INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 02/20/15 for the Period Ending 02/20/15

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
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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): February 20, 2015

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, MA (Address of principal executive offices)	02116 (Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(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 February 2015

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: February 20, 2015

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

Exhibit 99.1

NYSE MKT: NSPR

February 2015

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 control of InspireMD, Inc. (the "Company"), 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 the Company's 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 the Company's products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) product malfunctions, (vii) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payors for the Company's products, (ix) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) the Company's reliance on single suppliers for certain product components, (xii) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain, (xiii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing it 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 and (xiv) the escalation of hostilities in Israel, which could impair the Company's ability to manufacture its products. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements are set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Transition Report on Form 10-K/T and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these reports free of charge on the Securities and Exchange Commission's web site at 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

- 2015 return to revenue growth with improved coronary product for near term international opportunities.
- Immediate product portfolio expansion: Carotid RX product with revolutionary design and strong First in Man clinical data.
- Operating and financial realignment inline with development and growth initiatives.
- Expanding partnerships in both coronary and carotid segments to advance adoption and accelerate revenue growth.
- Advancing into Neuro and Peripheral markets to leverage technology into high growth segments.
- Experienced management team and strong Chairman with track record of success in building highly valued enterprises.

Leadership

Solid Commercial & Clinical Capabilities

Executive Team

Alan Milinazzo

President, CEO & Director

- Medtronic
- Boston Scientific

Eli Bar

CTO

- Nicast

Craig Shore

CFO

- Pfizer
- General Electric

Gwen Bame

VP Corporate Development

- Boston Scientific
- Covidien

Dr. James Barry

COO

- Boston Scientific
- Howmedica Division of Pfizer

David Blossom

VP Global Marketing & Strategy

- Boston Scientific
- Covidien

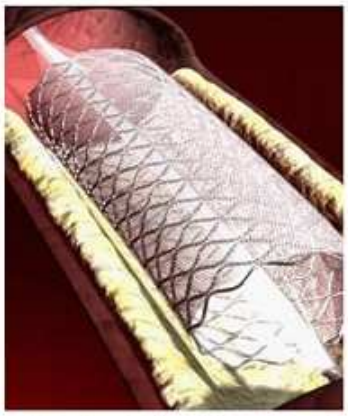
Technology: MicroNet™

Beyond Stenting: MicroNet Mesh for Embolic Protection

MGuard Embolic Protection System

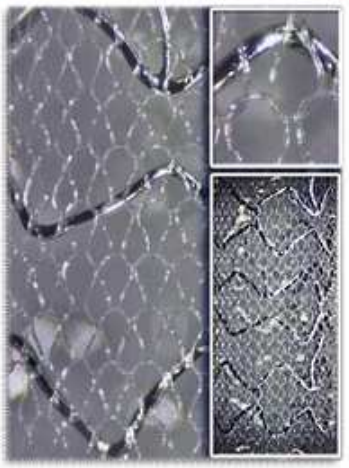
Combines stent and embolic protection in a single device

- Stent platform provides revascularization benefit
- MicroNet then acts as safety net by offering greater surface area coverage to prevent large debris flow
- Mesh configuration allows perfusion to vessel wall



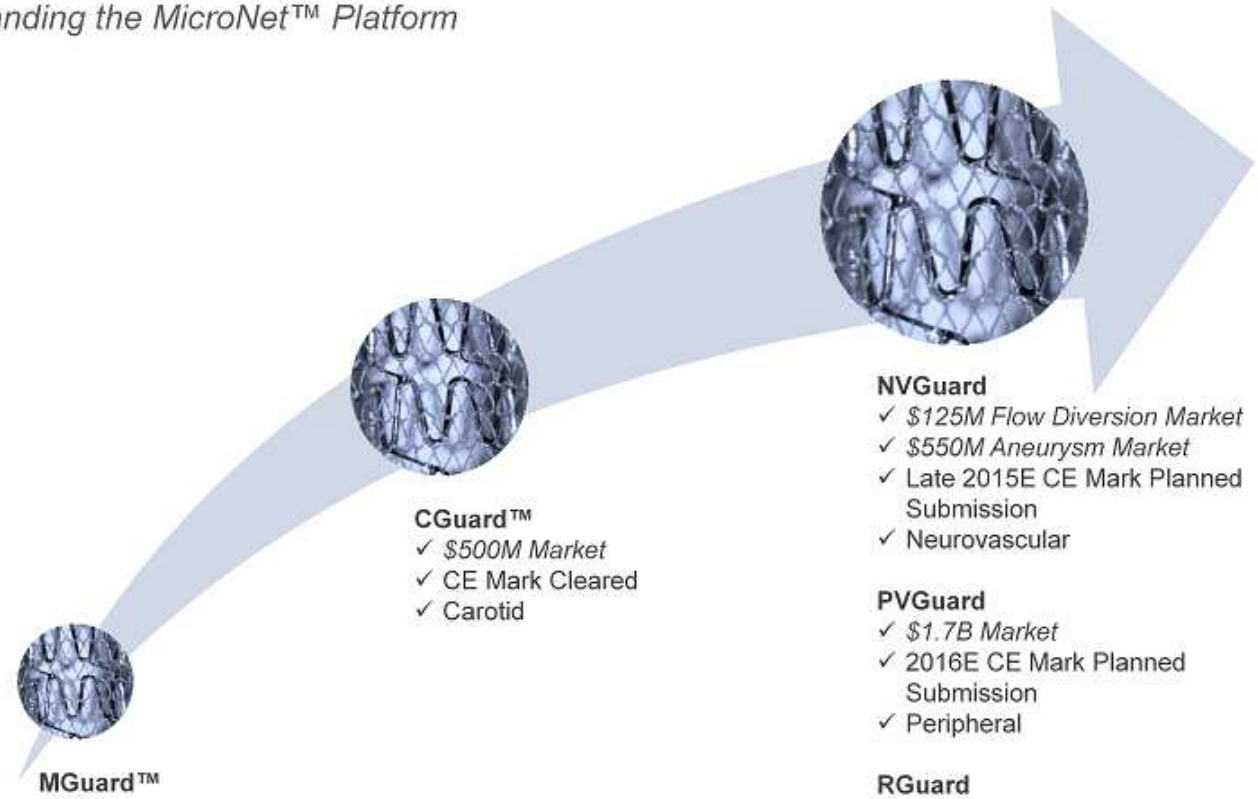
MicroNet Platform

- Proprietary circular knitted mesh wraps around stent to protect patient from plaque debris flowing downstream upon deployment
- Made of a single fiber from a biocompatible polymer, widely used in medical implantations
- Flexible structure
- Does not promote thrombosis



Large Addressable Markets

Expanding the MicroNet™ Platform



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

CGuard™
- ✓ *$500M Market*
- ✓ CE Mark Cleared
- ✓ Carotid

NVGuard
- ✓ *$125M Flow Diversion Market*
- ✓ *$550M Aneurysm Market*
- ✓ Late 2015E CE Mark Planned Submission
- ✓ Neurovascular

PVGuard
- ✓ *$1.7B Market*
- ✓ 2016E CE Mark Planned Submission
- ✓ Peripheral

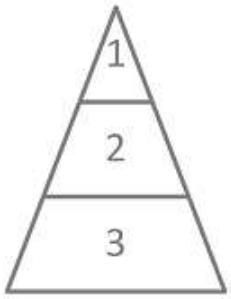
RGuard
- ✓ *$100M Market*
- ✓ Renal

Coronary MGuard™ EPS

Improving AMI Patient Outcomes

- Current stents not specifically designed for AMI
- Distal embolization occurs in up to 73% of cases*
- Majority of AMI market is outside of the U.S. (~60%)
- MGuard clinical experience including two randomized trials with data showing sustained mortality rates

Targeted Share Capture: Selectively scaling global reach and frequency



Tier 1
- Mix of direct sales representatives, agents and distributors, with focus on KOL's/high-volume AMI centers
- 14-18 countries, primarily Europe and select Latin American and Middle East countries with favorable STEMI market factors

Tier 2
- Country or regional partnerships with high quality local distributors or strategic partners with regional AMI focused strategies

Tier 3
- United States - Pending successful partnership strategy
- Japan - Pending successful partnership strategy

Source: Health Research International, (June 2012) | *JAMA, March 2, 2005—Vol 293, No. 9 1063 Gregg W. Stone

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

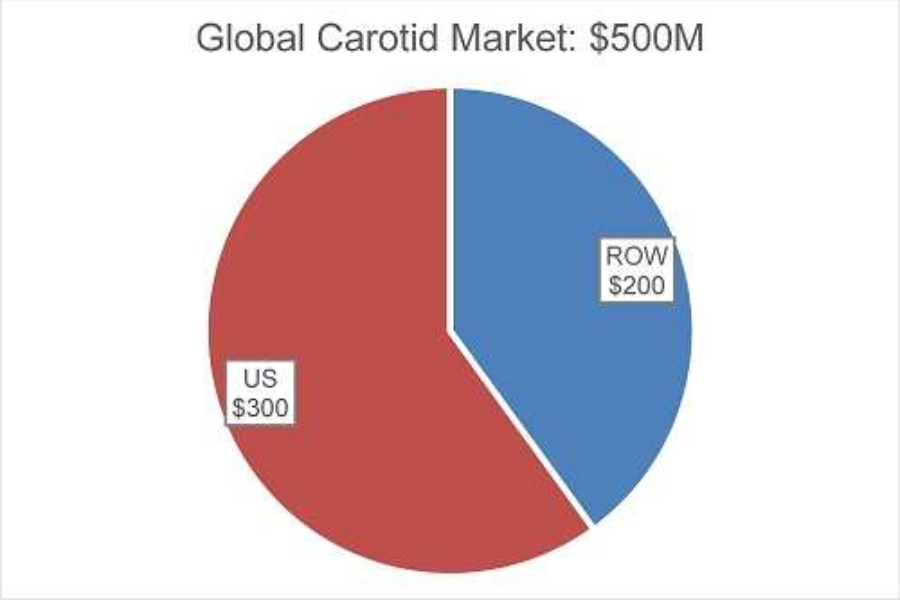
By THOMAS M. BURTON

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.

Carotid Market Opportunity

An Enhanced Minimally Invasive Solution

- Standard of care: Open surgery: Carotid EndArterectomy (CEA)
- Current stents have not improved on CEA stroke rates (CREST)
- Mesh covered stent category has the potential to convert CEA to CAS
- CARENET 30-day data show CGuard device better than previous technology/therapy
- Immediate commercial opportunity with revenue ramp throughout 2015



Source: JMP Securities, 2014

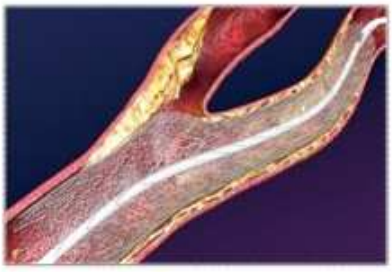
Carotid Solution

Safety Net with Greater Plaque Protection

CGuard™ Embolic Prevention System

Combines stent and embolic protection in a single device

- Stent platform provides revascularization benefits
- MicroNet acts as safety net by offering greater plaque scaffolding to prevent prolapse related to late embolization
- Allows perfusion to vessel wall, does not inhibit endothelialization



- CE marked
- Self-expanding nitinol stent
- Global market valued at $500M*
- Strong CARENET FIM data released 9/14 and 1/15
- First commercial orders (LMR) received Q4 2014

* Health Research International, 2011

Positive CGuard™ FIM* Clinical Experience

CARENET Design (CARotid Embolic protection using microNET)

- 30 Patient Safety and efficacy clinical trial
- Prospective, multi-center, multispecialty, non-randomized single arm study
- Diffusion weighted MRI follow ups at 48hrs and 30 days for "gold-standard" neurological analysis

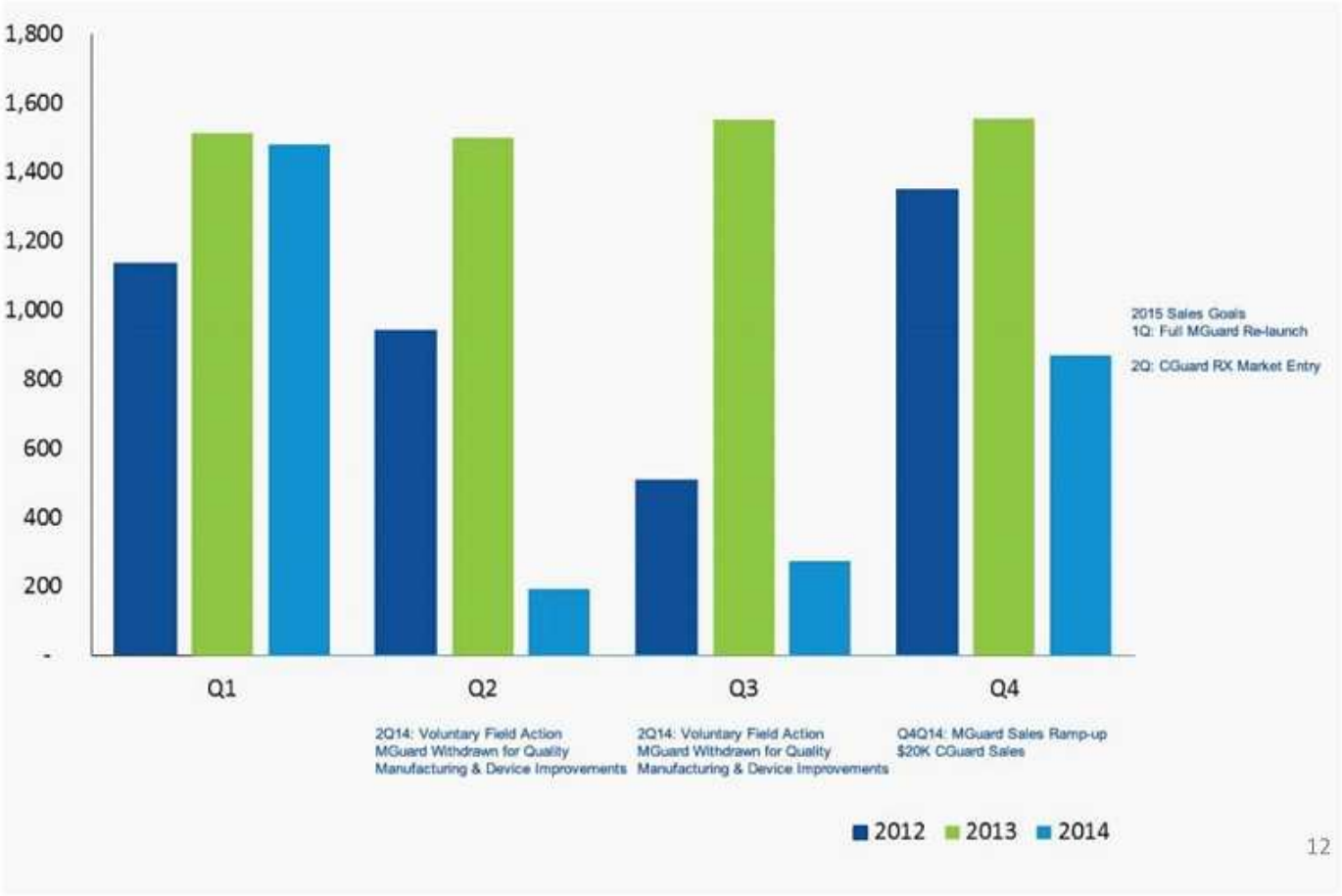
CARENET Highlights: Results Announced at TCT 2014

- Achieved primary end point
- 100% procedural success
- Zero MACCE at 30 days
- 50% fewer new ischemic lesions compared to historical non-mesh carotid artery stenting data
- Average lesion volume per patient 10 times smaller compared to historical non-mesh carotid artery stenting data

** FIM , First in Man*

2015 Return to Growth

Revenue Growth with MGuard™ and NEW CGuard™ RX



Carotid CGuard™ Commercialization Strategy

CGuard Embolic Prevention System

Commercial Activities to Complement MGuard Sales Activities

Q4 2014 – Limited Market Release

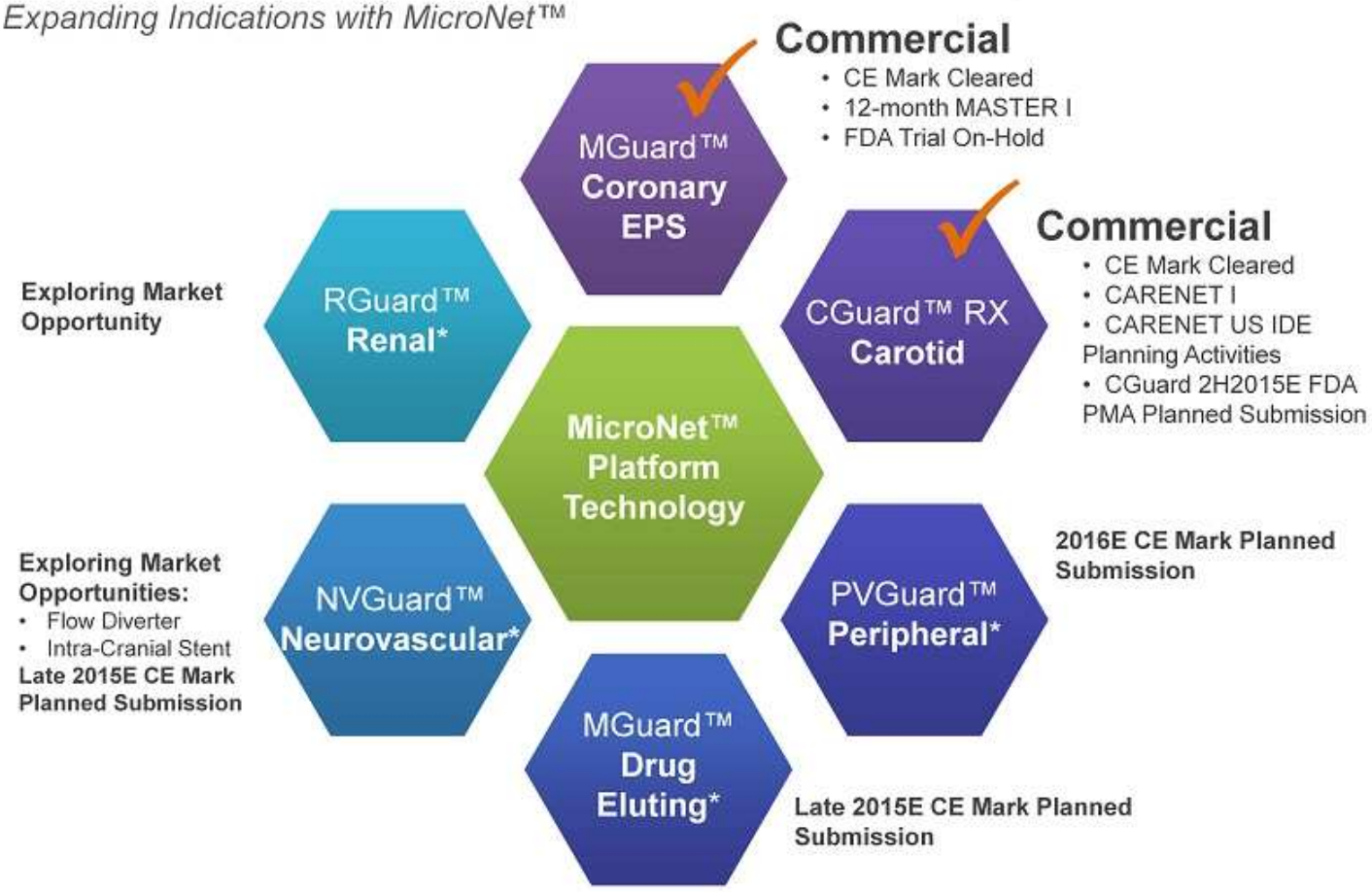
- Germany, Poland, Switzerland, Belgium, Italy, and Spain
- 100+ CGuard cases performed to date from 14 sites
- FIM data supports full commercial release

Q1/Q2 2015 – International Launch

- Full launch of rapid exchange (RX) system focused on EU and LATAM
- Primarily targeting high volume centers in core European markets
- Revenue impact to the company in 2015 is expected to be significant and will complement coronary selling strategies

Robust Pipeline

Expanding Indications with MicroNet™



*Planning & Development Phase

Neurovascular Market Opportunity

Innovation Leads Growth

The Flow Diversion System

The preferred solution for unruptured aneurysm treatment

- Current designs have sub-optimal trackability and in vessel flexibility
- MicroNet meets need to simultaneously manage thrombosis of the aneurysmal sac while preserving the patency of the adjacent small vessels

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

Source: MRG Neuro Report, Ev3 Revenue Data

NVGuard™ Neurovascular

Differentiation Yields Increased Utility

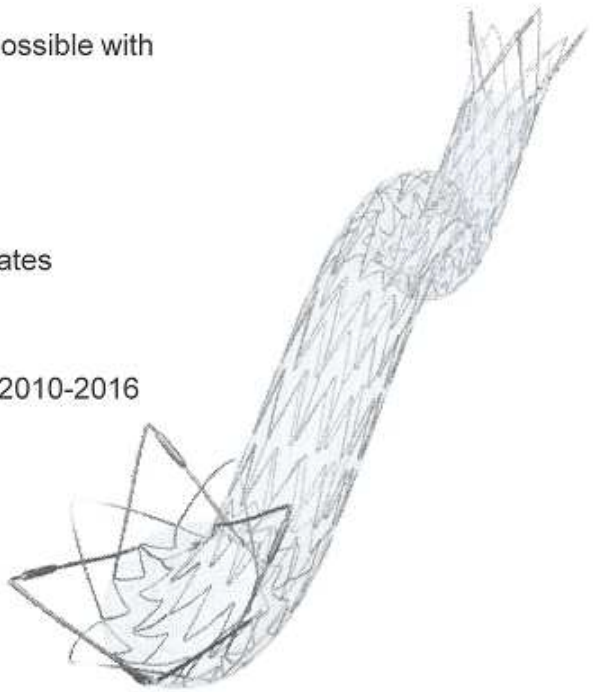
Our Significant Advantage Over Existing Flow Diverters

- MicroNet aperture & size
- Low metal to artery ratio
- Can be placed in side branches and bifurcations, which is impossible with current technology

Total Aneurysm Market Value: $946M

- Aneurysm Therapy (all types): $550M
- Aneurysms account for 74% of neuroendovascular disease states
- Estimated that flow diverters can treat 25% of all aneurysms
- Wide-neck Aneurysm Procedures: $350M
- Non-coil neurovascular products: estimated 12% CAGR from 2010-2016

"Devices in the European neurovascular device market will face significant competition from emerging treatments, such as INR flow diversion"



Source: MRG

PVGuard™ Peripheral

Enabling a New Solution: Peripheral Embolic Protection

The Embolic Prevention System

A new stent category as the preferred solution for peripheral intervention

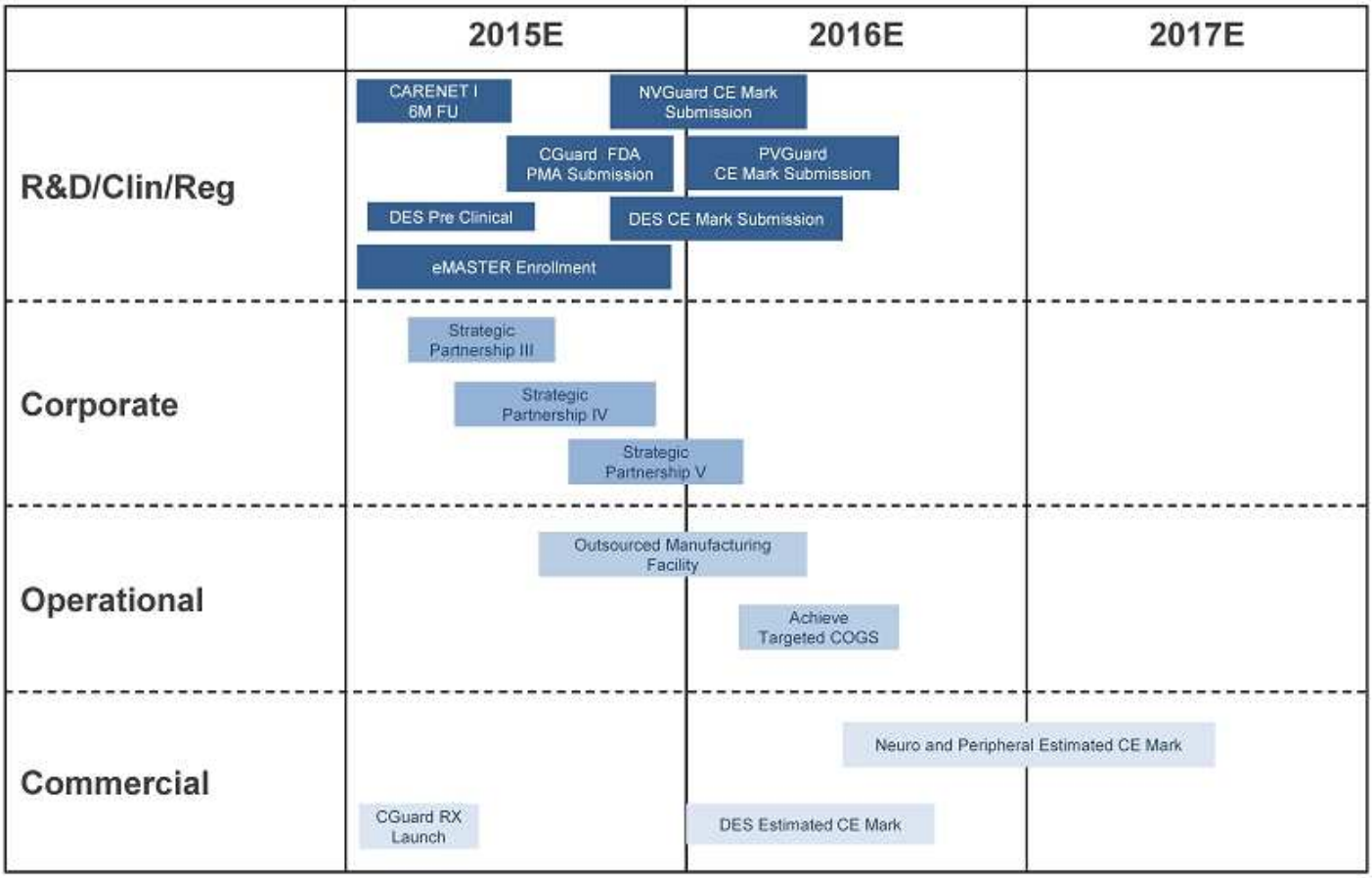
- Current stents not specifically designed for embolic protection
- Mesh covered stent category emerging as immediate opportunity
- Strong global growth profile with increased clinical complexity

Market Landscape 2014	
Company	EU Market Share
Abbott Laboratories	15%
Boston Scientific	15%
C. R. Bard	12%
W. L. Gore	10%
Covidien	9.5%
Cordis	7%

Source: MRG 2013/2014,ReportLinker

Target Milestones

Support & Execute on Growth Initiatives



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- Operating and financial realignment inline with development and growth initiatives.
- Expanding partnerships in both coronary and carotid segments to advance adoption and accelerate revenue growth.
- Advancing into Neuro and Peripheral markets to leverage technology into high growth segments.
- Attractive valuation entry point with multiple near term growth drivers.

Alan Milinazzo, CEO
(888) 776-6804
alanm@inspiremd.com

Craig Shore, CFO
(888) 776-6804
craigs@inspiremd.com