INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 08/10/16 for the Period Ending 08/10/16

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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): August 10, 2016

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 305-2410

(Former name or former address, if changed since last report)

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))

Item 7.01 Regulation FD Disclosure.

InspireMD, Inc. (the "Company") intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and other conferences a slide presentation, which is attached hereto as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Slide Presentation of InspireMD, Inc. dated August 2016

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

InspireMD, Inc.

Date: August 10, 2016

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

NYSE MKT: NSPR

August 2016

InspireMD

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

NYSE MKT: **NSPR**

Stock Price (8/5/16):	$0.19
52 Week Range:	$0.17-$2.5
Average Volume:	1.1 M
Shares Outstanding (8/5/16):	29.6 M
Shares Outstanding Including Future Pref. Stock Conv. (8/5/16):	90.3 M
Market Capitalization (8/5/16):	$17.2 M
Analyst Coverage:	H.C. Wainwright: Yi Chen Empire Asset Management: Cathy Reese
Total Cash (6/30/16):	$0.9 M
US Headquarters:	Boston, MA
International Headquarters:	Tel Aviv, Israel
# of Employees (8/5/2016):	32

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 **NGuard™** 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

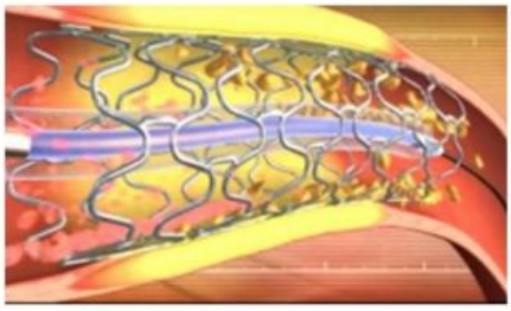
By THOMAS M. BURTON

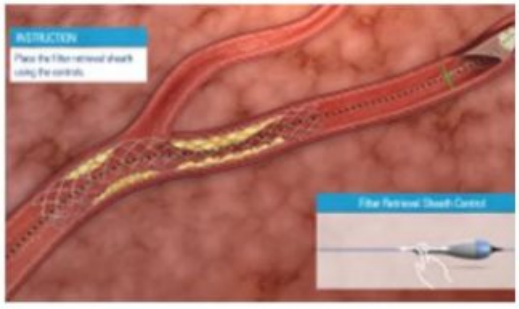
Using a device to extract blood clots from brain arteries can significantly improve patients' ability to rebound from a stroke, according to a landmark study published Wednesday.

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.*"*



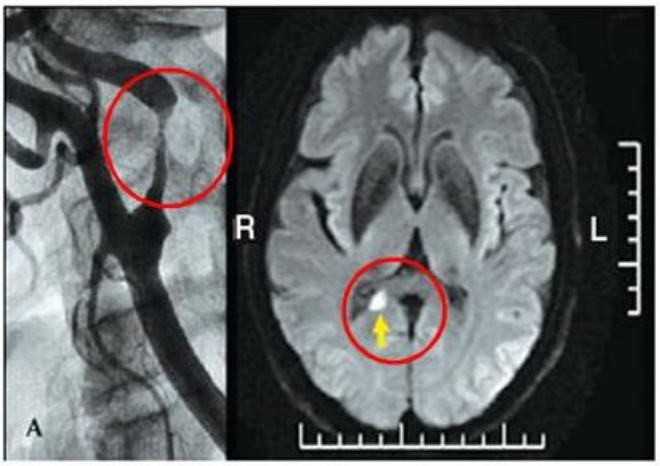


2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

* 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

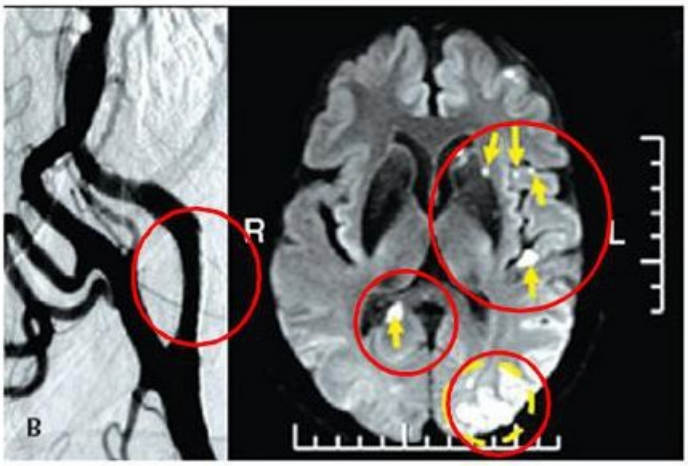
The Consequences

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.

Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64

MicroNet™

Proprietary technology for preventing distal embolization and other vascular disease challenges

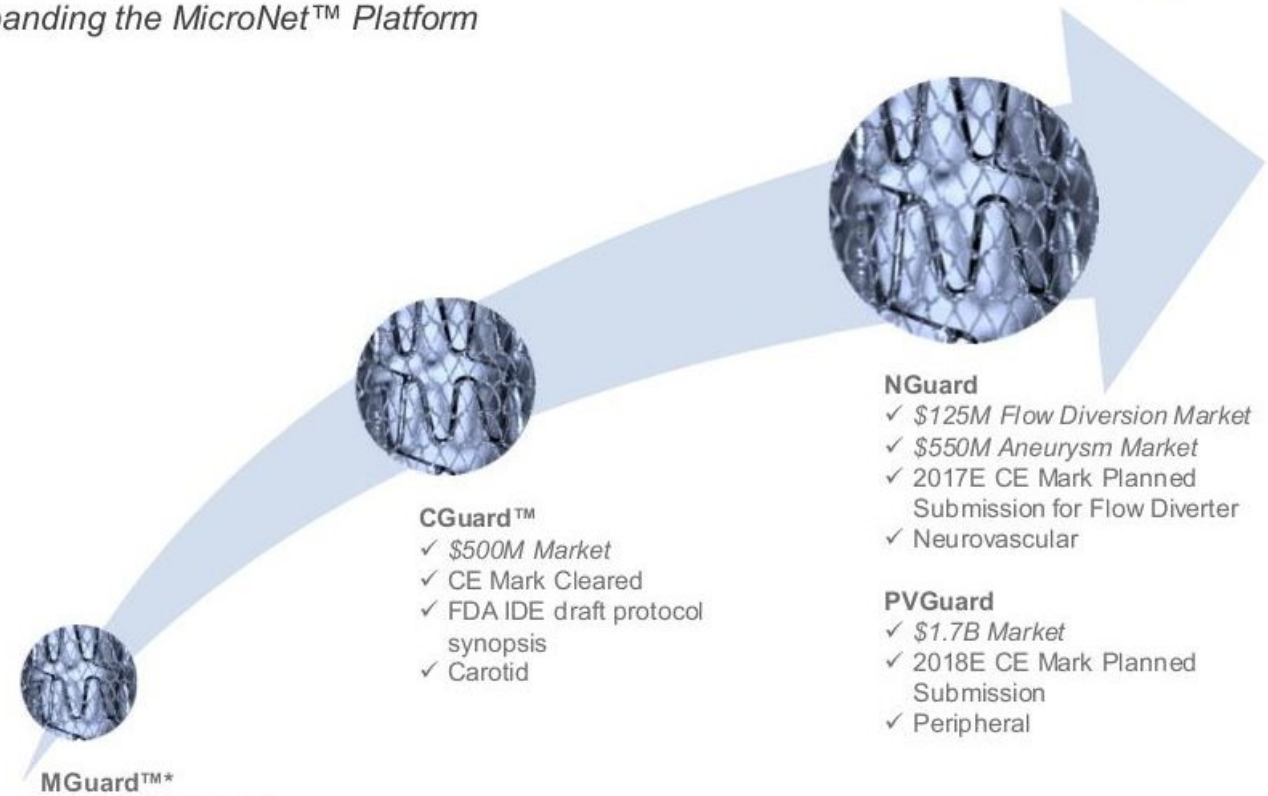
Ultrathin PET mesh provides meaningful clinical benefit to conventional devices*

- 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™*
- ✓ *$1.7B AMI Market*
- ✓ CE Mark Cleared
- ✓ Coronary AMI, SVG

CGuard™
- ✓ *$500M Market*
- ✓ CE Mark Cleared
- ✓ FDA IDE draft protocol synopsis
- ✓ Carotid

NGuard
- ✓ *$125M Flow Diversion Market*
- ✓ *$550M Aneurysm Market*
- ✓ 2017E CE Mark Planned Submission for Flow Diverter
- ✓ Neurovascular

PVGuard
- ✓ *$1.7B Market*
- ✓ 2018E CE Mark Planned Submission
- ✓ Peripheral

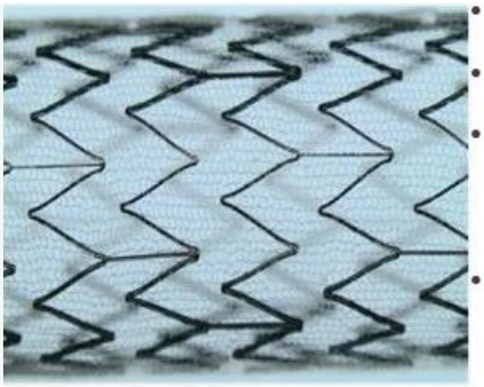
* MGuard is a bare metal stent scaffold

Carotid Solution: Mesh Covered Technology

An emerging market opportunity

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 in May 2016 at EuroPCR 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.[1]
  - Higher risks of stroke at 10 years appear to be attributable to the peri-procedural differences in risk.[2]
  - Mesh-covered carotid stents may lower the rates of peri-procedural stroke.[2]
- 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

"The most important theme during [EuroPCR 2016] was carotid artery stenting….[The double layered mesh stents] will resolve the main problem of carotid artery stents which was late embolic events."
A. Cremonesi

[1] *Musialek, EuroIntervention 2016:12 online publish ahead of print May 2016*
[2] *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

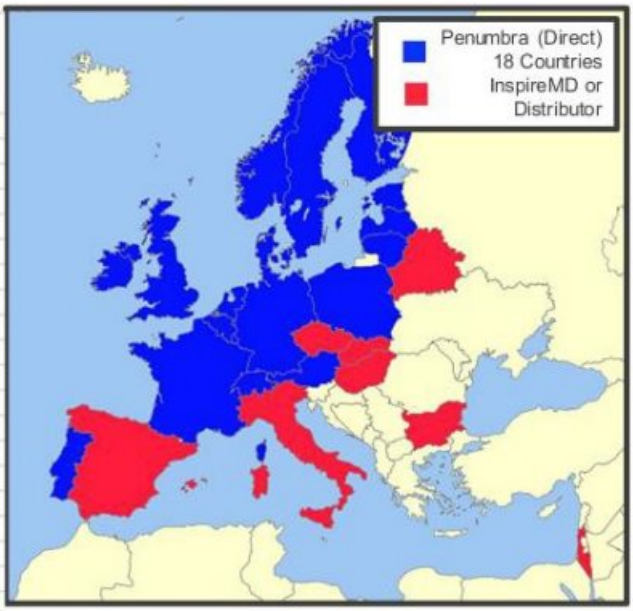
Penumbra

- 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

CGuard Distribution (EU)

	Sales Channel	Q115	Q215	Q315	Q415	Q116	Q216 E	Q316 E
UK	P			OLT		HOC	IND	
France	P			OLT	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)



CGuard™ Country Case Study

Italy – A leading indicator of CGuard Growth

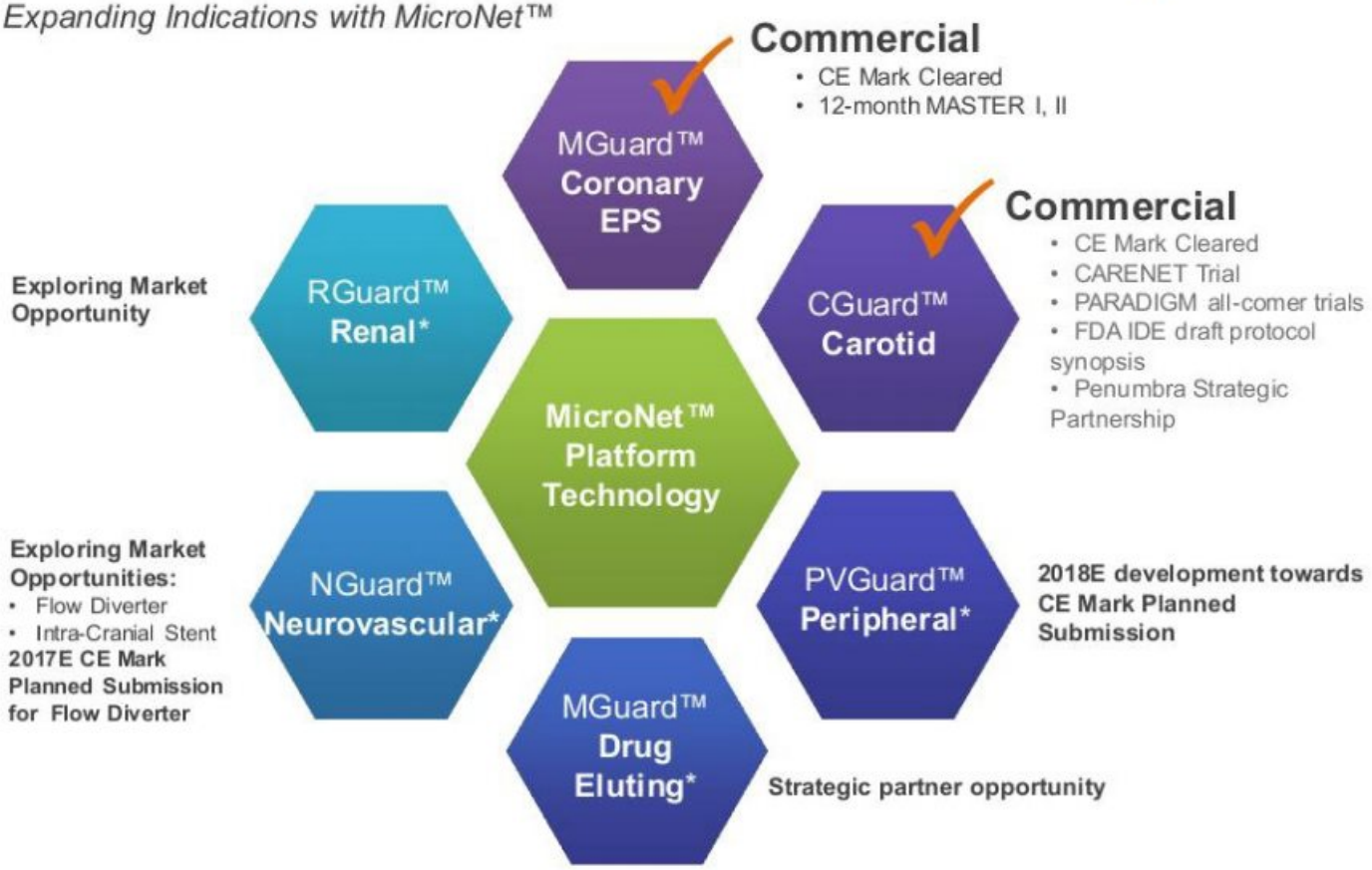
- *CGuard covered by 2 distributors*
- *Initial success drove 29 Italian carotid interventionalists to initiate the IRON-Guard* registry last year*

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

Note: Revenue in $000's

Robust Pipeline

Expanding Indications with MicroNet™



*Planning & Development Phase

Neurovascular Aneurysms

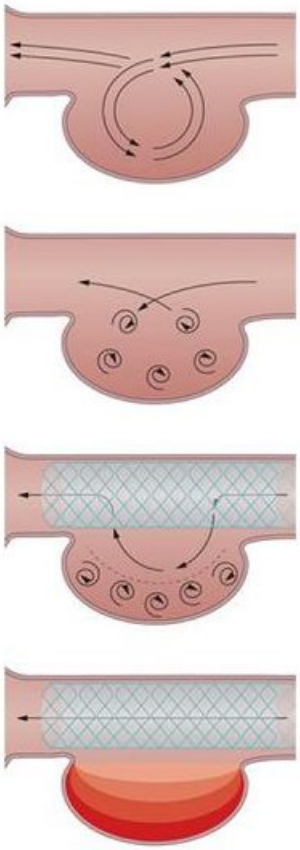
Flow Diversion

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



http://www.nature.com/nrcardio/journal/v11/n2/full/nrcardio.2013.196.html

Neurovascular Market Opportunity

Innovation leads growth

Flow Diversion For Unruptured Brain Aneurysms

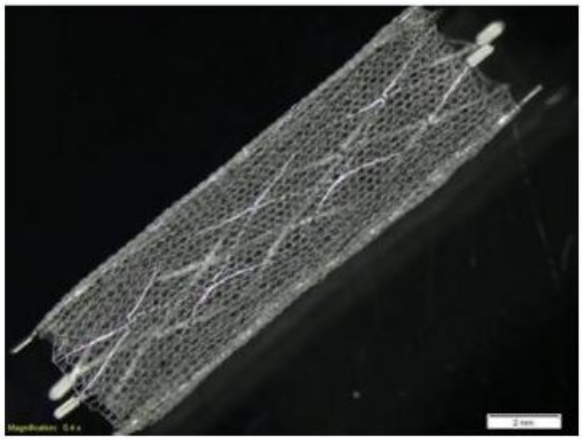
Next Generation Technology

- 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

InspireMD Flow Diverter Advantage



- 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

Intellectual Property Portfolio

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 and CEO
- 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

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jimb@inspiremd.com

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