

# INSPIREMD, INC.

## FORM FWP

(Free Writing Prospectus - Filing under Securities Act Rules 163/433)

Filed 06/07/16

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

Issuer Free Writing Prospectus  
Filed Pursuant to Rule 433 of  
the Securities Act of 1933, as amended  
Registration Statement No. 333-210760



NYSE MKT: NSPR

June 2016

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# Forward Looking Statements

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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. 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 payers 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.

# Free Writing Prospectus

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This presentation highlights basic information about InspireMD, Inc. and the offering. InspireMD, Inc. has filed a registration statement on Form S-1 (Registration No. 333-210760) (including a prospectus) with the U.S. Securities and Exchange Commission (the “SEC”) for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including, among other things, risk factors described therein) and other documents the issuer has filed with the SEC for more complete information about InspireMD, Inc. and this offering. The preliminary prospectus dated April 14, 2016, and subsequent amendments are available at the SEC website. You may get these documents for free by visiting EDGAR on the SEC website at [www.sec.gov](http://www.sec.gov). Alternatively, InspireMD, Inc. or any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it by contacting Dawson James Securities, Inc., Attention: Prospectus Department, 1 North Federal Highway, 5th Floor, Boca Raton, FL 33432, [mmaclaren@dawsonjames.com](mailto:mmaclaren@dawsonjames.com) or toll free at 866.928.0928.

*Pioneering fully integrated embolic prevention systems and other advanced medical technology for vascular procedures*

## NYSE MKT: NSPR

<b>Stock Price (5/31/16):</b>	\$0.465
<b>52 Week Range:</b>	\$0.32-\$4.20
<b>Average Volume:</b>	89K
<b>Shares Outstanding (5/31/16):</b>	10.7 M
<b>Market Capitalization (5/31/16):</b>	\$4.98 M
<b>Analyst Coverage:</b>	H.C. Wainwright: Yi Chen Dawson James: Sherry Grisewood Empire Asset Management: Cathy Reese
<b>Total Cash (3/31/16):</b>	\$2.0 M
<b>US Headquarters:</b>	Boston, MA
<b>International Headquarters:</b>	Tel Aviv, Israel
<b># of Employees (5/31/2016):</b>	33



# Investment Highlights



*Focused on commercial execution of CGuard™ EPS and development of pipeline products*

- 2016 focus on revenue growth driven by a broader EU launch of **CGuard**
  - Strategic distribution partnership with Penumbra (NYSE:PEN)
  - Significant growth in Italy over the last 3 quarters serving as a leading indicator
  - Positive clinical trial results using CGuard in a broad patient population, including high risk patients
- Advancing into the growing neurovascular and peripheral vascular markets
  - 2017E CE Mark Submission for **NVGuard™** flow diverter for treatment of cerebral vascular aneurysms enabling EU commercialization post approval
- A broad portfolio of assets supported by aggressive pursuit of intellectual property protection
- Well positioned for strategic collaboration on multiple **MicroNet™** product applications
- Continued financial discipline in line with development and growth initiatives

# The Problem

*Embolization can lead to catastrophic health events*

THE WALL STREET JOURNAL. U.S.

U.S. NEWS

## Stents Boost Stroke Recovery, Study Finds

Using Devices to Pull Clots From Brain Arteries Can Help Patients

By THOMAS M. BURTON

Using a device to extract blood clots from brain arteries can significantly improve patients' ability to rebound from a stroke, according to a landmark study published Wednesday.



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REPORTERS FILE

### Precious Hours, Then Lives, Lost in Stroke's Wake



Well Time Parker-Pope on Health

Genes Tell Only Part of the Story

February 16, 2015

When Grief Won't Relent

February 16, 2015

Not Your Bubbe's Kasia

February 13, 2015

Ask Well: Put on the Snowshoes

February 13, 2015

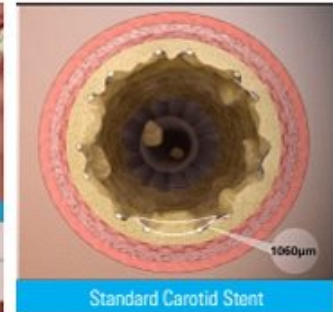
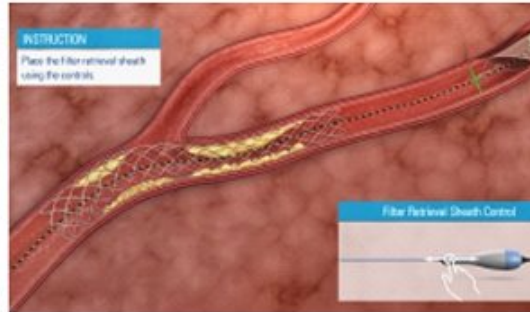
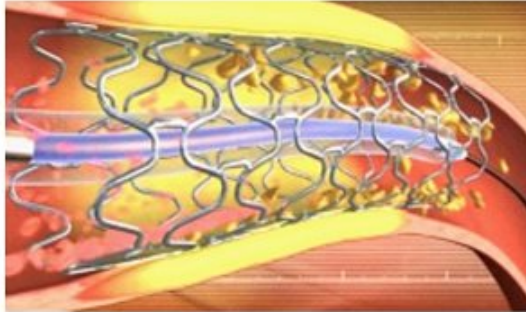
Think Like a Doctor: Swept Off Her Feet Solved

February 12, 2015

The IBM Cloud

# Embolization following Carotid Artery Stenting **InspireMD**

***“Plaque protrusion through stent struts occurs in up to 65.5% of conventional carotid stents in relation to plaque morphology/symptomatic status and stent type, providing a **mechanism for** post carotid artery stenting (CAS) **cerebral embolization**, either directly or via additional thrombus formation. <sup>\*</sup>”***



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

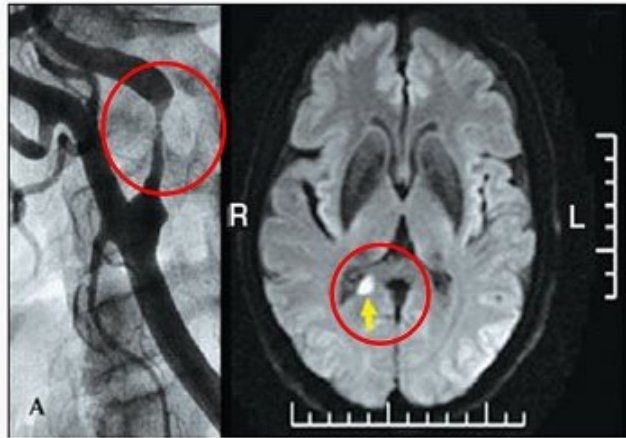
\* Musialek, et.al. Eurointerventions 2016;12 published online ahead of print May 2016

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



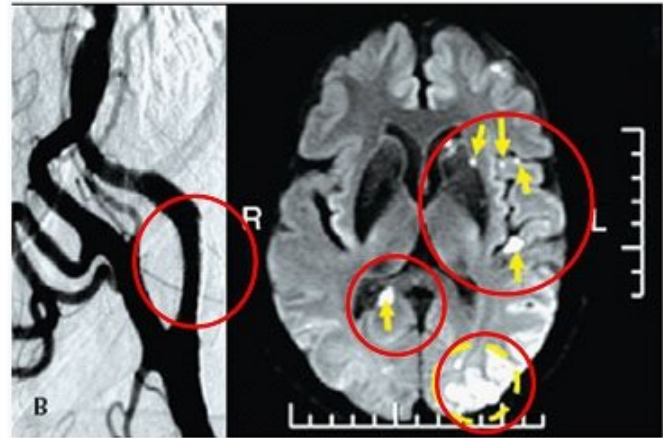
# The Consequences

*Range from neurological deficit to stroke to death*



Pre-Procedure

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



Post-Procedure

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

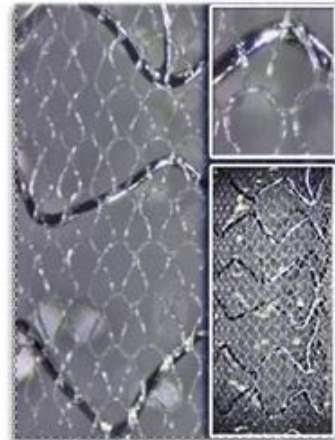
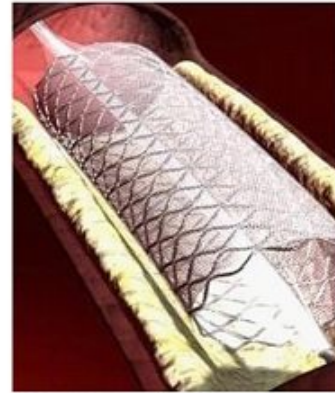
# MicroNet™



*Proprietary technology for preventing distal embolization and other vascular disease challenges*

*Ultrathin PET\* mesh provides meaningful clinical benefit to conventional devices*

- Provides revascularization benefit
- MicroNet acts as "safety net" by offering greater vessel area coverage to prevent large debris flow through the scaffold
- Made of a single fiber from a biocompatible polymer, widely used in other medical implants

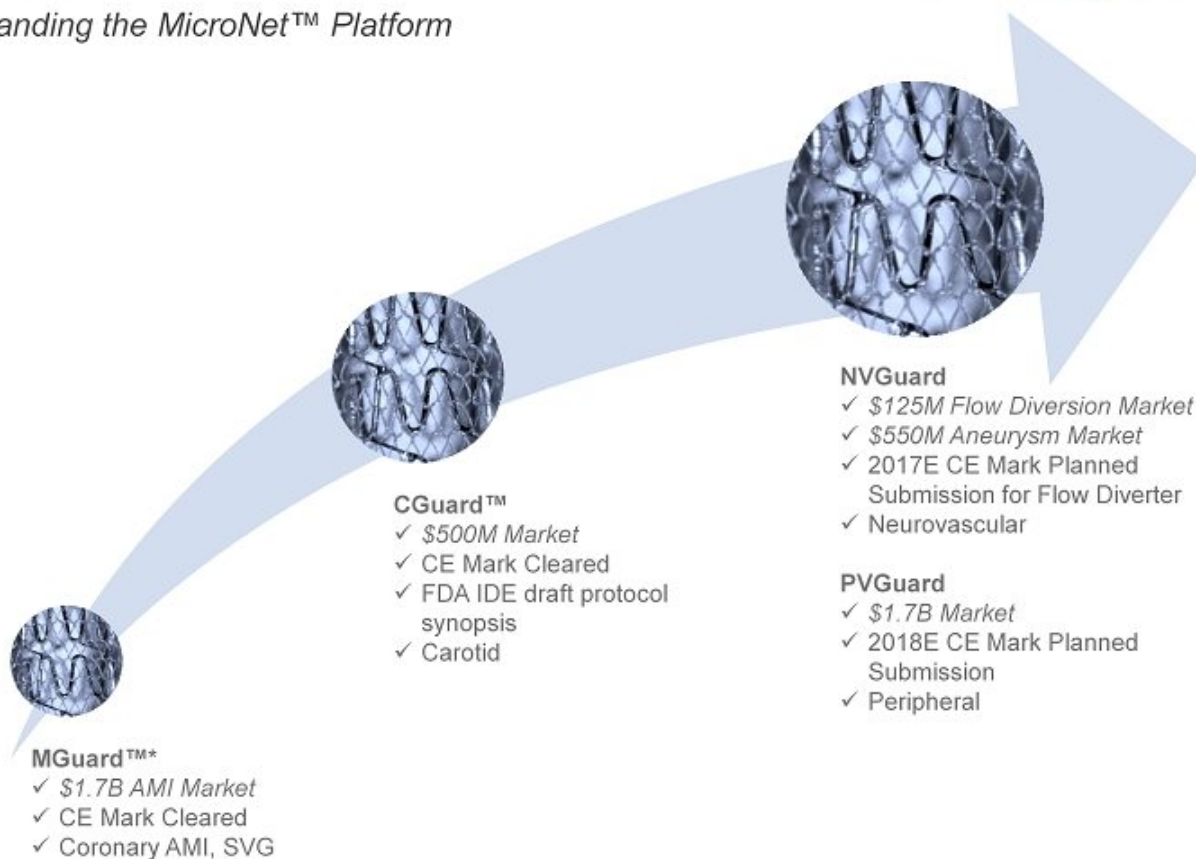


\*PET – polyethylene terephthalate

# Large Addressable Market



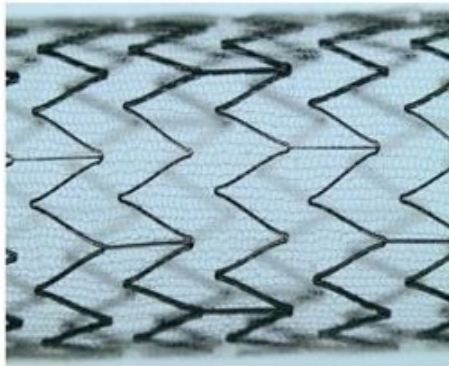
Expanding the MicroNet™ Platform



\* MGuard is a bare metal stent scaffold

### **CGuard™ Embolic Prevention System(EPS)**

*Combines stent and embolic protection in a single device*



- CE marked
- Self-expanding nitinol stent
- Global market valued at \$500M\*
- Positive CARENET data released 9/14, 1/15 and 5/16 documenting the safety and patency of the CGuard EPS
- Positive all-comer data from PARADIGM trials presented 5/15 and 5/16 documenting the safety and benefits of the CGuard EPS
- Ongoing launch in Europe, Latin America, South America, & other regions

\*Source: JMP Securities, 2014 and Cowen 2014.



# Positive CGuard™ Clinical Experience



## CARENET Clinical Trial

- 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 full 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 Clinical Trial

101 patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)

- **99.1% device success**
- **0% MACCE (Death/stroke/MI) @ 48 hr**
- **0% MACCE @ 30 day** as determined by independent neurological and angiographic evaluation



*"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

# Carotid Market Opportunity



## *"Game Changing" Minimally Invasive Solution*

- Current standard of care: Surgery
  - Carotid Endarterectomy (CEA)
- The risk of post-procedural cerebral events has been related to [conventional] carotid stents.<sup>1</sup>
  - Higher risks of stroke at 10 years appear to be attributable to the peri-procedural differences in risk.<sup>2</sup>
  - Mesh-covered carotid stents may lower the rates of peri-procedural stroke.<sup>2</sup>
- CGuard™ clinical studies have demonstrated superior safety
  - CARENET
  - PARADIGM
  - PARADIGM 101
- Immediate EU commercial opportunity (non-US)
  - EU pursued via new strategic partner Penumbra
  - Europe, Latin America and other regions are covered by experienced distributors
  - U.S. development and clinical plan to follow



<sup>1</sup> Musialek, EuroIntervention 2016;12 online publish ahead of print May 2016

<sup>2</sup> Brott, T. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis, New England Journal of Medicine, March 17, 2016

# Strategic Distribution Partnership

*Broad European commercialization support from a growing neurovascular leader*



- Distribution agreement with Penumbra
- 18 European markets with opportunity to expand
- Comprehensive neurovascular product portfolio
- CGuard is a synergistic product offering
- Growing direct sales force throughout Europe
- Establishing a direct sales force focused on peripheral vascular
- Successful IPO in September 2015



# CGuard Distribution (EU)



	Sales Channel							
		Q115	Q215	Q315	Q415	Q116	Q216 E	Q316 E
UK	P			OLT	HOC	HOC	IND	
France	P			OLT	HOC	HOC	IND	
Belgium	P			OLT	HOC		IND	
Netherlands	P			OLT		HOC	IND	
Luxemburg	P			OLT		HOC	IND	
Norway	P			OLT			HOC	IND
Sweden	P			OLT			HOC	IND
Denmark	P			OLT			HOC	IND
Finland	P			OLT			HOC	IND
Germany	P					OLT	HOC	IND
Austria	P					OLT	HOC	IND
Switzerland	P					OLT	HOC	IND
Portugal	P			OLT	HOC	IND		
Poland	P			OLT	HOC	IND		
Latvia	P			OLT		HOC	IND	
Lithuania	P			OLT		HOC	IND	
Estonia	P			OLT		HOC	IND	
Italy	CK	OLT	HOC	IND				
Israel	IN	OLT	HOC	IND				

NOTE: (P) Penumbra, CK (Crossmed/Kaster), IZ (Izasa), IN (InspireMD/Distributor)

OLT

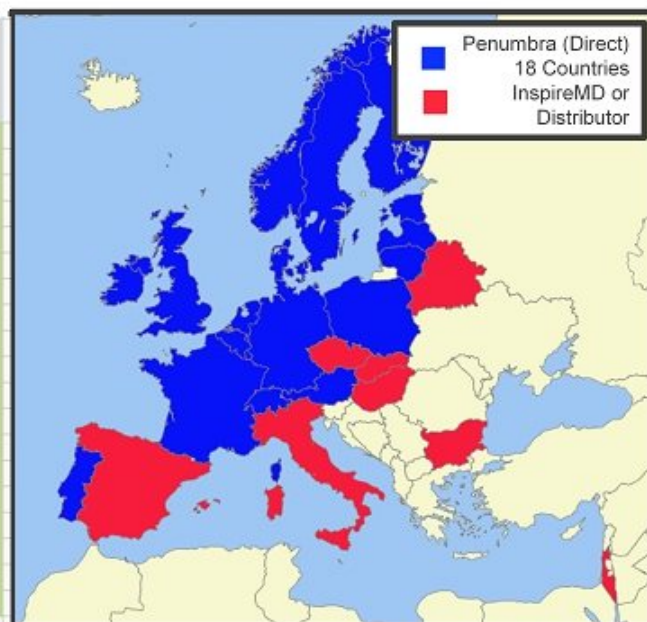
Online Training

HOC

•Hands On Training  
•Case Observation

IND

Independent





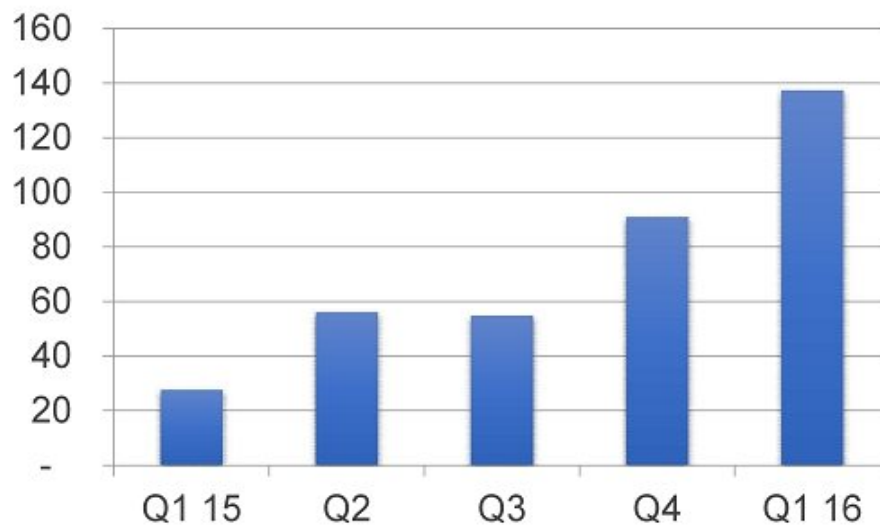
# CGuard™ Country Case Study



*Italy – A leading indicator of CGuard Growth*

- CGuard covered by 2 distributors
- Initial success drove 29 Italian carotid interventionalists to initiate the IRON-Guard\* registry last year

## Italy CGuard Revenue

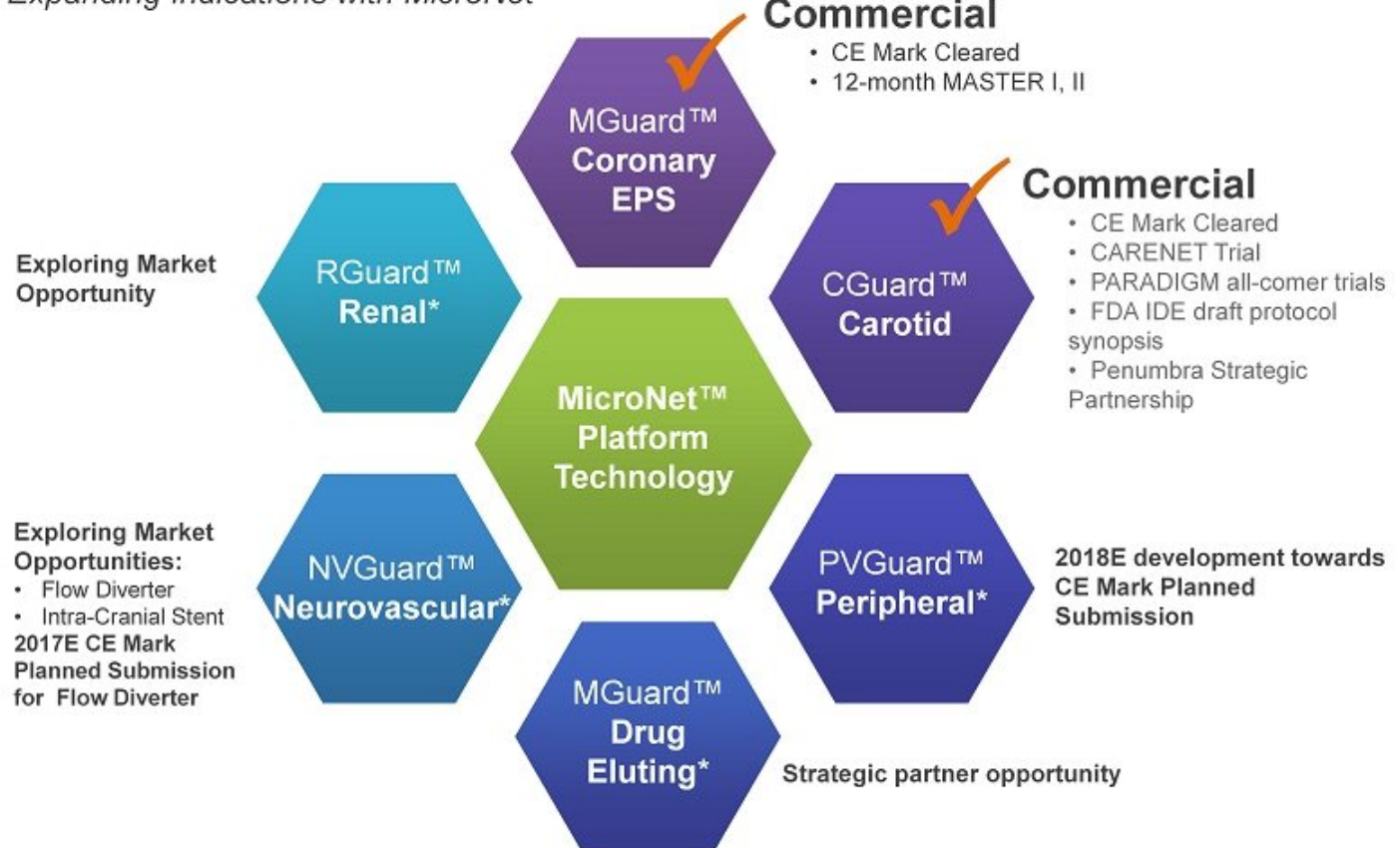


\*Setacci, et. al., J Cardiovasc Surg. 2015 May 21

Note: Revenue in \$000's

# Robust Pipeline

Expanding Indications with MicroNet™

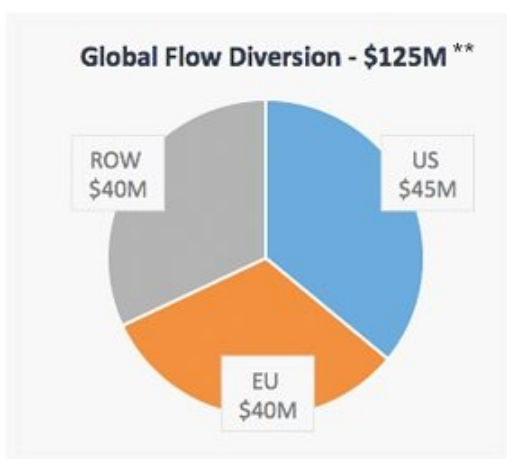


*Innovation leads growth*

## Flow Diversion For Unruptured Brain Aneurysms

*Next Generation Technology*

- Aneurysm Therapy (all types): \$550M\*
- Flow diverters are estimated to be 25% of the aneurysm market
- Neurovascular products: estimated 15% CAGR from 2010-2016



2014 Competitive Landscape: Relatively Fewer Players		
Product	Company	Approval
Pipeline	Medtronic/Covidien	CE Mark 2014 FDA 2011
Surpass	Stryker	CE Mark 2010
Silk	Balt Extrusion	CE Mark 2008

\* 2013 MRG Neuro Report, 2010 Ev3 Revenue Data

\*\* 2014 projection based on 2013 actuals

# Neurovascular Aneurysms

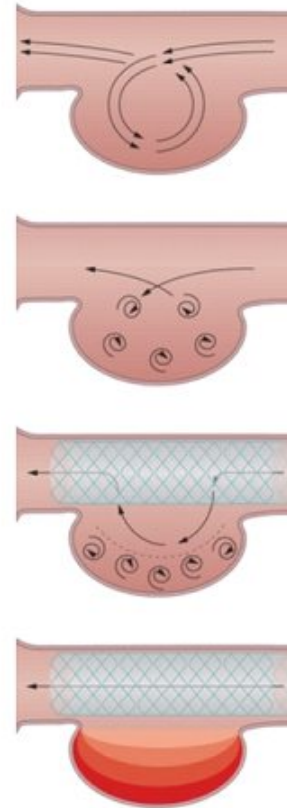
## *Flow Diversion*

### Objective

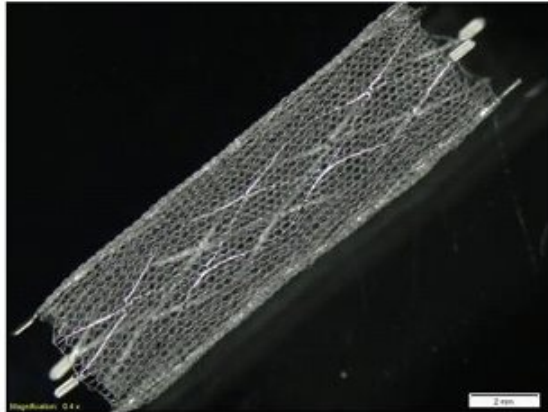
- Seal the aneurysm and prevent rupture

### Current device therapies

- **Coils** to pack the aneurysm
- **Flow diverters**
  - Highly flexible, dense metal “tube”
  - Placed in main artery to seal off aneurysm and cause aneurysm thrombosis
  - Precise delivery required to avoid blocking other vessels







- Low profile, flexible, open cell scaffold = Easy to delivery
- Low metal ratio = Potential for reduced anti-thrombosis medication
- Re-accessible through MicroNet™ = Allows for further treatment, if needed which is impossible with current flow diverters
- Can be placed in side branches and bifurcations = Will not block blood flow into major side vessels, which is impossible with current technology
- Published success with MicroNet in coronary and carotid aneurysms

PATENT RIGHTS	Issued	Allowed	Pending
US	4	0	11
Rest of World (ROW)	16	0	13

*Continue to strengthen and broaden patent protection globally. Progress over the last year imparts important rights on existing products and technologies and will enable future pipeline products.*

# Leadership



*Significant Track Records of Success*

## EXECUTIVE TEAM

**Dr. James Barry, President and CEO**

- Boston Scientific
- Howmedica Division of Pfizer

**Craig Shore, CFO**

- Pfizer
- General Electric

**David Blossom, VP Global Marketing & Strategy**

- Boston Scientific
- Covidien

## BOARD OF DIRECTORS

**Dr. Sol Barer, Chairman**

- Former Chairman and CEO, Celgene

**Isaac Blech, Vice Chairman**

- Private financier in the life science industries

**Dr. James Barry, President, CEO and Director**

- SVP Corporate Technology Development at Boston Scientific
- Howmedica Division of Pfizer

**Michael Berman**

- Pres. Boston Scientific/Scimed
- Founder, Velocimed
- Director Lutonix

**Paul Stuka**

- Founder, Osiris
- Fidelity Management and Research

**Dr. Campbell Rogers**

- CMO, Heartflow
- CSO, Cordis/JNJ
- Associate Professor, Harvard School of Medicine

# Use of Proceeds

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- Commercial Execution of CGuard™ and MGuard™ EPS
- Development of NVGuard™ Flow Diverter through CE submission
- Working Capital
- General Corporate Purposes



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