INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 10/15/15 for the Period Ending 10/15/15

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): October 15, 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, Massachusetts	02116
(Address of principal executive offices)	(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 October 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: October 15, 2015

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

NYSE MKT: NSPR

October 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 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.

An emerging medical device company developing and commercializing advanced technology for interventional cardiology and other vascular procedures

NYSE MKT: **NSPR**

Stock Price (10/14/15):	$1.70
52 Week Range:	$1.22 - $19.8
Average Volume:	74K
Shares Outstanding (10/1/15):	7.8 M
Market Capitalization (10/14/15):	$13.3 M
Analyst Coverage:	Cowen Group: Josh Jennings Empire Asset Management: Cathy Reese
Total Cash (6/30/15):	$9.8 M
US Headquarters:	Boston, MA
International Headquarters:	Tel Aviv, Israel
# of Employees (10/1/2015):	43

Investment Highlights

Effectively Executing a "Neck Up" Interventional Strategy

- 2015 return to revenue growth driven by the full launch of carotid platform through strategic distribution partnership with Penumbra, Inc.
- Operating and financial realignment inline with development and growth initiatives.
- Advancing into highly valued Neuro and Peripheral markets to leverage MicroNet technology into high growth segments.
- Expanding collaboration activities on multiple MicroNet technology applications.

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

The IBM Cloud is the cloud for business.

Tap into the IBM Cloud. Learn more

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

Well

The IBM Cloud

TIME

THE SECRET KILLER

INFLAMMATION

Leadership: Significant Track Records of Success

EXECUTIVE TEAM

Alan Milinazzo, President, CEO & Director
- Medtronic
- Boston Scientific

Craig Shore, CFO
- Pfizer
- General Electric

Dr. James Barry, COO
- Boston Scientific
- Howmedica Division of Pfizer

Eli Bar, CTO
- Nicast

Gwen Bame, VP Corporate Development
- Boston Scientific
- Covidien

David Blossom, VP Global Marketing & Strategy
- Boston Scientific
- Covidien

InspireMD

BOARD OF DIRECTORS

Dr. Sol Barer, Chairman
- Former Chairman and CEO, Celgene

Alan Milinazzo, President, CEO & Director
- Medtronic
- Boston Scientific

Dr. James Barry
- SVP Corporate Technology Development at Boston Scientific
- Howmedica Division of Pfizer

Michael Berman
- Pres. Boston Scientific/Scimed
- Founder, Velocimed and Lutonix

James Loughlin
- KPMG
- Celgene Audit Chair

Paul Stuka
- Founder, Osiris
- Fidelity Management and Research

Dr. Campbell Rogers
- CMO, Heartflow
- CSO, Cordis/JNJ
- Associate Professor, Harvard School of Medicine

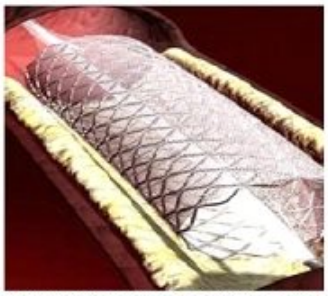
Technology: MicroNet™

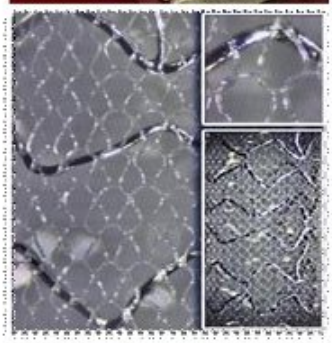
Proprietary MicroNet Mesh for Embolic Prevention and Flow Diversion

MicroNet Platform

Ultra thin PET enhances clinical benefit of scaffold devices

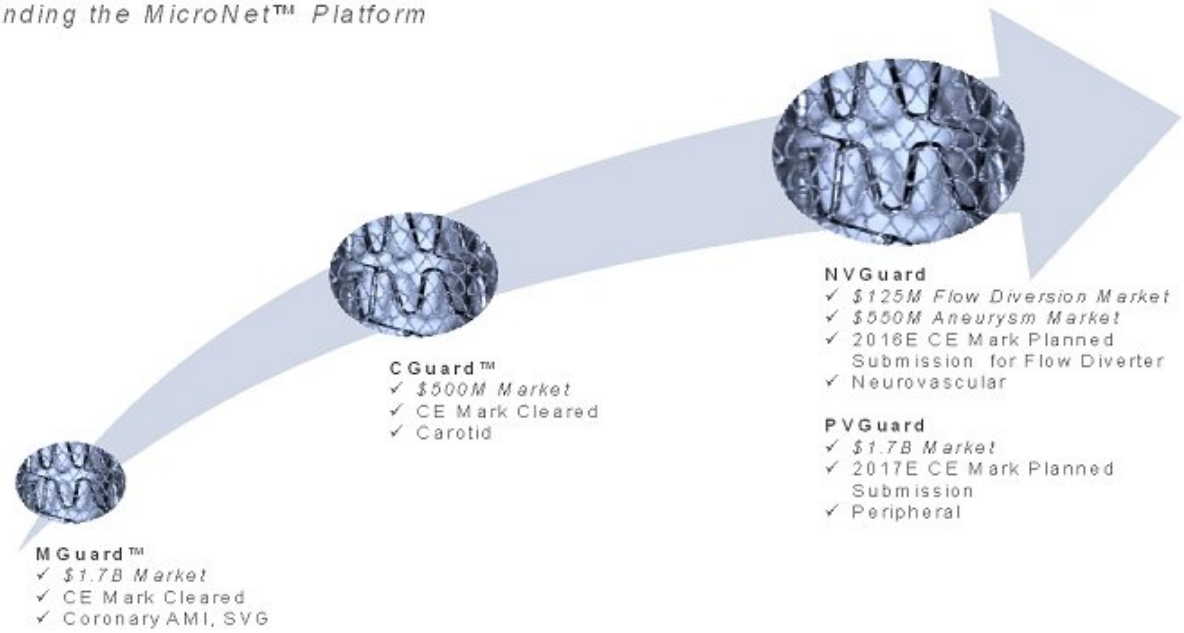
- Provides revascularization benefit
- MicroNet acts as safety net by offering greater surface area coverage to prevent large debris flow
- Mesh configuration allows perfusion to vessel wall
- Made of a single fiber from a biocompatible polymer, widely used in medical implantations





Large Addressable Markets

Expanding the MicroNet™ Platform



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

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

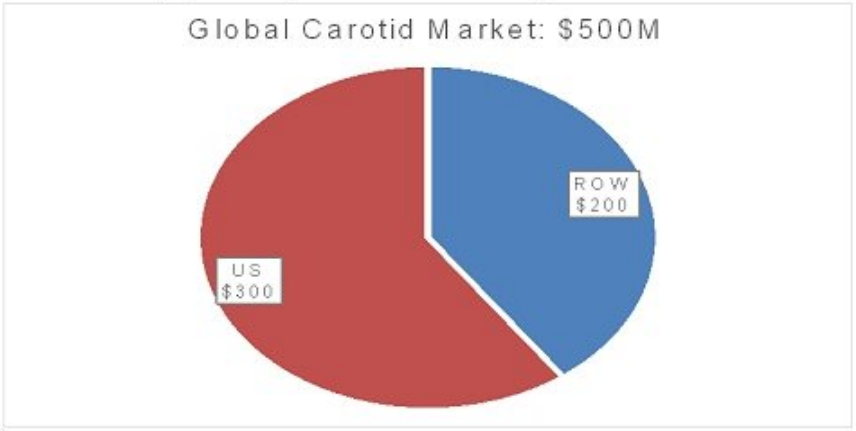
NVGuard
- ✓ *$125M Flow Diversion Market*
- ✓ *$550M Aneurysm Market*
- ✓ 2016E CE Mark Planned Submission for Flow Diverter
- ✓ Neurovascular

PVGuard
- ✓ *$1.7B Market*
- ✓ 2017E CE Mark Planned Submission
- ✓ Peripheral

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 and 6-mo data show CGuard better than previous technology/therapy
- PARADIGM physician-initiated trial validated benefits of CGuard in an all-comer population
- Immediate commercial opportunity with new Strategic Partner Penumbra



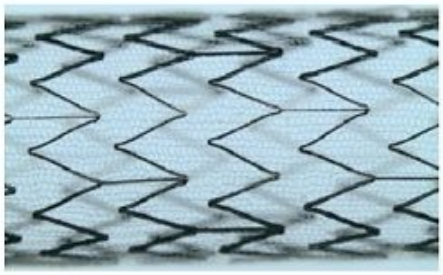
Source: JMP Securities, 2014

Carotid Solution

Emerging Market Opportunity

CGuard™ Embolic Prevention System

Combines stent and embolic protection in a single device



- CE marked
- Self-expanding nitinol stent
- Global market valued at $500M*
- Strong CARENET FIM data released 9/14 and 1/15
- Impressive all-comer data from PARADIGM presented 5/15
- Full launch planned for Q4 2015

*Source: JMP Securities, 2014

Positive CGuard™ Clinical Experience

CARENET (CARotid Embolic protection using microNET) FIM* Clinical Trial

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

CARENET Highlights: 30 day Results

- 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

CARENET Highlights: 6 mo Results

- 3.6% MACCE rate at 6 months (Comparative data 8.09%)
- 6 month ultrasound analysis was indicative of healthy healing without restenosis concern with patent external and internal carotid arteries

** FIM , First in Man*

Positive CGuard™ Clinical Experience

PARADIGM (Prospective evaluation of All-comer perRcutaneous cArotiD revascularization In symptomatic and increased-risk asymptomatic carotid artery stenosis using CGuard™ Mesh-covered embolic prevention system) Physician Initiated All-Comers Study

- Objective: To evaluate feasibility and outcome of routine anti-embolic stent system in unselected, consecutive carotid patients (all-comers)
- Investigator-independent neurological and angiographic evaluation
- 71 CGuard devices placed in 68 pts
- Device success: 100%; Procedure success: 100%
- MACCE (Death/stroke/MI) @ 48 hr: 0% @ 30 day: 0%
- Conclusions:
  - "> 90% all-comer carotid artery stenosis pts, including >50% symptomatic pts, can be treated using CGuard."

* FIM , First in Man

Strategic Distribution Partnership

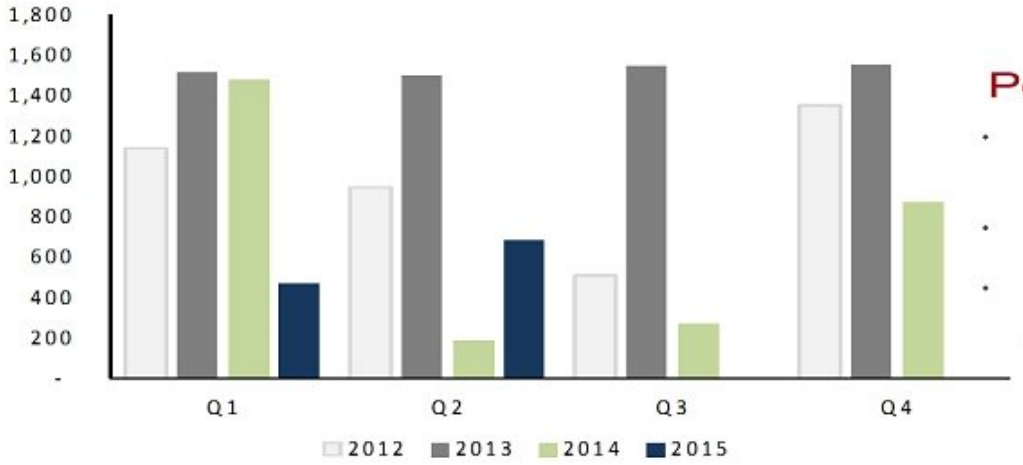
Rationale: Predictable, Sustainable & Profitable Revenue Growth

Penumbra

- Founded in 2005 as a Neurovascular company with a clinically-driven product development strategy. Very successful IPO in September.
- Reputation as the innovation leader in the neurovascular field
- Extending success beyond stroke into the periphery and neurosurgical markets
- Track record of consistent, profitable growth
- Management team with decades of vascular experience
- Entering carotid market to complement their stroke portfolio

Commercial Profile

Revenue Growth Driven by CGuard™ RX



Penumbra

- Late September 2015: Full Total Systems Solution Launch
- Key European Territories Targeted
- Opportunity to Increase Number of Target Territories

Note: Revenue in $000

Robust Pipeline

Expanding Indications with MicroNet™

Commercial
- CE Mark Cleared
- 12-month MASTER I, II

Commercial
- CE Mark Cleared
- CARENET Trial
- PARADIGM all-comer study
- CGuard FDA IDE protocol in draft form
- Penumbra Strategic Partnership

Exploring Market Opportunity

Exploring Market Opportunities:
- Flow Diverter
- Intra-Cranial Stent

2016E CE Mark Planned Submission for Flow Diverter

2017E CE Mark Planned Submission

CE Mark Planned Submission, Subject to Strategic Partner Support

**Planning & Development Phase*

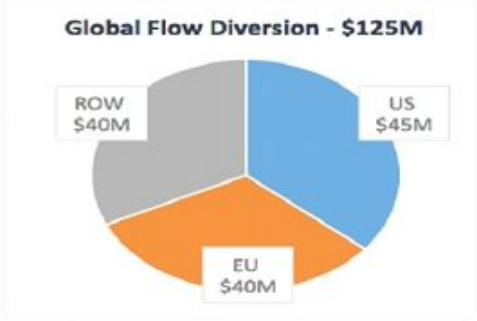
Neurovascular Market Opportunity

Innovation Leads Growth

Flow Diversion For Unruptured Brain Aneurysms

Next Generation Combination Technology

- Current designs have sub-optimal trackability and in vessel flexibility: metal on metal devices
- MicroNet has proven flow diversion effect with ultra low profile and improves device flexiblity to improve device deliverability



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

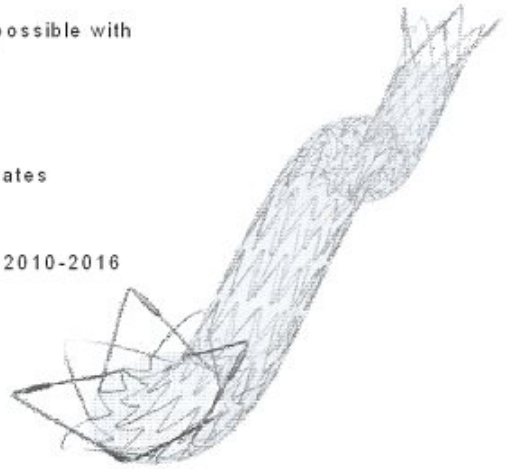
Our Significant Advantage Over Existing Flow Diverters

- 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

Advanced neurovascular technologies are highly valued as the market segment expands with improved device performance



Source: MRG

Neurovascular Market

High Strategic interest with attractive valuations

- Medtronic acquires Medina Medical for $150 million
- Stryker Acquires Surpass Medical for $135 million
- Covidien Acquires Chestnut Medical for $150 million *
- Medtronic Acquires Lazarus Effect for $100 million

*Based on milestones achieved as part of structured deal

Intellectual Property Portfolio

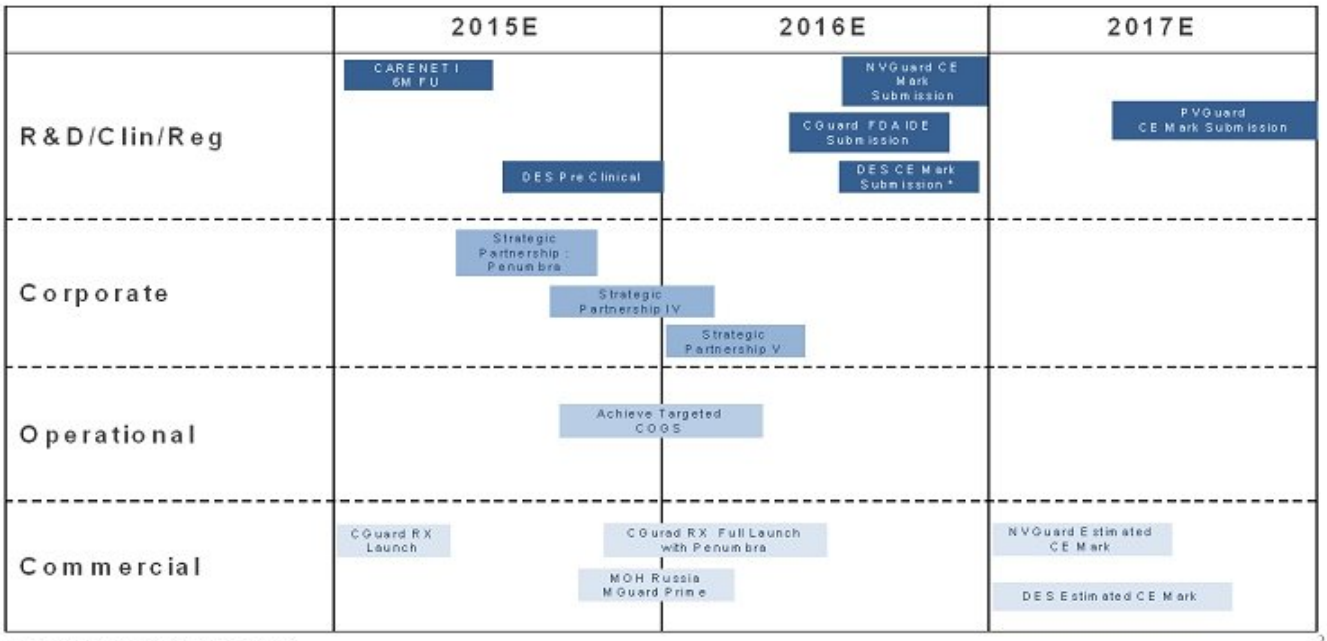
PATENT RIGHTS	Issued	Allowed	Pending
US	4	0	9
Rest of World (ROW)	13	3	16

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

Source: MRG

Target Milestones

Support & Execute on Growth Initiatives



*Subject to Strategic Partner Support

Investment Highlights

Effectively Executing a "Neck Up" Interventional Strategy

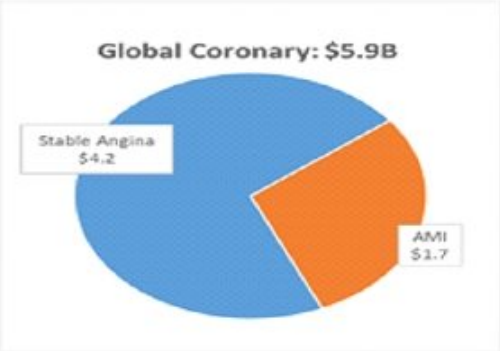
- 2015 return to revenue growth driven by the full launch of carotid platform through strategic distribution partnership with Penumbra, Inc.
- Operating and financial realignment inline with development and growth initiatives.
- Advancing into highly valued Neuro and Peripheral markets to leverage MicroNet technology into high growth segments.
- Expanding collaboration activities on multiple MicroNet technology applications.

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

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

Coronary MGuard™ EPS

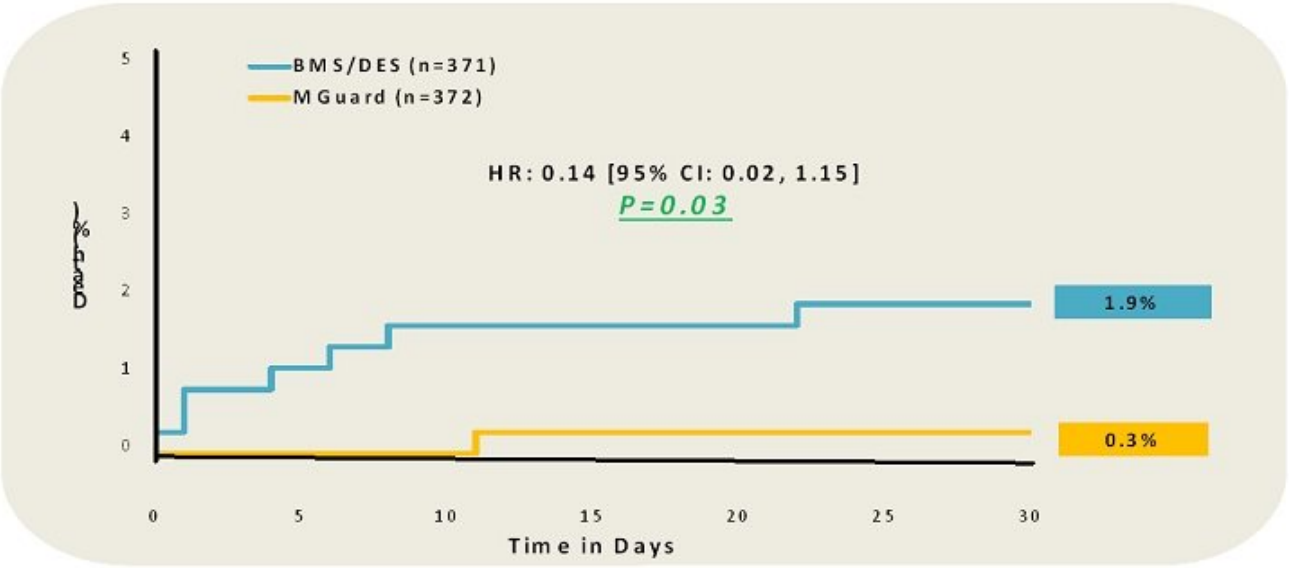
Improving AMI Patient Outcomes



- 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 MASTER I and MASTER II with data showing sustained mortality rates
- Coronary market to be pursued with strategic partner support

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

MASTER I & II Pooled: All Cause Mortality at 30 days (743 patients)



InspireMD

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