INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 10/20/16 for the Period Ending 10/20/16

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 & Distribution
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): October 20, 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.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that InspireMD, Inc. will present on October 20, 2016 at the Dawson James Securities 2nd Annual Growth Stock Conference in Jupiter, Florida.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for 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 such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Dawson James Securities 2nd Annual Growth Stock Conference Presentation dated October 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: October 20, 2016

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Corporate Presentation

NYSE MKT: NSPR, NSPR.WS

October 2016

Forward Looking Statements

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.

Investment Highlights

- Revenue growth driven by broader EU and Latin American launch of CGuard™
- Strategic distribution partnership with Penumbra (NYSE: PEN)
- Multiple and consistent clinical trial results using CGuard in a broad patient population, including high risk patients
- Expanding opportunities in the growing neurovascular and peripheral vascular markets
- Strategic collaboration opportunities on multiple MicroNet™ product applications
- Broad portfolio of patent-protected assets
- Financial discipline in line with development and growth initiatives

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.

The New York Times

Times Essentials

Inside Health

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

Well

Genes Tell Only Part of the Story

When Grief Won't Relent

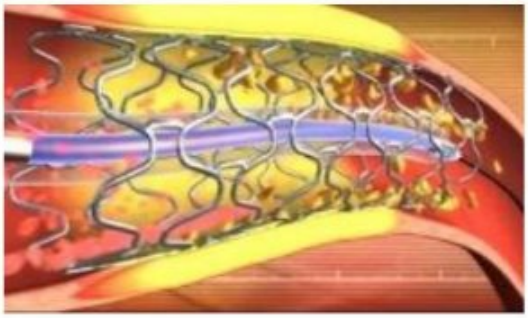
Not Your Bubbe's Kasha

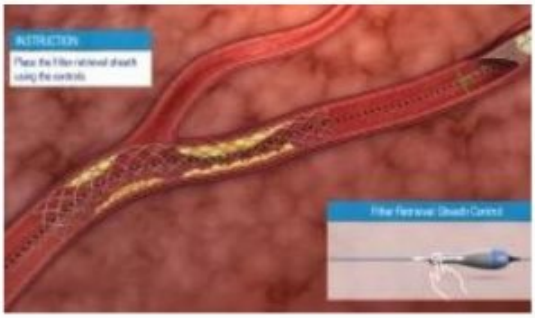
Ask Well: Put on the Snowshoes

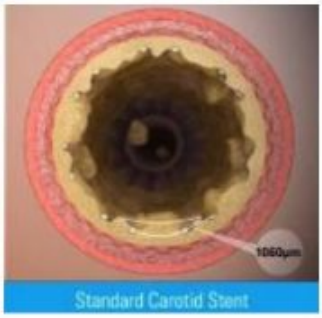
Think Like a Doctor: Swept Off Her Feet Solved

Embolization Following Carotid Artery Stenting

"Plaque protrusion through stent struts occurs in up to 65% 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."*



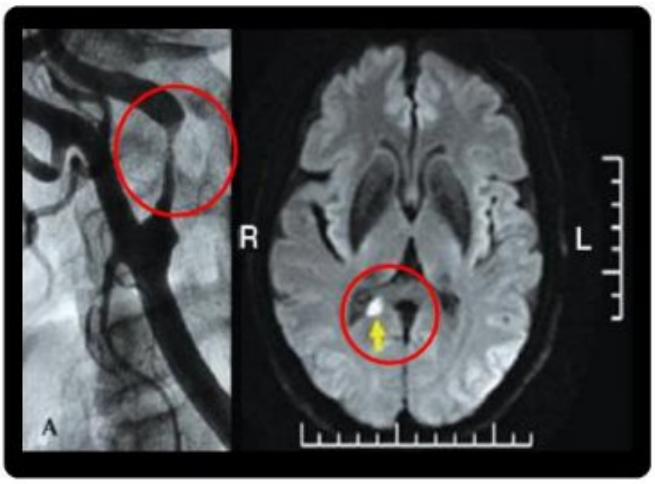




2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

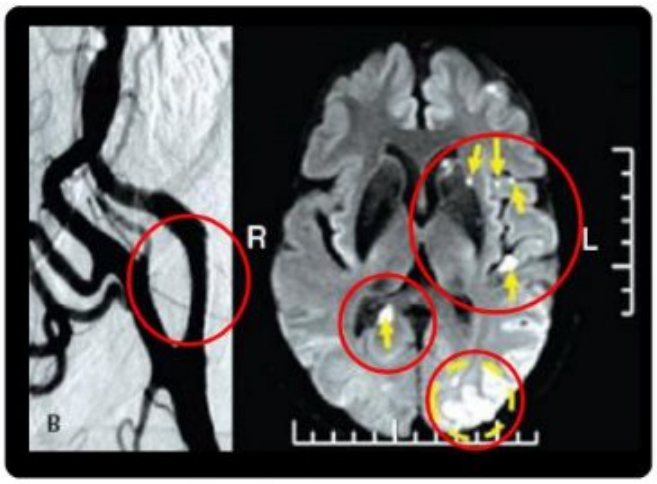
* Musialek, et al. Eurointerventions 2016;12 August 2016.
** Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

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).



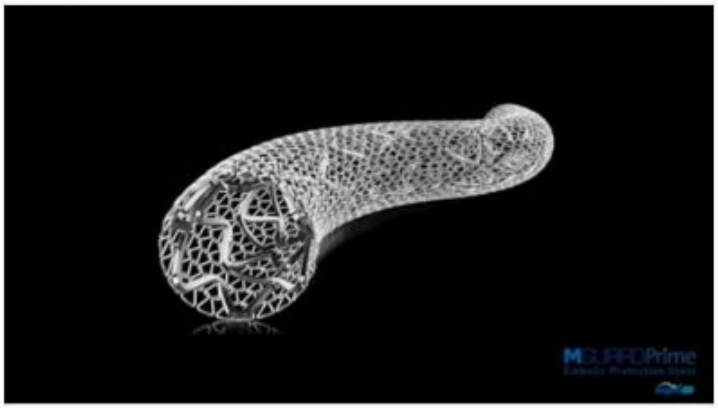
Post-Procedure

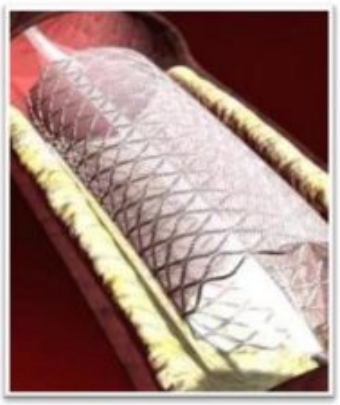
Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

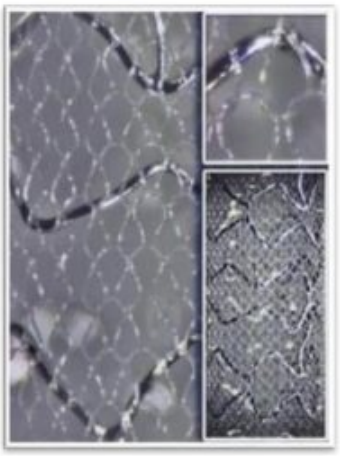
Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.

MicroNet Prevents Distal Embolization and Other Vascular Disease Challenges

- Proprietary technology
- Ultrathin PET* mesh provides meaningful clinical benefit versus conventional devices
- Provides revascularization benefit
- MicroNet acts as “safety net” by offering greater vessel area coverage to prevent large debris protrusion through the scaffold
- Made of a single fiber from a biocompatible polymer, widely used in other medical implants

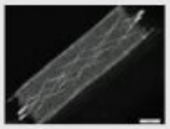






*PET – polyethylene terephthalate

Large Addressable Market

Embolic Prevention Products		Market Opportunity	CE Mark	Focus Area
MGuard™*		$1.7B	✓	Coronary AMI & SVG
CGuard™		$500M	✓ (FDA IDE draft protocol synopsis)	Carotid
NGuard™		$675M	2017E Planned Submission	Neurovascular
PVGuard™		$1.7B	2018E Planned Submission	Peripheral

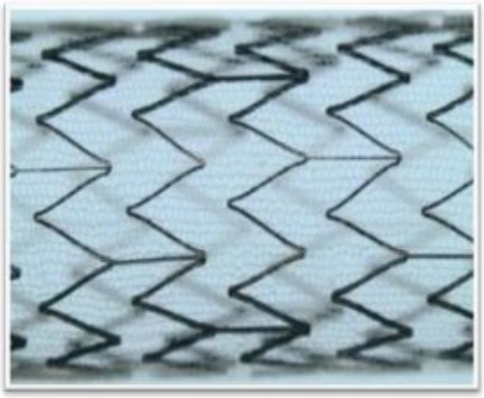
* MGuard is a bare metal stent scaffold

Carotid Solution: Mesh Covered Technology

CGuard Embolic Prevention System(EPS)

Combines stent and embolic protection in a single system

- CE marked
- Self-expanding nitinol stent
- Emerging global market opportunity 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 Cguard EPS
- Positive data presented at CIRSE 2016 and published in *Journal of Endovascular Therapy***
- Ongoing launch in Europe, Latin America, South America, & other regions



* Source: JMP Securities, 2014 and Cowen 2014. ** Wissgott, et.al. J Endovasc Ther 2016

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

Additional Independent Clinical Data Supports Use of CGuard*

Independent study conducted in 30 patients with internal carotid artery disease

Clinical results

- 100% success in implanting the CGuard EPS
- No peri- or post-procedural complications
- No deaths, major adverse events, minor or major strokes, or new neurologic symptoms during the six months following the procedure
- All vessels treated with the CGuard system remained patent (open) at six months
- DW-MRI performed in 19 of 30 patients found no new ipsilateral lesions after 30 days and after six months compared with baseline DW-MRI studies

Clinical Investigation

ENDOVASCULAR THERAPY

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

SAGE

Christian Wissgott, MD[1], Wolfram Schmidt, PhD[2], Christoph Brandt-Wunderlich, MSc[2], Peter Behrens, MSc[2], and Reinmar Andresen, MD[1]

Abstract

Purpose: To report early clinical outcomes with a novel double-layer stent for the internal carotid artery (ICA) and the in vitro investigation of the stent's mechanical properties. Methods: A prospective single-center study enrolled 30 consecutive patients (mean age 71.1±6.3 years; 21 men) with symptomatic (n=25) or high-grade (n=5) ICA stenosis treated with the new double-layer current CGUARD Embolic Prevention System (EPS) stent, which has an inner open-cell nitinol design with an outer closed-cell polyethylene terephthalate layer. The average stenosis of the treated arteries was 84.1%±7.4% with a mean lesion length of 14.6±5.1 mm. In the laboratory, 8×40-mm stents were tested in vitro with respect to their radial force during expansion, the bending stiffness of the stent system and the expanded stent, as well as the collapse pressure on thin- and flexible sheath. The vital adaptation was assessed using fluoroscopy after stent release in step and curved vessel models. Results: The stent was successfully implanted in all patients. No peri- or postprocedural complications occurred; no minor or major stroke was observed in the 6-month follow-up. The bending stiffness of the expanded stent was 431 N·mm² and (and unexpectedly) was clearly lower than that of the stent system (620.5 N·mm²). The normalized radial force during expansion of the stent to 7.0 mm, consistent with in vivo sizing, was relatively high (0.016 N/mm), which correlates well with the collapse pressure of 0.17 bars. Vessel wall adaptation was harmonic and caused no straightening of the vessel after clinical application. Conclusion: Because of its structure, the novel CGUARD EPS stent is characterized by a high flexibility combined with a high radial force and very good plaque coverage. These first clinical results demonstrate a very safe implantation behavior without any strokes up to 6 months after the procedure.

Keywords

carotid artery stent, closed-cell design, double-layer stent, embolic filter, internal carotid artery, in vitro testing, mechanical behavior, nitinol, open-cell design, radial force, stenosis, stent

Introduction

So-call studies have demonstrated that carotid artery stenting (CAS) of the endovascular treated carotid artery (ECA) is a well-established and equally good option for treating atherosclerotic carotid stenoses in comparison with carotid endarterectomy (CEA).[1–4] Although CEA is still considered the gold standard therapy of carotid stenosis[5,6] because of a lower risk of procedure related and periprocedural cerebral stroke, stent implantation is a valuable treatment option because of its less invasive character.[7,8]

Despite the fact that procedure related events can be caused by lesion crossing and pre-/postdilatation,[9] particular attention has been focused on the stent design because postprocedure diffusion-weighted magnetic resonance imaging (DW-MRI) lesions were more numerous in patients treated with an open-cell design vs a closed-cell stent.[10]

The perfect stent should safely cover the plaque for maximal embolic protection like an ultra-closed-cell stent and allow high flexibility and conformability like an open-cell stent.[11] The first reports of a closed-cell stent with double nitinol layers showed promising clinical results with respect to its implantation behavior based on the closed-cell design.[12,13] This article presents the clinical results

[1]Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westküstenklinikum Heide–Academic Teaching Hospital of the Universities of Kiel, Lübeck, and Hamburg, Heide, Germany
[2]Institute for Biomedical Engineering, Research University Medical Center Rostock, Germany

Corresponding Author:
Christian Wissgott, Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westküstenklinikum Heide–Academic Teaching Hospital of the Universities of Kiel, Lübeck and Hamburg, Esmarchstraße 50, 25746 Heide, Germany.
Email: cwissgott@web.de

"CGuard EPS is an important new treatment option for both symptomatic and asymptomatic carotid artery stenosis patients."
C. Wissgott, MD

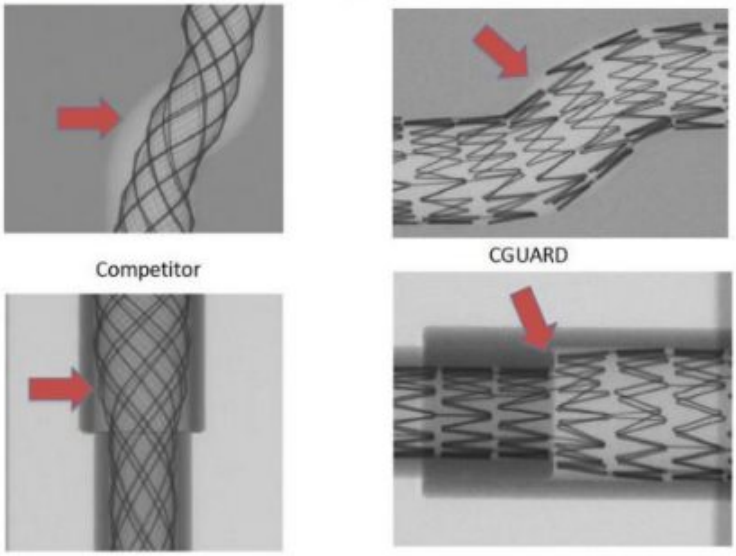
* Wissgott, et.al. J Endovasc Ther 2018.

Data Presented at CIRSE 2016

Laboratory engineering evaluations

- CGuard EPS provides high radial force and strong support in long stenotic lesions
- Structure adapted well to changes in vessel diameter and direction
- MicroNet mesh of CGuard EPS did not cause any measurable changes to specific mechanical parameters of the underlying stent
- CGuard EPS more readily adapts to vessel dimensions and shape than a competitor product

Wall adaption in comparison to Competitor



"The CGuard EPS is easy and safe to implant because it more readily adapts to the shape and diameter of the vessel wall versus other carotid artery stents."
C. Wissgott, MD

* Wissgott, C, 2016. Data presented at CIRSE 2016.

CGuard is a "Game Changing" Carotid Market Opportunity

Current standard of care: Carotid Endarterectomy (CEA) = Surgery

The risk of post-procedural cerebral events has been related to [conventional] carotid stents*

- Higher risks of stroke at 10 years appear to be attributable to the peri-procedural differences in risk**
- Mesh-covered carotid stents may lower the rates of peri-procedural stroke**

CGuard clinical studies have demonstrated superior safety

- CARENET
- PARADIGM
- PARADIGM 101
- Wissgott 30-patient independent study***

Immediate EU and Latin America commercial opportunity

- Majority of EU pursued via new strategic partner Penumbra
- Europe, Latin America and other regions are covered by experienced distributors
- U.S. development and clinical plan in process

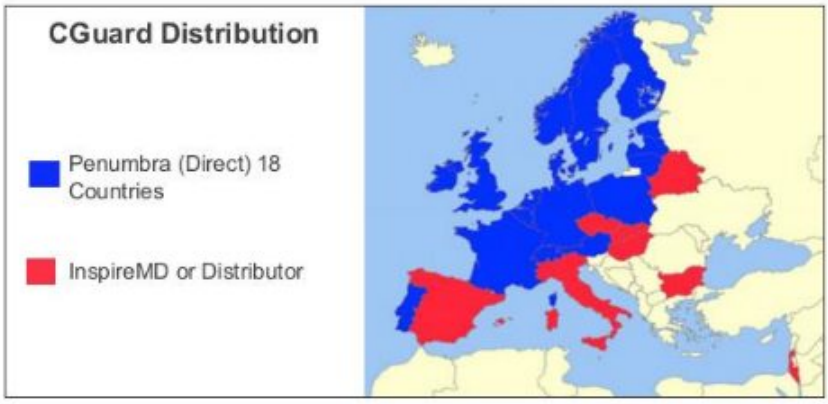
"The most important theme during [EuroPCR 2016] was carotid artery stenting….[The double layered mesh stents] will resolve the main problem of carotid artery stents which was late embolic events."
A.Cremonesi
Chief of Cardiovascular Department at Maria Cecilia Hospital

* Musialek, et al. Eurointerventions 2016;12 (5) August 2016. ** Brott, T. NEJM, March 17, 2016. *** Wissgott, et al. J Endovasc Ther 2016.

Broad EU Commercialization Support from a Growing Neurovascular Leader

Penumbra

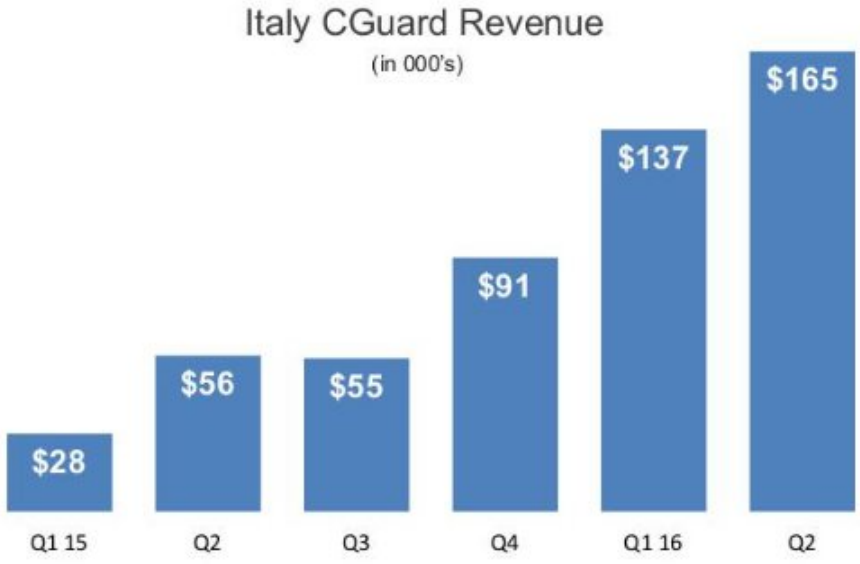
- Strategic distribution agreement with Penumbra
- 18 European markets with opportunity to expand
- Comprehensive neurovascular product portfolio
- CGuard is a synergistic product offering
- Growing direct sales force throughout Europe
- Establishing a direct sales force focused on peripheral vascular



CGuard Country Case Study - Italy

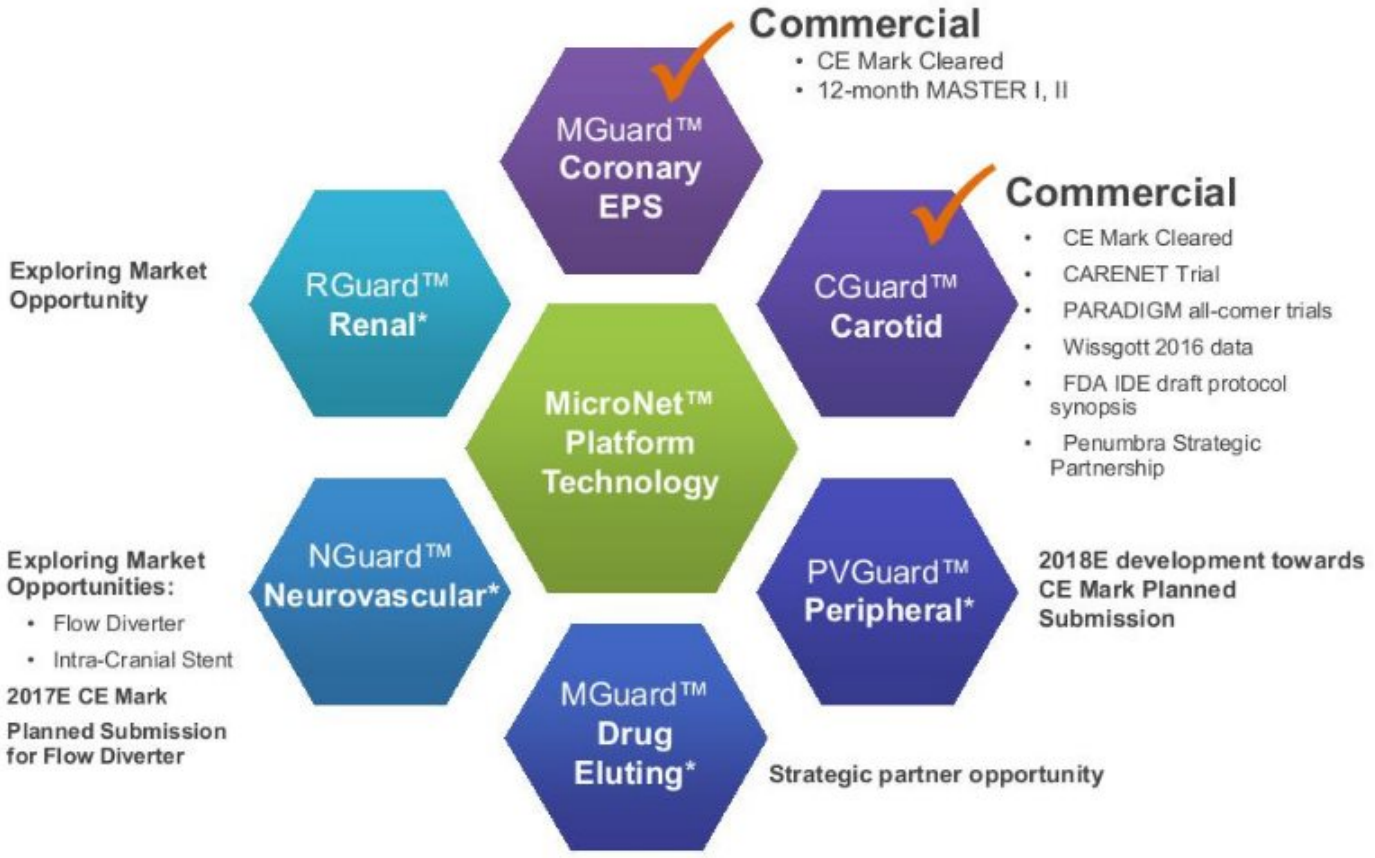
194% sales growth in Q2 2016, compared to Q2 2015

20% growth compared to the Q1 2016



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

Expanding Pipeline Opportunities with MicroNet



* Planning & Development Phase

Flow Diversion for Neurovascular Aneurysms

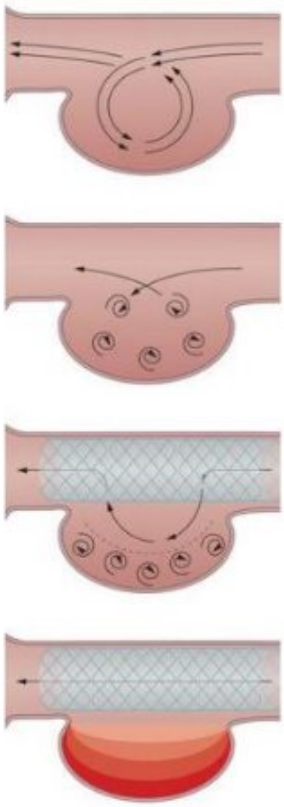
InspireMD

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

Innovation Enables Growth in the Neurovascular Market

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

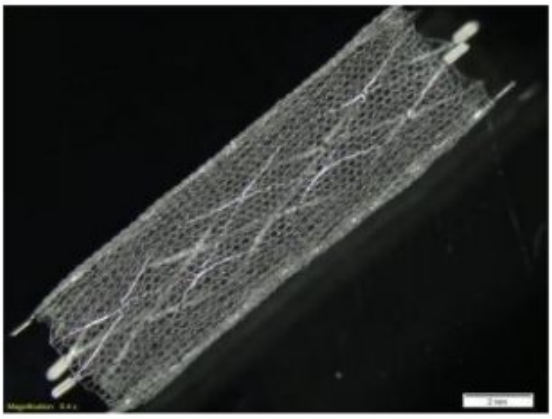
Global Flow Diversion - $125M**

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



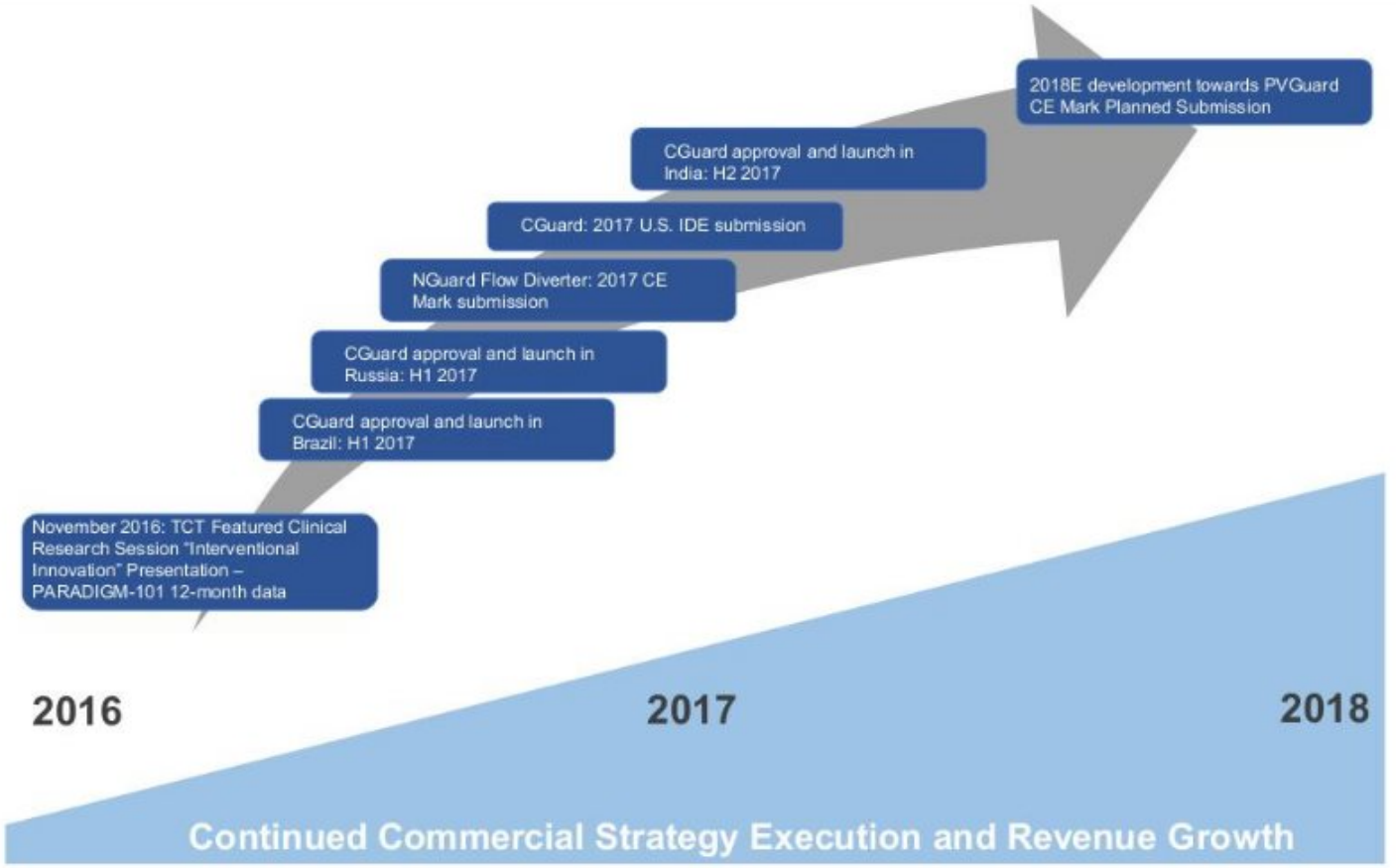
- Low profile, flexible, open cell scaffold = Easy to deliver
- Low metal ratio = Potential for reduced anti-thrombosis medication
- Re-accessible through MicroNet = Allows for further treatment, if needed which is impossible with current flow diverters
- Can be placed in side branches and bifurcations = 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

- Proprietary platform technology supported by a robust intellectual property portfolio.
- 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.

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
US	4	**1**	12
Rest of World (ROW)	16	**1**	14

Upcoming Anticipated Milestones



Leadership

Significant track records of success

Dr. James Barry	President and CEO	Boston Scientific, Pfizer
Craig Shore	CFO	Pfizer, GE
David Blossom	VP Global Marketing & Strategy	Boston Scientific, COVIDIEN
Dr. Sol Barer	Chairman	Celgene
Isaac Blech	Vice Chairman	cerecor, ContraFect, medgenics, sapience therapeutics
Michael Berman	Director	Boston Scientific, Velocimed, LUTONIX
Paul Stuka	Director	OSIRIS, Fidelity INVESTMENTS
Dr. Campbell Rogers	Director	HeartFlow, Cordis, HARVARD MEDICAL SCHOOL
Thomas Kester	Director	Kester Search Group, KPMG

Financial Snapshot

NYSE MKT: NSPR, NSPR.WS

Stock Price (10/14/16):	$2.65
Average Volume:	190 K
Shares Outstanding (9/30/16):	1.4 M
Shares Outstanding Including Future Pref. Stock Conv. (9/30/16):	3.6 M
Market Capitalization (10/14/16):	$9.6 M
Total Cash:	$0.9 M as of 6/30/2016 ($13M net proceeds from financing completed on 7/7/2016)
US Headquarters:	Boston, MA
International Headquarters:	Tel Aviv, Israel
# of Employees (9/30/2016):	36

Investment Highlights

- **Revenue growth** driven by broader EU and Latin American launch of **CGuard**
  - Strategic distribution partnership with Penumbra (NYSE: PEN)
  - Strong, and growing, direct sales teams across key countries
  - Significant growth in Italy over the last 4 quarters
  - Multiple and consistent clinical trial results using CGuard in a broad patient population, including high risk patients
- **Expanding opportunities** in the growing neurovascular and peripheral vascular markets
  - 2017E CE Mark Submission for NGuard
- **Broad portfolio** of patent-protected assets
- **Strategic collaboration opportunities** on multiple **MicroNet** product applications
- **Financial discipline** in line with development and growth initiatives

James Barry, Ph.D., President and CEO
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Craig Shore, CFO
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