

InspireMD

James Barry, Ph.D. President and CEO | November 2019

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About InspireMD

InspireMD is a commercial-stage medical device company focused on stroke prevention for patients with carotid artery disease and other vascular diseases utilizing an integrated embolic protection technology

COMPANY

NYSE AMER: NSPR

Employees: 46

Headquarters: Tel Aviv

Manufacturing Facility: Tel Aviv

Commercial and Germany

Clinical Employees: UK

Spain

Israel



PRODUCTS

Commercial: CGuard™ EPS

(Carotid)

MGuard™ EPS

(Coronary)

CGuard™ EPS USA Pipeline:

Next Gen CGuard™

PVGuard™ (Peripheral)

NGuard[™] (Neuro)



Company Highlights

CGuard™ EPS	Enabling a paradigm shift (CAS) in the treatment of carotid artery disease and stroke prevention Breakthrough platform: Highly differentiated, with strong support from leading clinicians MicroNet TM technology that is elegantly simple, propriety and easily leveraged to other medical devices
Benefits demonstrated in multiple trials	Clinical Evidence / Data Driven: 7 completed and 4 ongoing clinical trials Differentiation versus conventional carotid stents and surgery Outcomes based: No device related major adverse events. No major strokes Sustainable results: Long term benefit reported in all-comer population
Commercial Growth	Expanding Existing Footprint: Deeper penetration within key markets Results: 2018 CGuard™ EPS sales increased 55% YoY Commercial Model Development: Evaluating opportunities to go direct in key markets
1B Global Market Opportunity	Expansion into OUS Markets: Near Term: Brazil; Strategic Partners Discussions in Japan and China United States: IDE FDA submission for CGuard™ EPS July 2019 Additional request from FDA for information in support of application August 2019 Working closely with FDA to resolve additional requests for information Critical step in commencing human trial in the USA
Capital Structure	Recapitalized the company to clean up the capital structure and prepare for growth Capital use focused on commercial execution, IDE and pipeline
Pipeline and Strategic Opportunities	Leverage MicroNet TM into other pipeline opportunities in neurovascular and peripheral vascular diseases Proactively seek synergistic product opportunities Add BD resources to effectively assess inbound queries and implement a more focused and proactive BD strategy.

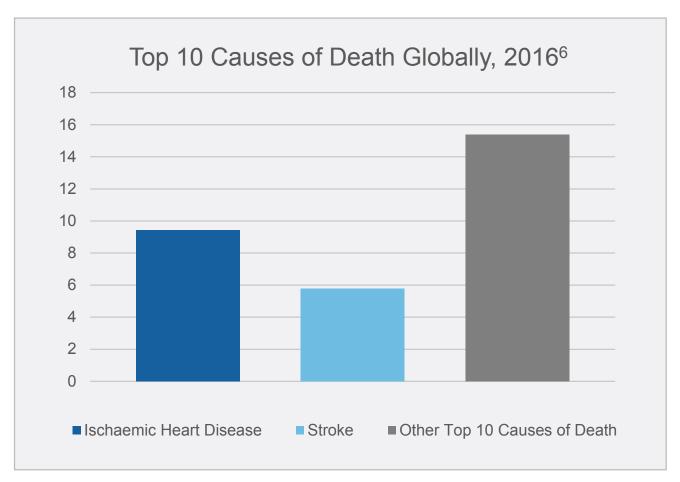




Stroke is the Second Biggest Cause of Death

An estimated 15 million people suffer from stroke annually³

- 6.2 million deaths¹
- 5 million people left permanently disabled³
- \$34 billion associated with stroke management in the US alone²
- ~ 85% of all strokes are ischemic strokes, which result from a lack of blood flow to the brain⁴
- Carotid artery disease (CAD) is a major risk factor for stroke
- Approximately 20% of all ischemic strokes are estimated to be caused by CAD (2.2-2.4 million)⁵





¹ https://www.worldstrokecampaign.org/learn/facts-and-figures.html

² Center For Disease Control and Prevention – Stroke Facts – 2017

http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html

⁴ State of the Nation Stroke statistics - January 2016

September 2019 I 5 5 https://www.nejm.org/doi/full/10.1056/nejm200006083422302

⁶ https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

Unmet Need: A Safer Technology for Stroke Prevention in CAD

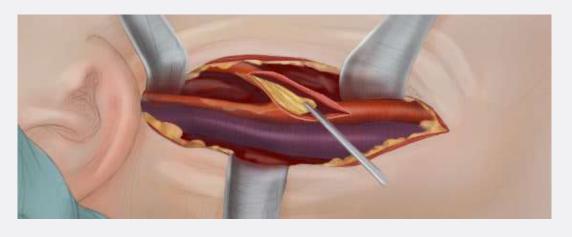
Surgery vs. Carotid Artery Stenting

Carotid Endarterectomy (CEA)

"Gold standard"¹, but...

Invasive; risk of surgical complications

- Myocardial Infarction¹
- Risk of cranial nerve injury²
- Esthetic concern



Filter Protected Stenting (CAS)

Patient friendly, long-term durability¹,

Non-Invasive; risk of complications

- Procedural minor stroke risk (with conventional stents)¹
- Post-procedural minor stroke risk (with conventional stents)¹



Based on the CREST clinical trial data, in which only conventional carotid stents were used vs.surgery



Current Treatments for Carotid Artery Disease

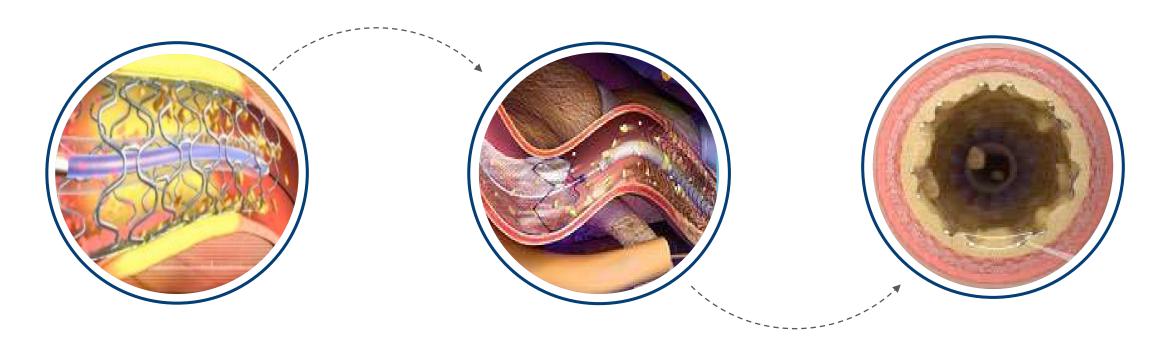
Surgery (Carotid Endardarectomy) (CEA) vs. Conventional Carotid Stents (CAS)

			Periprocedural Period	N Engl J Med 2	010;363:11-23
CREST	CAS (N=1262)	CEA (N = 1240)	Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patie	nts (% ±SE)	percentage points		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (-0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (-0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (-0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	-1.1 (-2.2 to -0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	28 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (-0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or post- procedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (-1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38



Embolization Following Carotid Artery Stenting

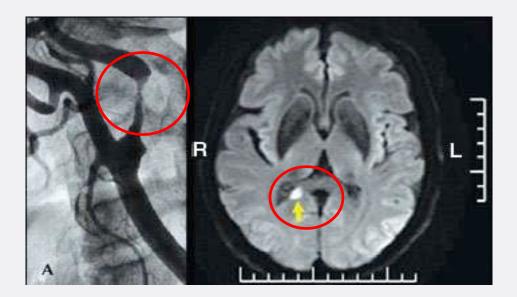
Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents, depending on plaque morphology/symptomatic status and stent type. The consequence is cerebral embolization, either directly or via additional thrombus formation.



2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

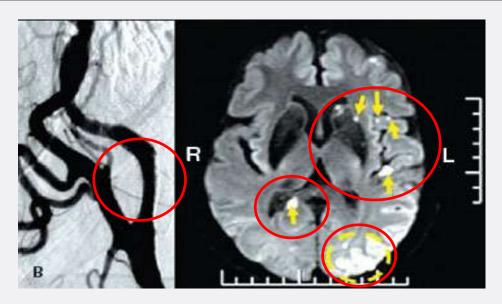
Consequences Range from Neurological Deficit to Stroke

Pre-Procedure



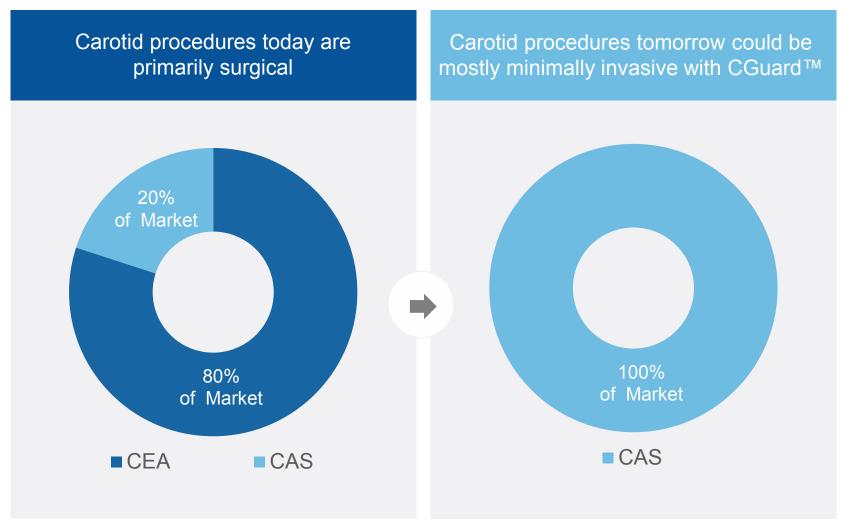
Pre-intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction).

Post-Procedure



Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) postprocedure due to liberation of embolic particles.

A Billion Dollar Market Opportunity

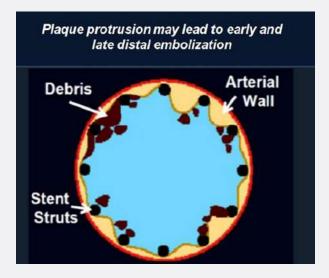


- 2.2M diagnosed with carotid artery disease
- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD
- At present, ~80% are surgically treated with carotid endarderectomy (CEA)
- At a price of \$1,650 per stent, the addressable market is estimated to be more than \$1 billion

MicroNet[™] covered stents could become the Gold Standard

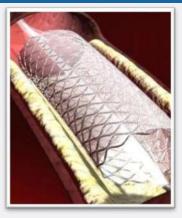
The InspireMD Solution: CGuard™ EPS

Conventional Carotid Stent



Carotid plaque can protrude through the stent struts

CGuard™ EPS





- The MicroNetTM **permanently covers** plaque and stops "debris" from passing through the mesh.
- Ultrathin PET mesh made of a single 20 micron fibre from a biocompatible polymer - widely used in other medical implants
- MicroNet[™] acts as a "safety net" with greater vessel area coverage to prevent plaque protrusion through the stent into the blood vessel

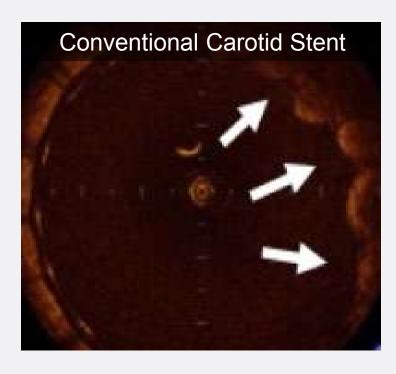
CGuard™ EPS has been shown to prevent embolic debris passing into the carotid artery and traveling to the brain



The InspireMD Solution: CGuard™ EPS

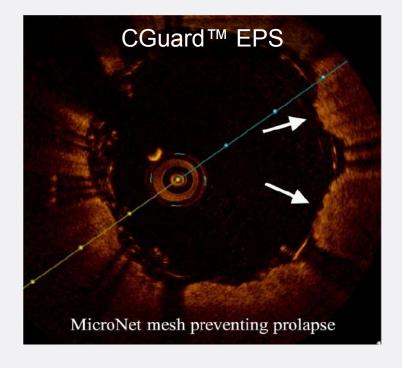
Conventional Carotid Stents ¹

No plaque coverage - leading to plaque protrusions or prolapse passing into the vessel lumen



CGuard™ EPS²

The MicroNetTM permanently covers plaque and prevents "debris" from passing through the mesh.





Positive CGuard™ EPS Clinical Experience

CARENET Clinical Trial (2014)

30 Patient Safety and Efficacy clinical trial

Zero major adverse cardiac or cerebral events (MACCE) at 30 days (Comparative data 5.72%*)

50% fewer new ischemic lesions with lesion volume being 10x times smaller compared to historical non-mesh carotid artery stenting data

All new ischemic lesions fully resolved at 30 days except one

3.6% MACCE rate at 6 months (Comparative data 8.09%**)

Zero strokes or stroke related deaths at 12 months

PARADIGM 101 and PARADIGM Extend Clinical Trials (2015, 2016, 2018, and 2019)

402 patients, 436 devices ongoing registry evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)

99.1% device success in PARADIGM 101

0% major stroke @ 30 days (0-402) <1% any stroke (minor), death or myocardial infarction (4/402)

0 strokes from 30 days to 1 year (n=311)

0 ipsilateral (device related) strokes from 30 days to 2 years (n=205)

1 ipsilateral stroke at 3 years (1/108)

1 ipsilateral stroke at 4 years (1/61)

1 case of instent restenosis at 1 year (1/106)



"CGuard can safely be used on more than 90% of all-comer patients that have carotid artery stenosis."

- P. Musialek, MD



* Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVERIC 1+2, MAVERIC International, PRIAMUS, SAPPHIRE. SECURITY. PROFI. ICSS

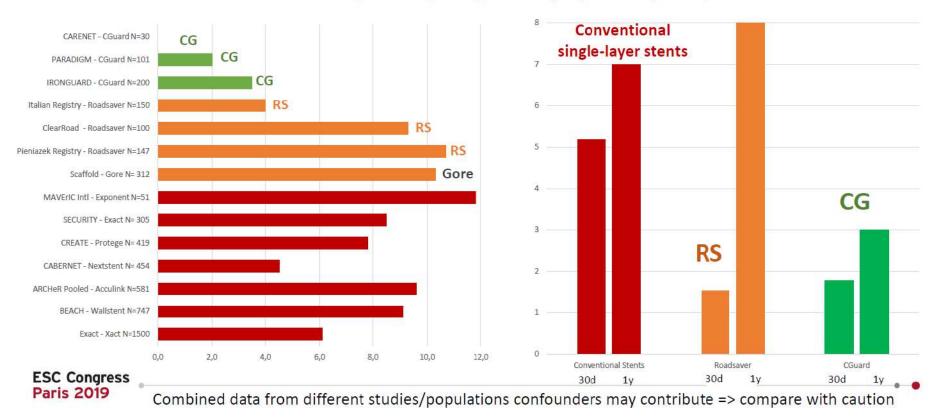
Values extrapolated from event curves

*** Musialek, Presentation at the 2019 Joint Congress of the World Heart Federation and the European Society of Cardiology, Paris FR

Analysis of Published Carotid Stent Trial Data

Comparative analysis of the carotid stent data available in public domains (journal publications plus congress presentations published on-line)

Cumulative Incidence of Death/Stroke/MI @ 30 days plus 1-year ipislateral stroke rate



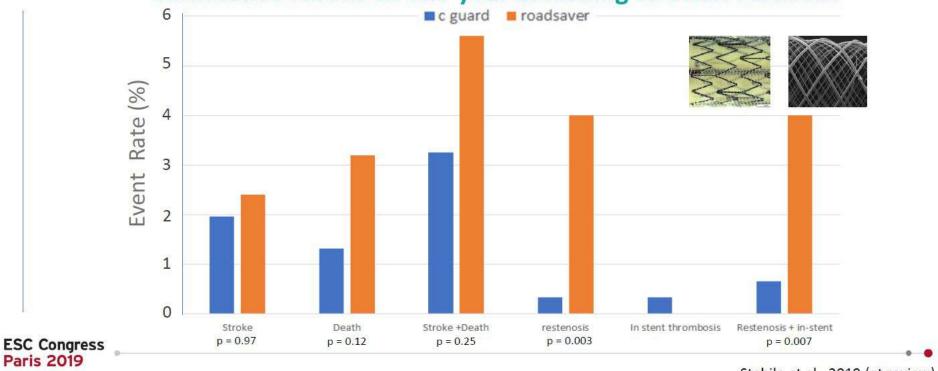


Analysis of Published Next Generation Carotid Device Trial Data*

Patient-level meta-analysis 556 patients / 4 trials (both symptomatic and asymptomatic) **

Dual-layer stents 1-year data



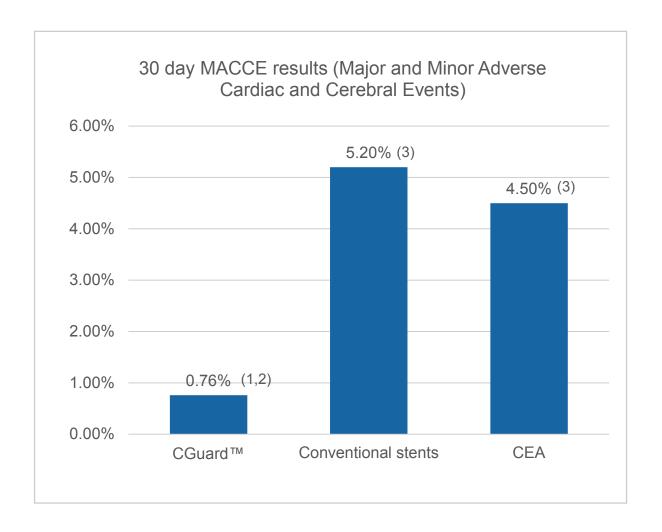






CGuard™ EPS vs Conventional Stents and Surgery

- CGuard[™] EPS has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
- 7 completed clinical trials and 4 ongoing trials





A Leading Vascular Surgeon's View



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"The CGuard™, in comparison to other [carotid] stents, even in comparison to other mesh covered stents, is a very easy to use device. Very simple, you take it off the shelf and you use it and that's it."

"Patient risks associated with stenting using CGuard™ are far lower than those associated with CEA or with other types of carotid stents.

"CGuard™ will become a major factor in preventing strokes caused by carotid artery disease."

"With CGuard™ we can get excellent results, probably better than open surgery, the Gold Standard"



Commercial Strategy

Transition current users of carotid stents to CGuard™ **EPS**

Continued communication of CGuard™ EPS clinical data

Continue to support investigator initiated clinical registries

Continue to develop network of KOLs, broaden centers of excellence to multiple clinical disciplines

Transition Vascular Surgeons to CGuard™

Advisory boards, surgeon specific clinical registries, centers of excellence

Publish, present, and communicate data demonstrating that CGuard™ is as safe as CEA

Establish a presence at major vascular surgery meetings

Expand digital, social and other tools to more effectively communicate

Expand footprint in existing geographical areas

Focus limited resources on larger markets with highest opportunities - Germany, Italy, Spain, Poland

Support regional clinical and clinical specialty registries to build on the clinical database and broaden support

Evaluating further market growth via direct sales in key regional markets

Continue geographical expansion where strategically relevant

Ongoing discussions with partners to bring CGuard To Japan and China

Obtain US IDE approval



CGuard™ EPS Product Development

US FDA

- IDE FDA submission for CGuard™ EPS July 2019
- Additional request from FDA for information in support of application August 2019
- Working closely with FDA to resolve additional requests for information
- Critical step in commencing human trial in the USA

Innovative Pipeline Developments

- CGuard continuous improvements (including COGS)
- Peripheral vascular products
- Neurovascular

Evaluating external opportunities

- Proactively evaluating synergistic opportunities to further broaden the product portfolio and take advantage of the global distribution network that has been developed
- Add BD resources to effectively assess inbound queries and implement a more focused and proactive BD strategy



Addressable Stroke Prevention Device Market











13mn people globally with high grade carotid stenosis (HGS)

2.2mn people with HGS diagnosed

~600,000 received surgical/stent treatment

Untapped market: At least 1.6mn patients could be helped by CGuard EPS

Plus roughly 10mn people who are undiagnosed

2017: ~600,000 patients with high grade carotid stenosis (HGS) require interventions for CAD. At present, ~80% are surgically treated with carotid endarterectomy (CEA)

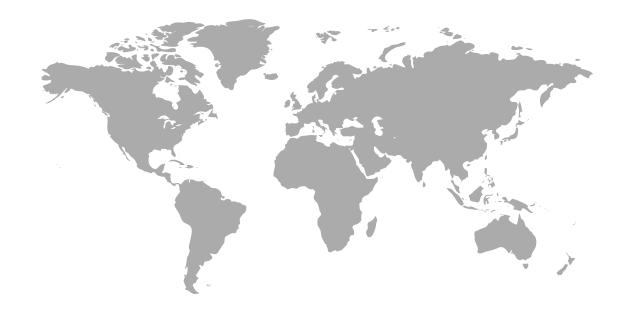
The balance are treated with conventional carotid stents (CAS) with an average of 1.05 stents/procedure

At a price of \$1,650 per stent, the addressable market is estimated to be more than \$1 billion



Intellectual Property Portfolio

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	13	2	6
Rest of World	47	0	19



Proprietary platform technology supported by a robust intellectual property portfolio

Continue to strengthen and broaden patent protection globally to enable future pipeline products



Leadership

Significant track records of success

James Barry, Ph.D. President and CEO	Scientific Pfizer
Craig Shore CFO	Pfizer & Bristol-Myers Squilbb
Paul Stuka Chairman	OSIRIS Fidelity.
Michael Berman Director	Scientific Science LUTONIX
Campbell Rogers, M.D. Director	HARVARD **Globassia-Goldssian company** HARVARD MEDICAL SCHOOL
Thomas Kester Director	Kester Search Group® Clear objectives. Precise solutions.
Sol Barer, Ph.D. Special Advisor to the Board	Celgene TEVA PHARMACEUTICAL INDUSTRIES LTD.



Summary Financials

NYSE AMERICAN	NSPR
Stock Price (10/31/19):	\$1.13
Average last month daily trading volume:	242 K
Shares outstanding (10/31/19):	3.6 M
Shares outstanding including full conversion of preferred shares and prefunded warrants (10/31/19):	4.9 M
Market capitalization including full conversion of preferred shares and prefunded warrants (10/31/19):	\$5.5 M
Cash (9/30/19):	\$7.2 M



Summary



Focused on the deadly and catastrophic problem of stroke that is estimated to cost the healthcare system more than \$34BB annually in the US alone



The current addressable market for CGuard TM EPS is estimated to be \$1BB with the potential to further expand into the 1.6MM patient population which is diagnosed but not treated



Currently, vascular surgeons treat the majority of patients with carotid artery disease: Focus will be on converting the vascular surgeons to use CGuard™ EPS



Strong and consistent clinical data continues to validate the safety profile of CGuardTM EPS even in a large "all comer" patient population with data indicating sustained benefit out to 3 years



Increasingly more presentations and live clinical cases with CGuardTM EPS are featured at major and regional clinical conferences



Following the sterilizer event in Q1, company made a solid recovery and has returned to normal operations



Increased focus, positive large clinical trials and significant investment in minimally invasive treatment of carotid artery disease is creating a tailwind for CGuard™ EPS



Product pipeline to support continued growth in all geographies, including the United States



