INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/05/13 for the Period Ending 11/05/13

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): November 5, 2013

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.)

800 Boylston Street, 16th Floor Boston, MA	02199
(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 November 2013

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: November 5, 2013

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

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NYSE MKT: NSPR

November 2013

Disclaimer

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.

InspireMD

InspireMD

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

- NYSE MKT: NSPR
- Stock Price (10/31/13): $2.82
- Shares Outstanding (10/21/13): 34.5 Million
- Total Cash (6/30/13): $14.8 Million*

* Excludes venture debt of $10.0 million (10/24/2013)

Investment Highlights

- 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)
  - MGuard™ is the only stand alone stent technology proven to demonstrate a positive effect on STEMI patients in a randomized clinical trial
  - Broad pipeline in development for multiple indications
- Pivotal 12-month clinical data released Oct 29, 2013 for the MASTER trial
  - Achieved primary endpoint with sustained mortality benefit at 30 days, 6 months and 12 months
- Commercialization:
  - 12 month MASTER data to provide clinical platform to accelerate sales activities in key international markets
  - U.S. sales pending FDA approval and completion of MASTER II trial

Revolutionary Technology

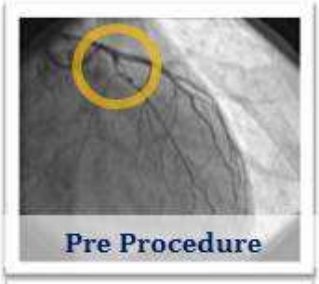
- Current stent technology:
  - Targets the Stable Angina patient (i.e. general chest pain from poor blood flow through the blood vessels in the heart)
  - Unstable Angina patients (i.e. AMI) represent complex clinical problem not addressed by current stent technologies

- InspireMD's MGuard™ is a game changing platform technology
  - Reduces mortality rate*
  - Reduces myocardial damage associated with AMI*
  - Based on proprietary MicroNet™ technology

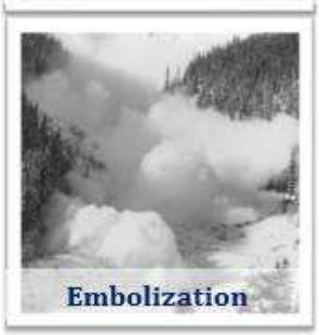
* Per the 12-month follow-up results from the MASTER trial

Suboptimal Standard of Care

Treating AMI



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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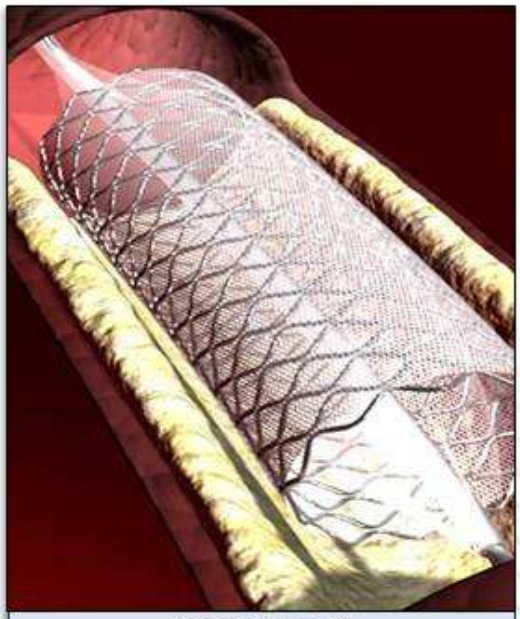
Technology Overview

- 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



After MGuard™
Particulate trapped behind mesh

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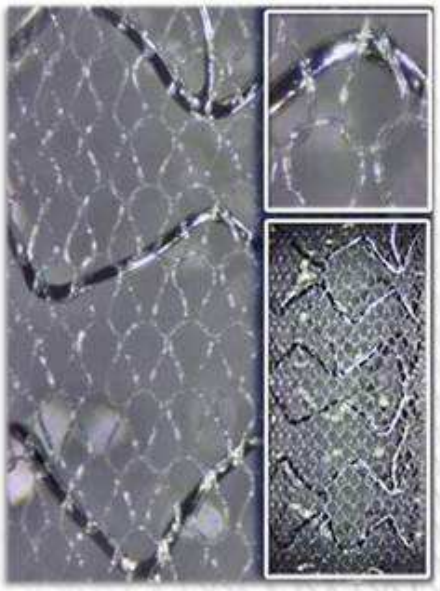
MicroNet™ Technology

Proprietary circular knitted mesh wraps around stent to protect patient from plaque debris flowing downstream upon deployment



Advantages of MicroNet™:

- Made of a single fiber from a biocompatible polymer, widely used in medical implantations
- Flexible structure
- Does not promote thrombosis

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InspireMD Pipeline

	Target Indication	Stage of Development	Market Size
Commercial	Coronary STEMI / AMI	• 12-month data released in October 2013 • Commercialization ramp anticipated • CE mark received • Seeking FDA approval by 2016	• AMI Segment: $1.7B
Developing	Coronary Drug Eluting	• Planned product	• Total Drug Eluting: $4.0B
	Carotid	• CE mark received	• Total Carotid: $250M
	Peripheral Vasculature	• CE mark anticipated in H2 2014	• Total Peripheral: $2B+
	Aneurysmal	• Planned product	• Total Aneurysm: $350M+
	Renal	• Planned product	• Total Renal: $100M+

MGuard™ Clinical Overview

Coronary EPS

- 6 single-center studies in Europe and South America
  - Consistent positive clinical outcomes
- MASTER Trial (**M**Guard™ for **A**cute **ST** **E**levation **R**eperfusion)
  - Multi-center, randomized clinical trial
  - Improved mortality, results confirmed*
- MASTER II (for FDA approval)
  - Began enrollment in July 2013
  - Enrollment expected to conclude in Q4 2014

* Per the 12-month follow-up results from the MASTER trial

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The MASTER Trial

MGuard™ for Acute ST Elevation Reperfusion

STEMI with symptom onset within 12 hours at
432 patients | 50 sites | 9 countries

PCI with BMS or DES

PCI with MGuard™

Recruitment:	7/2011 – 5/2012
Follow-up:	30 days, 6 months, 1 year
Primary endpoint:	ST-segment resolution at 60-90 minutes
Top Line Data:	8/2012
Detailed Data:	10/2012

Substudies

Cardiac MRI:	60 patients (30 in each arm) at 3-5 days
Angio FU:	50 patients in MGuard arm at 13 months

MASTER

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MASTER Trial Highlights

- 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*
  - 17.1gm (MGuard™) vs 22.3gm (BMS/DES)

*MRI Substudy – 60 patients

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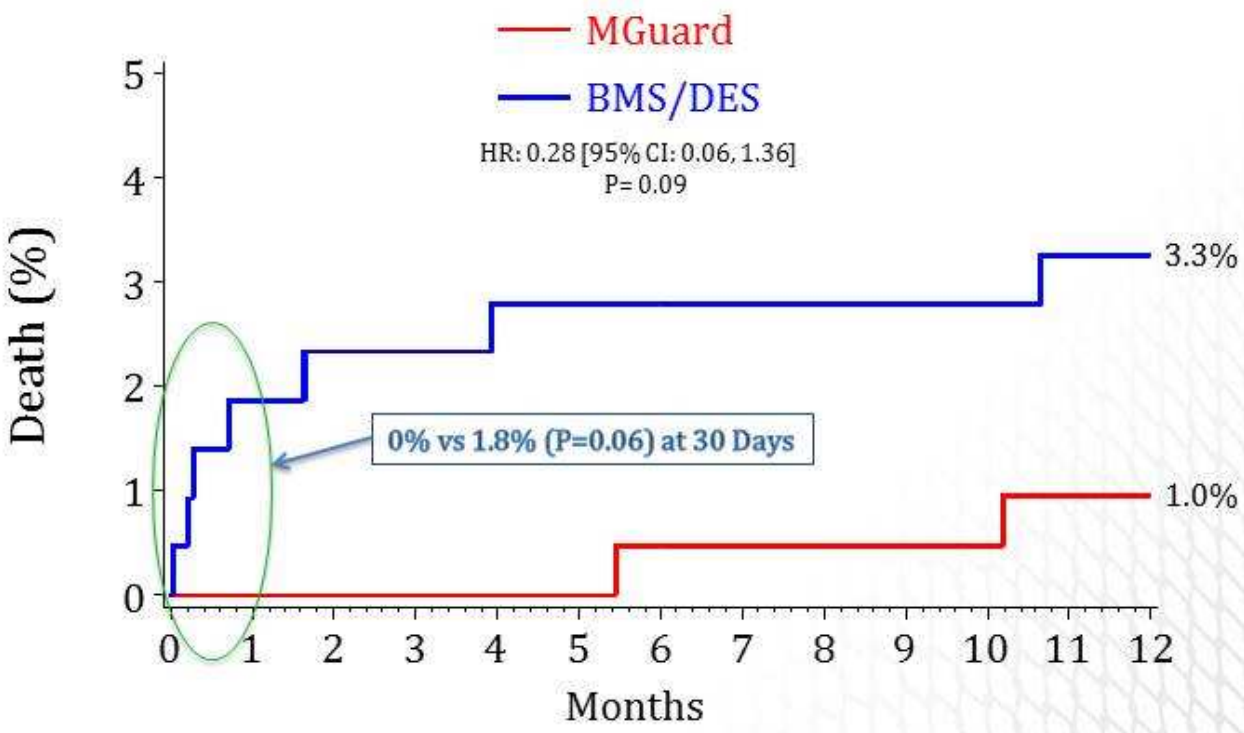
All Cause Mortality at 12 Months



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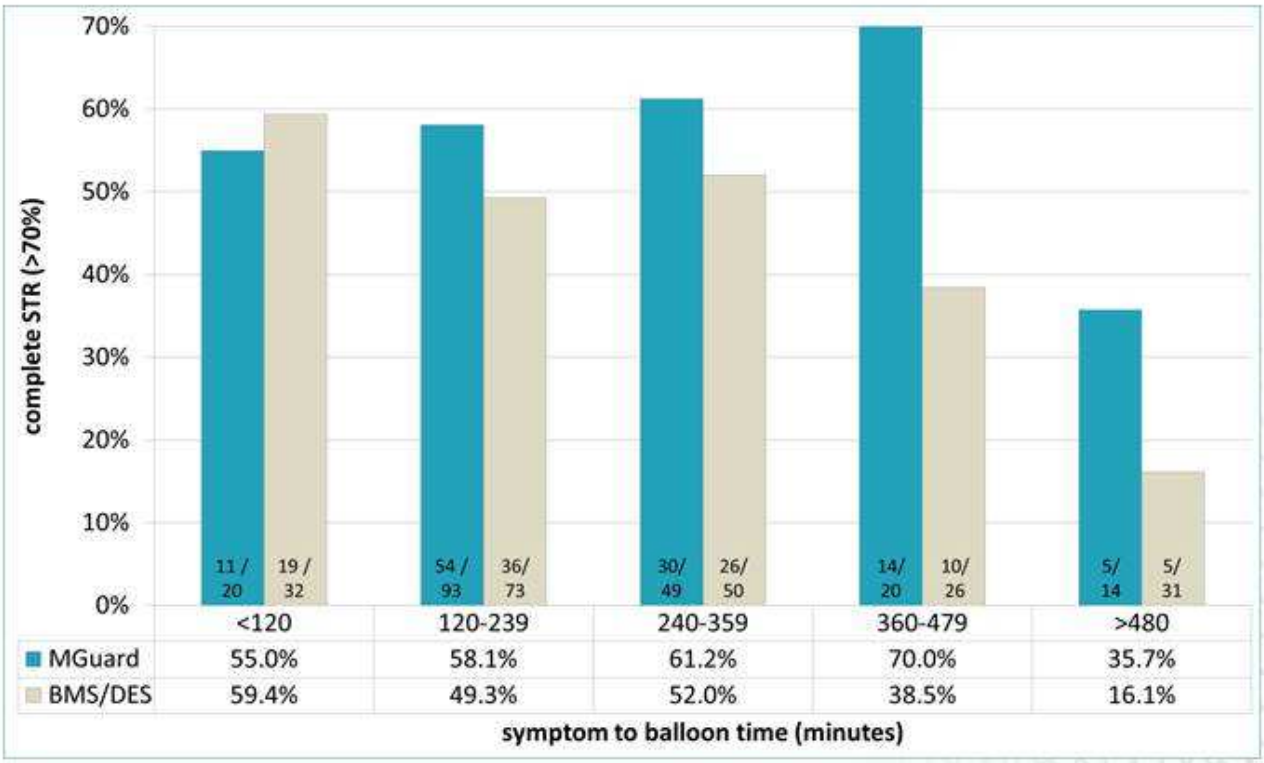
Efficacy of MGuard as a Function of Symptom Onset to Balloon Time



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MASTER II Trial

- **Status:** First patient recruited in July 2013
- **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), randomized trial
- **Population:** 1,100, STEMI Randomized 1:1 vs. FDA approved BMS or DES
- **PI's:**
  - Gregg Stone, M.D. FACC, Columbia University
  - Jose Henriques, M.D., University of Amsterdam

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MGuard™ EPS Commercialization

- Received CE Mark for AMI indication; expect to submit for FDA approval post-MASTER II trial
- Establishing Embolic Protection Stent (EPS) as a new stent category as the preferred solution for STEMI patients
- Developing sales infrastructure to support a focused and phased selling approach in select high-volume markets
  - Sales activities to accelerate with positive 12-month MASTER trial data
  - HealthLink Europe to support logistics and distribution capabilities

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MGuard™ EPS Sales Strategy

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

MGuard™ Manufacturing

- Platform technology (MicroNet™) produced in-house
- Bare metal stent and catheter manufactured by third-party
- Final product assembled at InspireMD facility, including attachment of proprietary mesh sleeve to the stent
- Recently consolidated facilities to capture additional margin
- Additional manufacturing expected to be fully outsourced

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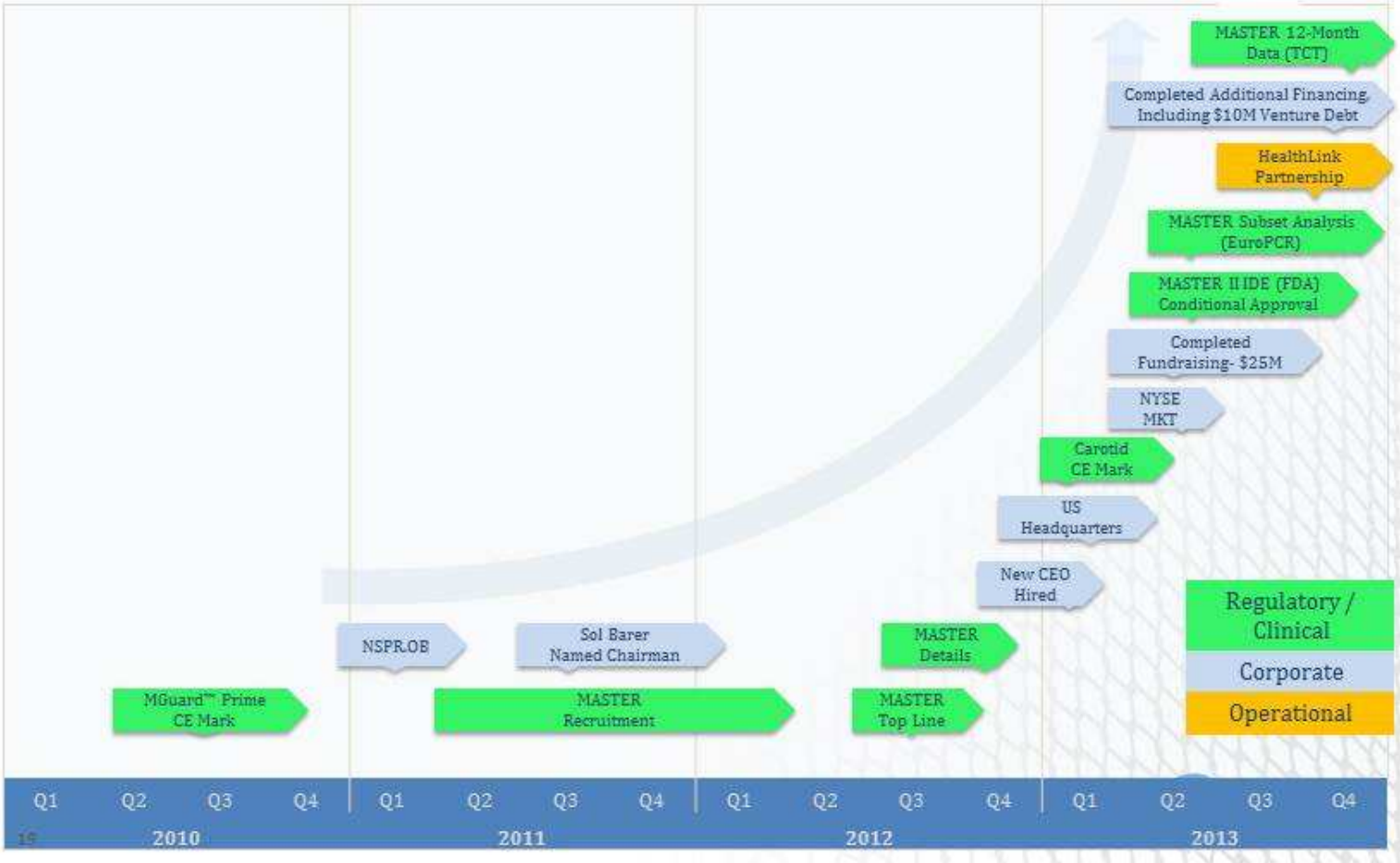
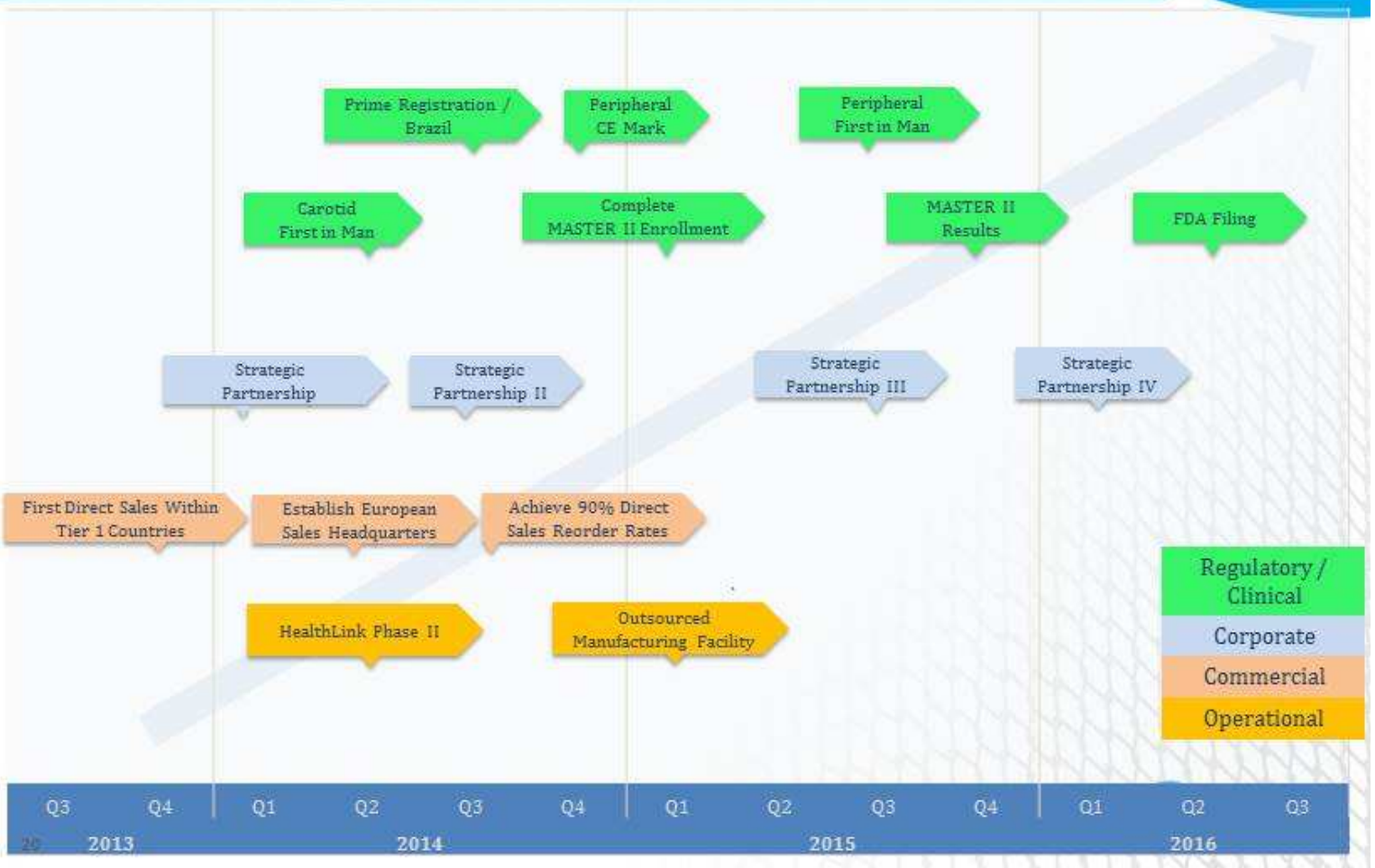
Milestones To-Date



Anticipated Future Milestones



Intellectual Property

- 7 Patent Families
- Filings in U.S. and overseas
- 37 patents
  - 6 granted (1 USA), 31 pending
- Stent platform: U.S. Freedom to Operate legal opinion

IP Protects Key Attributes of MicroNet™ Technology

Anchoring	Drug Delivery	Macro Structure	Fiber Width

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Experienced Leadership Team

Sol Barer, PhD
Chairman of the Board
- Former Chairman and CEO, Celgene, (NASDAQ: CELG)

Alan Milinazzo
President & CEO
- Orthofix
- Medtronic
- Boston Scientific

Campbell Rogers, PhD
Director
- CMO, Heartflow
- CSO, Cordis/JNJ
- Associate Professor, Harvard School of Medicine
- Recipient of grants from NIH and AHA

James Barry, PhD
Director
- EVP and COO, Arsenal Medical
- VP, Corporate Research and Advanced Technology Development at Boston Scientific
- Howmedica Division of Pfizer

Michael Berman, MBA
Director
- Pres. Boston Scientific/ Scimed
- Aetherworks
- Apnex
- Benechill
- Cardiosonic

Craig Shore, MBA
CFO
- Pfizer, Bristol Myers Squibb, and Dunn and Bradstreet, General Electric
- RIT Technologies (NASDAQ)

Eli Bar, BSc
CTO
- Product development
- R&D infrastructure
- Fully implantable VAD patent

Chaim Lotan, M.D., F.A.C.C. F.E.S.C
Medical Director
- Hebrew University
- Hadassah Medical Center

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Scientific Advisory Board

Prof. Gregg Stone
- Professor of Medicine at the Columbia University Medical Center
- Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapies at New York-Presbyterian Hospital, and CRF in New York, NY

Prof. Antonio Colombo
- Director of the Cardiac Catheterization
- Laboratory at Columbus Hospital
- Chief of Invasive Cardiology at San Raffaele Hospital, both in Milan, Italy

Prof. Dariusz Dudek
- Executive Board of the Working Group on Invasive Cardiology of the Polish Cardiac Society
- Associate professor of the Jagiellonian University, Krakow, Poland

Dr. Yaron Almagor
- Director of Cardiac Catheterization and Interventional Cardiology Laboratories at Jesselson Heart Center, Shaare Zedek Medical Center; Jerusalem, Israel

Prof. Elazer Edelman M.D., Ph.D., F.A.C.C
- Professor of Health Sciences and Technology at MIT. Cardiologist at the Brigham and Women's Hospital in Boston
- Directs the Harvard-MIT Biomedical Engineering Center (BMEC)

Dr. Martin B. Leon
- Director, Center for Interventional Vascular Therapy Columbia University Medical Center / New York-Presbyterian Hospital, New York.NY
- Professor of Medicine Columbia University College of Physicians and Surgeons New York, NY

Prof. Alexandre A. Abizaid
- Chief of Coronary Interventions at Institute Dante Pazzanese de Cardiologia in São Paulo, Brazil
- Associate-director of TCT (Columbia University, U.S.)

Prof. Eberhard Grube
- Professor of Medicine, Chief of the Department of Cardiology and Angiology at Siegburg Heart Centre, Germany

Dr. Edo Kaluski, MD, FACC, FESC
- Director of Cardiac Catheterization Laboratories and Invasive Cardiology at the University Hospital in Newark, New Jersey
- Co-founder of InspireMD

Prof. Chaim Lotan
- Head of The Heart Institute Hadassah University Medical Center.
- Chairman of the Ministry of Health Committee for Certification & Licensing of Coronary Stents

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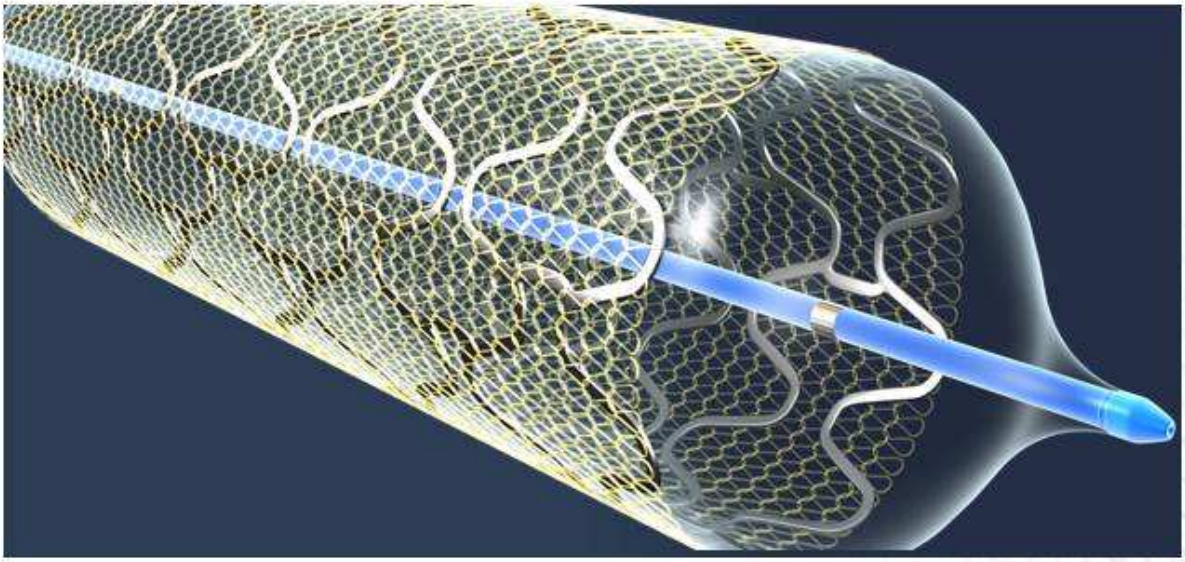
Thank You



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