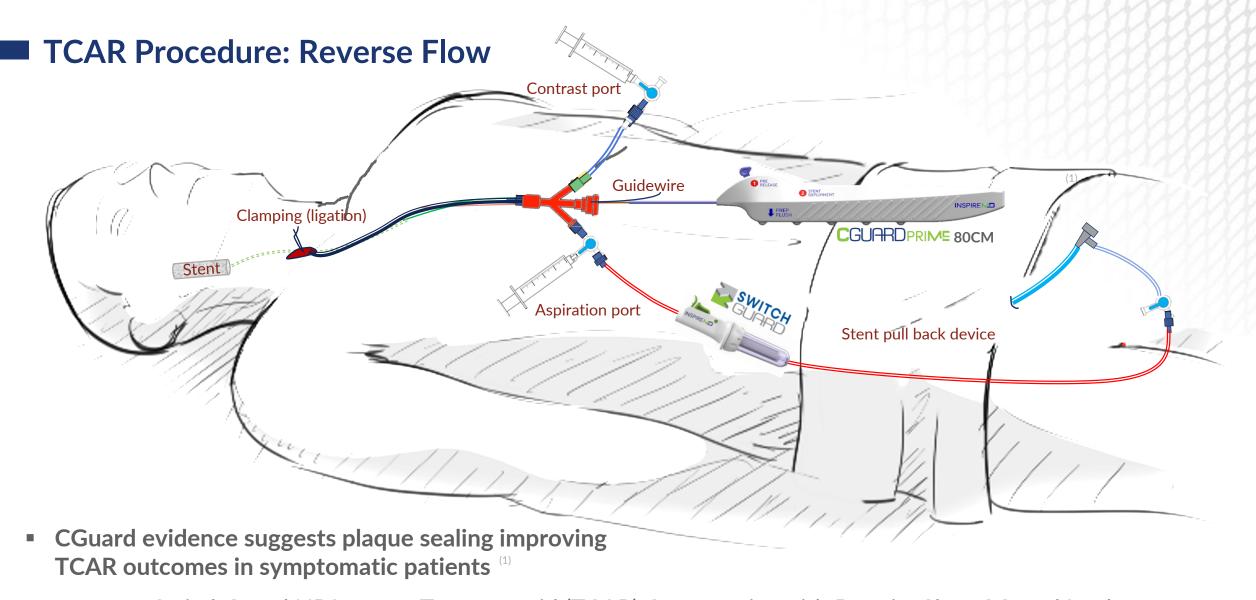
- Pivotal study objective evaluate the safety and efficacy of the CGuard™ Carotid Stent System in the treatment of carotid artery stenosis
  - Intent to Treat Protocol
  - Primary Endpoint: Symptomatic and asymptomatic patients undergoing carotid artery stenting (CAS) to a performance goal of <11.6% developed from published CAS literature. 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 Committee (CEC) adjudication or ipsilateral stroke from 31-365-day follow-up, based on CEC adjudication. The performance goal will consider to be met if the upper bound of the two-sided 95% confidence interval. calculated from the observed primary endpoint rate is <11.6% and the p-value is < 0.025.
  - In European clinical studies, CGuard data of 1.485 patients followed for one year 1.32%\*\*\*
- Chris Metzger, M.D. (Ballad Health): Primary Investigator
- 315 Patients Enrollment Complete (23 months)
- **25 Centers** (20 in the United States and 5 in Europe)
- HCC (Hart Clinical Consultants) CRO specializing in Carotid trial execution
- Christina Brennan, M.D. and Gary Roubin, M.D., PhD.: Supporting advisory experts

\*\*\* 1. IRONGUARD I EuroIntervention 2018 Nov 20. 14:1150-1152 2. IRONGUARD II 1-Year Results From a Prospective Experience on CAS Using the CGuard Stent System JACC: Cardiovascular Interventions Vol. 14, No. 17, 2021. 3. Academic Data Registry PARADIGN-EXTENDED Monitored 30 days and 12 Months Outcomes Report, Oct 24, 2022 (Prospective evaluation of All-comer percutaneous carotid revascularisation in symptomatic and increased risk asymptomatic carotid artery stenosis using CGuard MicroNet -covered embolic prevention stent system) 4. 5 Year Clinical Ultrasound Outcomes in CARENET Prospective Multicenter Trial of CGuard MicroNET Covered Stent JACC: Cardiovascular Interventions Vol. 15, No. 18, 2022 September 26, 2022:1183-1891



# **TCAR**





SwitchGuard NPS serves Trans carotid (TCAR) Opportunity with Best-in-Class CGuard Implant

<sup>1.</sup> 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



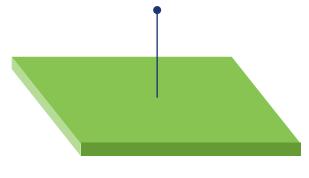
Roadmap + Milestones



#### **Our Advancement Roadmap / Milestones**

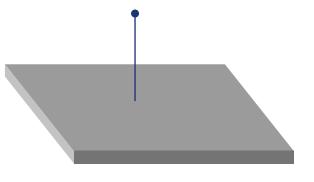
#### Our Expected Key Value Drivers and Strategic Pathways

- ✓ USA Trial Enrollment Complete
  - Inclusion of CGuard Prime
- SwitchGuard 510K clinical pre sub submission
- Acute Stroke (NGuard) EFS (early feasibility study)
- U.S. Standard Risk Reimbursement
- CGuard Prime Commercial Launch (EU)



2023

- FDA PMA Submission
- Acute Stroke (NGuard) Pivotal
- China Regulatory Submission
- NCD Reimbursement Decision
- SwitchGuard Clinical Submission

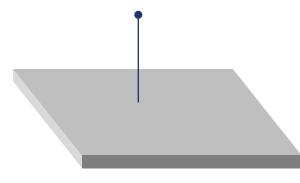


2024





- SwitchGuard (TCAR) Launch (U.S. + EU)
- U.S. Commercial Launch
- China Commercial Launch



2025







## Corporate



#### **Our Board of Directors**

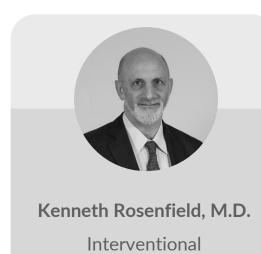
Marvin L. Slosman President and CEO	Mr. Slosman has over 30 years of experience in the medical device industry with focused leadership in commercialization and international market development in both public and privately held companies. He has had senior management roles in a variety of public and privately held companies.	<b>%</b>	Cordis.	INTEGR	IA.
Paul Stuka Chairman	Mr. Stuka was named to the Board of Directors in August of 2011 and serves as Chairman of the Board of Directors. Mr. Stuka is a Managing Member of Osiris Partners and a 30-year investment industry veteran.	(A <u>Fi</u>	delity	OSIRIS	<u> </u>
Michael Berman Director	Mr. Berman is a successful entrepreneur within the medical device industry.  He joined Scimed in 1986, leading its marketing activities until its merger with Boston Scientific in 1995. From 1995-2000, he served as President of Boston Scientific/Scimed. Venture partner in RiverVest Ventures	Velocimed	Scientif	ic LUTO	NIX.
Thomas Kester Director	Mr. Kester is CFO of Kester Search Group, Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies. He spent 28 years at KPMG LLP.	KP	MG ?	Kester Search Clear objectives. Precis	Group*
Gary Roubin, M.D.,Ph.D.  Director	Dr. Roubin was named to the board of Directors in October 2020. Dr. Roubin has co-authored more than 280 clinical publications and has contributed to 20 textbooks in the fields of Interventional Cardiology and Vascular Surgery. He was a key contributor in the CREST trial which has validated the use of carotid stents for the treatment of carotid artery stenosis.		Lenox Hi Hospital Northwe Health		
Katie Arnold	Ms. Arnold was named to the Board of Directors in May 2021. Ms. Arnold founded and leads SPRIG Consulting, providing the entire spectrum of strategic marketing services to medical companies. Ms. Arnold is currently an adjunct professor at	Kensey Na	ash SPF	RIg" □	UIDANT

Northwestern University's Kellogg School of Business, where she teaches medical product commercialization and financing.



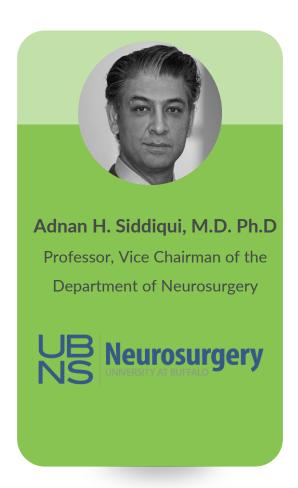
Director

## Scientific Advisory Board (Multidisciplinary KOLs)



Mass
General
Brigham

Cardiologist



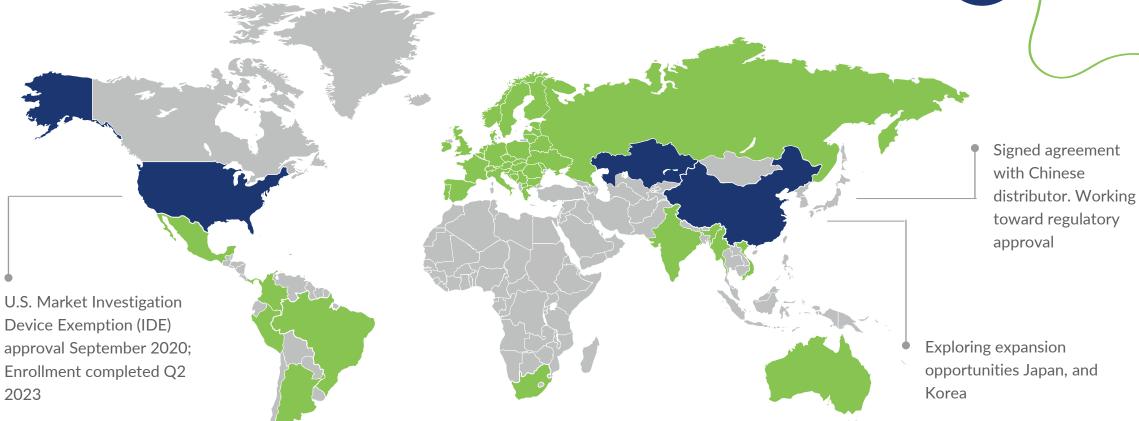




# **Commercial CGuard Footprint**

- Active selling CGuard in more than 30 countries
- Over 40K stents sold to date







Current Markets

Registration Work Underway

Company and Products Overview

#### **Our Robust Intellectual Property Portfolio**

Proprietary platform technology supported by IP

Patent Rights	Issued	Pending
USA	16	6
Rest of World	42	11

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

IP Counsel: Kligler and Associates, P.A.



## **Summary Financials**

June 23, 2023

NASDAQ Capital Markets	NSPR
Stock Price	\$2.14
Average 3 Month Volume	98.7K
Shares Outstanding	21.2M
Shares Outstanding with Prefunded Warrants	36.8M
Market Capitalization with Prefunded Warrants	\$78.8M
Cash Balance - March 31, 2023*	\$12.9M
Debt	\$0M

<sup>\*</sup> Post financing May 2023 cash balance as of May 21, 2023 is approximately \$48.2 million



