INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 03/05/14 for the Period Ending 03/05/14

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): March 5, 2014

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 March 2014

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: March 5, 2014

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

NYSE MKT: NSPR

March 2014

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) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payors for the Company's products, (viii) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) the Company's reliance on single suppliers for certain product components, (xi) 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 and (xii) 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. 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.

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

NYSE MKT: **NSPR**

Stock Price (2/28/14):	$3.13
52 Week Range:	$1.80 - 3.80
Shares Outstanding (2/28/14):	34.9 M
Market Capitalization	$109 M
Analyst Coverage	Cowen Group: Josh Jennings Oppenheimer & Co.: Steve Lichtman JMP Securities: Jose Haresco
Total Cash (12/31/13):	$17.5 M
US Headquarters	Boston, MA
International Headquarters	Tel Aviv, Israel

Leadership

EXECUTIVE TEAM

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

Craig Shore, CFO
- Pfizer
- General Electric

Eli Bar, CTO
- Nicast

Gwen Bame, VP Corporate Development
- Boston Scientific
- Covidien

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

Rick Olson, VP Sales
- Boston Scientific
- eV3/Covidien

BOARD OF DIRECTORS

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

Dr. James Barry
- VP, Corporate Research and Advanced 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

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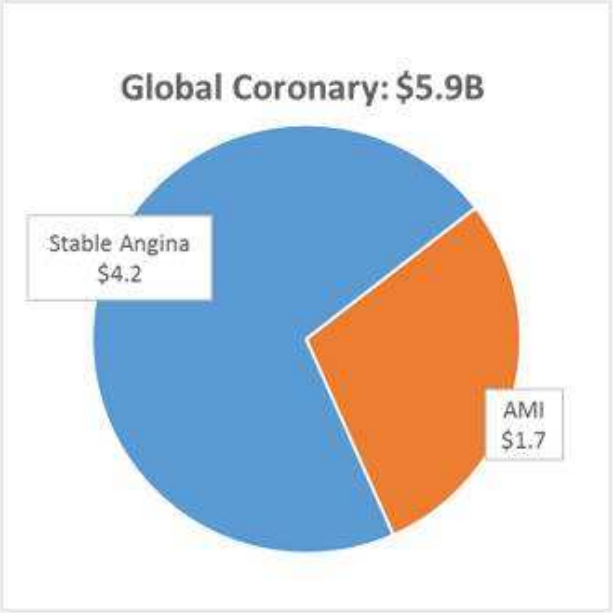
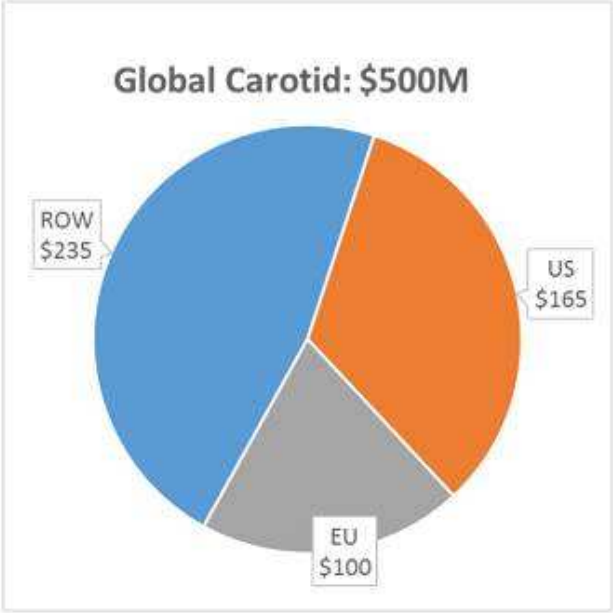
Global Market Values



- 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%)

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



- Current stents not specifically designed for embolic protection
- Mesh covered stent category emerging as immediate opportunity

Source: Health Research International, (2011)

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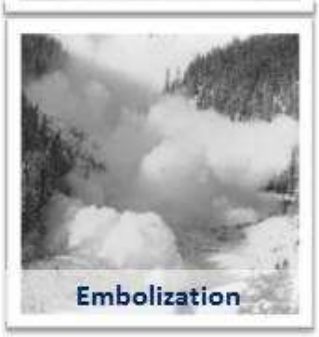
Current Coronary Problem


Pre Procedure


Embolization


Post Procedure

Minor heart attack treated with a Bare Metal Stent (BMS) or Drug Eluting Stent (DES) implant

Causes:

Debris can flow down stream, occluding small arteries "Distal Embolization"

Leading To:

Cardiac Mortality and Morbidity

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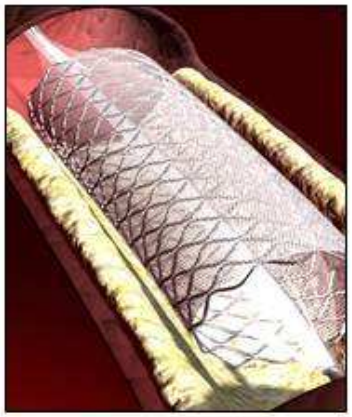
Technology

MGuard Embolic Protection System

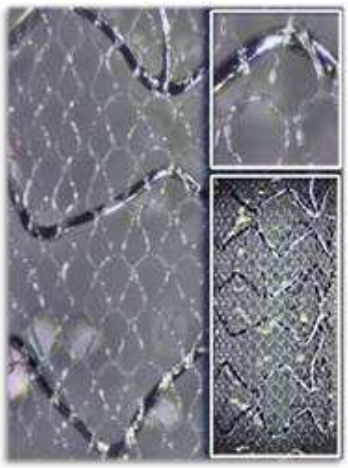
Combines stent and embolic protection in a single device

- Reduces risk of embolization by capturing potentially harmful debris against the artery wall
- Micro-particles then slowly re-enter the artery in a non-harmful way over approximately 30 days
- MicroNet acts as safety net by offering greater surface area coverage to prevent large debris flow
- Allows profusion 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



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Clinical Experience

Over 1,200 Patients Studied

Randomized – STEMI

- MICAMI (n=40)
- MASTER (n=432)

Single Arm – Vein Grafts & Native Vessels

- FIM (n=41)
- INSPIRE (n=30)

Single Arm – STEMI (& ACS)

- MAGICAL (n=60)
- PISCIONE(n=105)
- WEERACKODY (n=51)
- PREIS (n=24)
- ROMAGUERA (n=56)
- ANTHOPOULOS (n=73)

MASTER I Trial Highlights (432 Patients Studied*)

- Achieved primary end point
  - Superiority in ST Resolution – 57.8% vs. 44.7% (p-value = 0.008)
- Reduction in mortality rate at 12-months
  - Occurred in 2/217 (1.0%) patients with MGuard™
  - Occurred in 7/216 (3.3%) patients with BMS or DES
- Reduced Infarct size (30 Patients Sub-Study)
  - 17.1gm (MGuard™) vs 22.3gm (BMS/DES)

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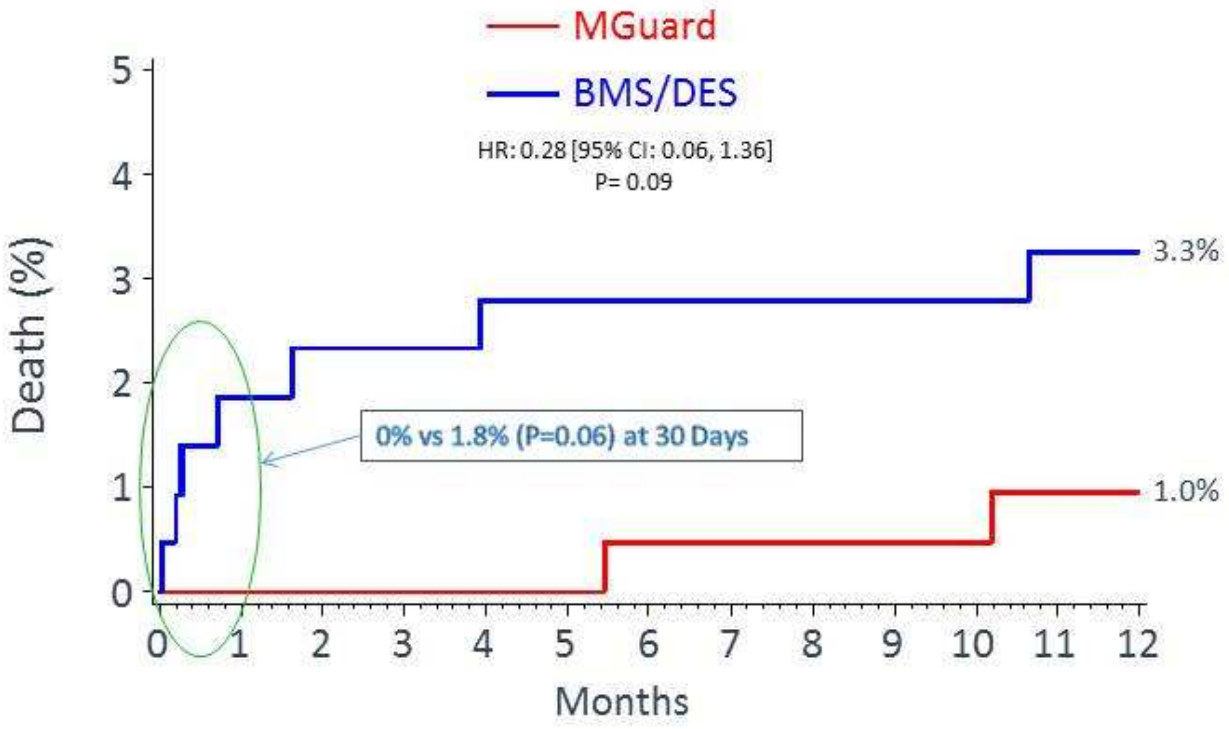
* Majority with MGuard – 12% MGuard Prime in MASTER EPS arm

All Cause Mortality at 12 Months



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MASTER II: US FDA PMA Trial

STATUS	• First patient recruited in Q3 2013 • International sites fully activated Q1 2014 • Anticipated enrollment completion end of 2014
OBJECTIVE	• Evaluate safety and efficacy of MGuard Prime Coronary vs. BMS and DES in STEMI
CO-PRIMARY ENDPOINTS	• Efficacy: Superiority in complete ST Resolution • Safety: Non inferiority in death and Target Vessel MI
DESIGN	• Multi-center (70 sites) • 35 North American sites, 35 international sites • Randomized
POPULATION	• 1,114, STEMI Randomized 1:1 vs. FDA approved BMS or DES • 300 patient MRI sub-study
PIs	• Gregg Stone, M.D. FACC, Columbia University • Jose Henriques, M.D., University of Amsterdam

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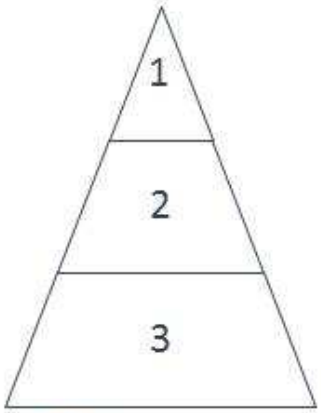
MGuard EPS Commercialization

The Embolic Protection Stent

A new stent category as the preferred solution for STEMI patients

- Received CE Mark for AMI indication; expect to submit for FDA approval post-MASTER II trial
- 2013 revenue of $6.1 million, a 56% increase over prior year
- Developing sales infrastructure to support a focused and phased selling approach in select high-volume markets

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 Brazil

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 clinical trial outcomes
- Japan - Pending successful clinical trial outcomes

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Product Development Pipeline

Therapeutic Area	Stage of Development	Market Size
Coronary	• CE mark received • 12-month MASTER I randomized data available October 2013 • FDA trial initiated • DES phase I initiated	• AMI Segment: $1.7B
Carotid	• CE mark received • CARENET enrollment Q2 2014	• Total Carotid: $500M
Peripheral Vasculature	• CE mark anticipated late 2014/early 2015	• Total Peripheral: $2B+
Aneurysmal	• Planned product	• Total Aneurysm: $350M+
Renal	• Planned product	• Total Renal: $100M+

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Coronary Drug Eluting Stent Development Strategy

Strategic Partnership: Attach MicroNet to clinically proven CE marked DES

- **Phase I:** Technical testing and feasibility
- **Phase II:** Animal testing
- **Phase III:** Clinical strategy

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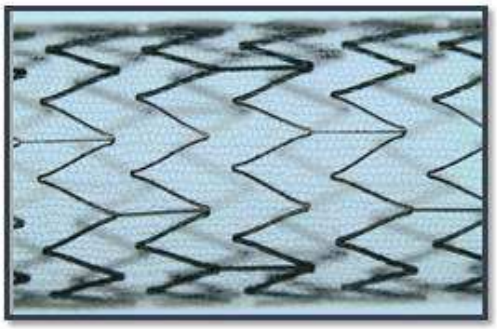
Carotid Development Program

CGuard Carotid Embolic Protection System



- CE marked
- Self-expanding nitinol stent
- Wrapped in InspireMD's MicroNet
- Current Global Market: $500M

CGuard CARENET Study

- CGuard CARENET (**CAR**otid **E**mbolic protection using micro**NET**) study
  - Multicenter study on the safety and efficacy of a novel mesh covered stent in 30 consecutive patients with symptomatic and asymptomatic carotid artery stenosis

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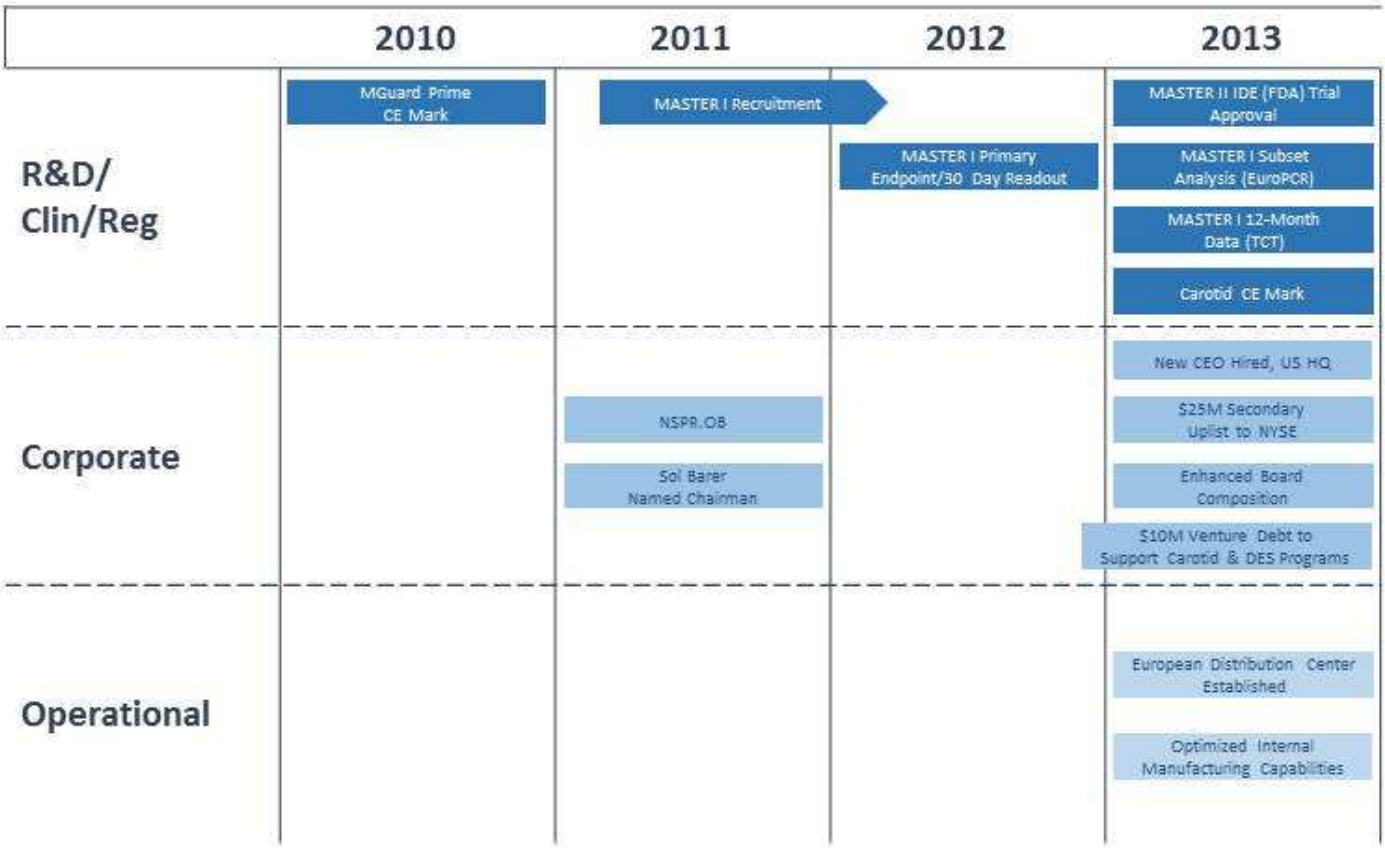
Milestones To-Date



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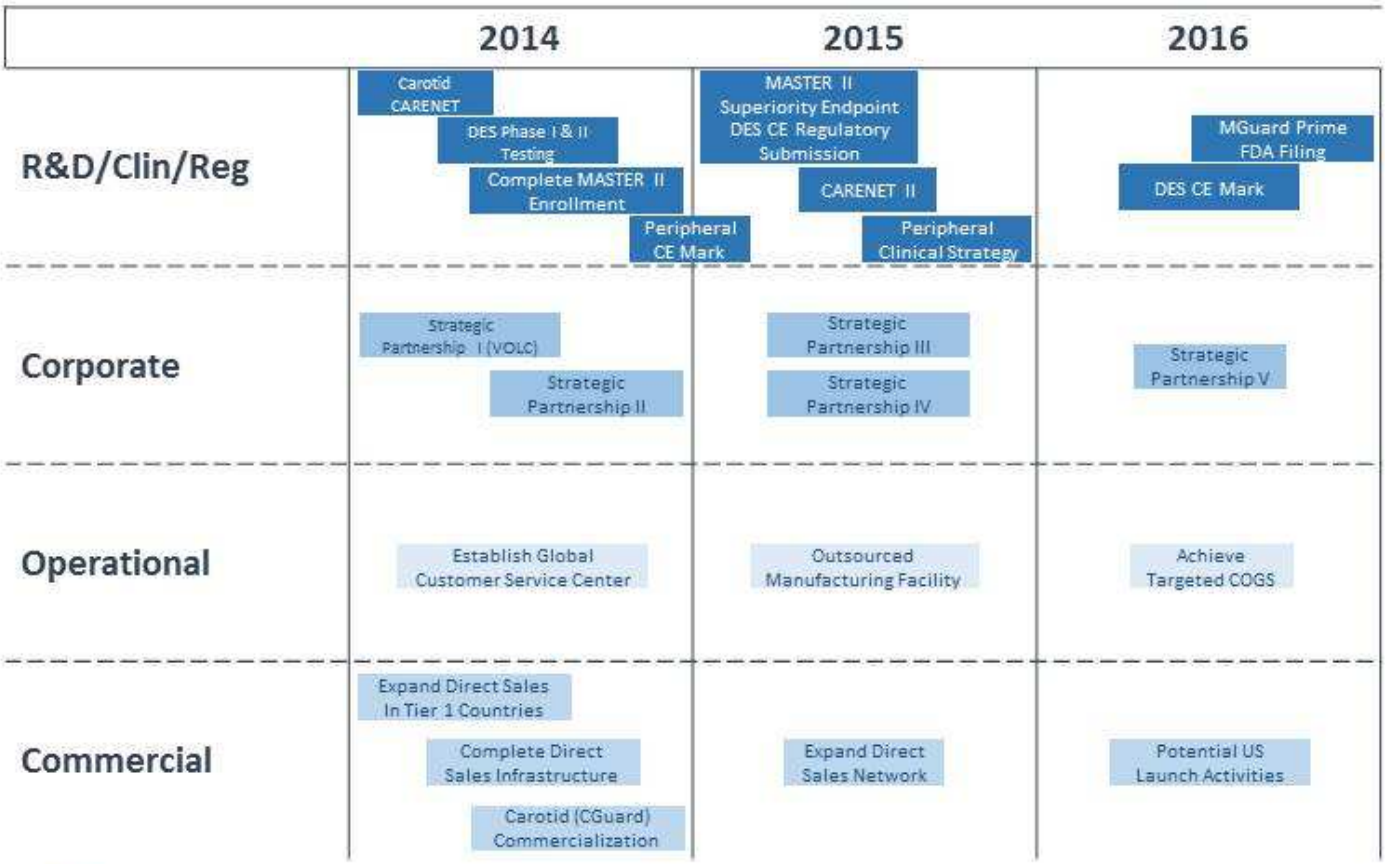
Anticipated Future Milestones



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Investment Summary

- Appointed new, experienced management and Board members with proven track records

- Proprietary platform technology addressing the multi-billion dollar global stent market
  - Initially targeting AMI market (i.e. heart attacks)
  - Early positive results with Carotid platform
  - Broad pipeline in development for multiple indications

- Pivotal 12-month clinical data released Oct 29, 2013 for the MASTER I trial
  - Achieved primary endpoint with sustained mortality benefit at 30 days, 6 months and 12 months
  - MASTER II US PMA trial to be completely enrolled by the end of 2014
  - Initiating CARENET carotid trial with data by Q3 2014

- Commercialization:
  - 12 month MASTER data supporting focused selling efforts in 14 – 18 countries
  - Building out sales infrastructure by mid 2014

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