INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 09/13/11 for the Period Ending 09/13/11

Telephone	(888) 776-6804
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): September 13, 2011

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	333-162168	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(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") is furnishing the text of presentation materials as Exhibit 99.1 to this report pursuant to Regulation FD promulgated by the Securities and Exchange Commission (the "SEC"). These materials will be used by the Company's management on September 13, 2011 at the Rodman & Renshaw Annual Global Investment Conference.

The information in this Current Report and the accompanying exhibits is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or 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.

The presentation slides contain "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, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) 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 (xi) 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, including the Company's Registration Statement on Form S-1 (File No. 333-174948), as amended. Investors and security holders are urged to read these documents free of charge on the SEC'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.

Item 9.01 Financial Statements and Exhibits.

Number	Description of Exhibit
99.1	Slide show presentation of InspireMD, Inc.

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: September 13, 2011

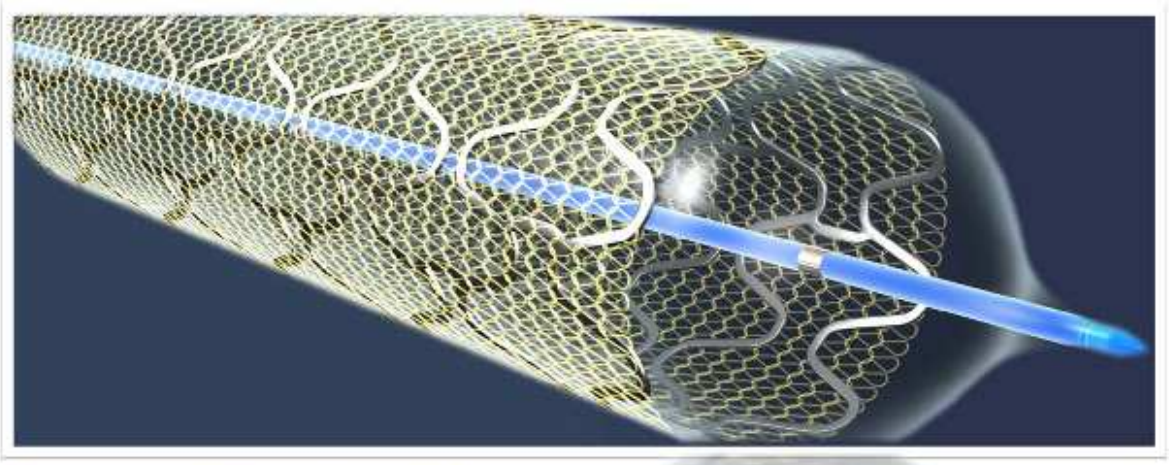
By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Number	Description of Exhibit
99.1	Slide show presentation of InspireMD, Inc.

InspireMD

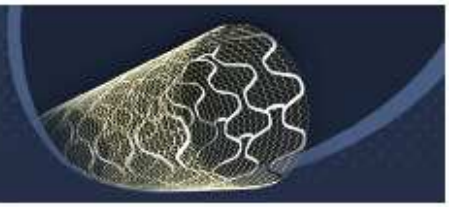
MGUARD



A stent solution that addresses an unmet need in the heart attack market

September 2011

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 is set forth in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's Registration Statement on Form S-1 filed with the SEC on August 26, 2011. Investors and security holders are urged to read these documents free of charge on the SEC'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.

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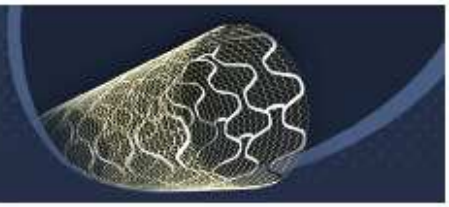
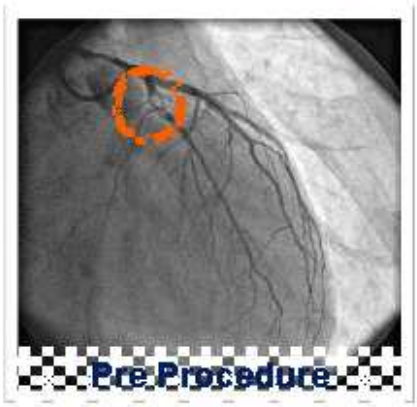
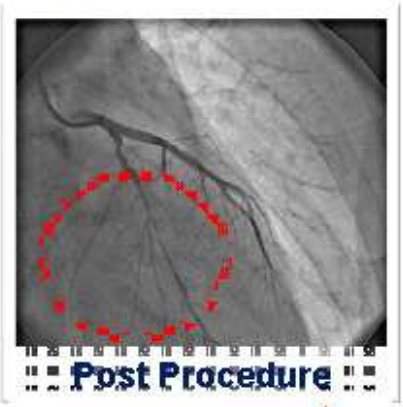
The Problem:



Heart Attacks (Acute MI) Can Be Deadly





Minor heart attack (single occlusion) Blood flow is not interrupted

Debris goes down stream closing tiny arteries

Downstream embolization leads to **major** heart attack

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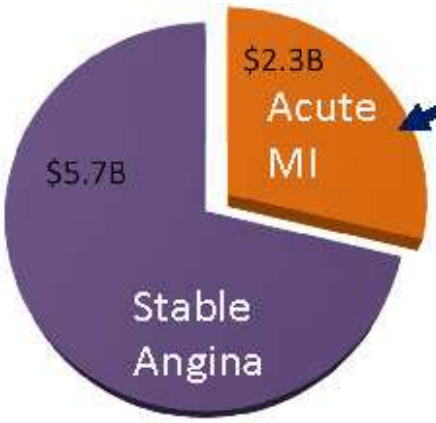
Addressing an Unmet Need:

Competition Neglects Huge and Growing Market



MGuard's Target Market

- **Inadequate** outcome as **Current** stents were designed primarily for the **Stable Angina** population
- Favorable growth demographics
  - Developing countries
  - Increase in awareness

Stable Angina (Chest Pain)

- Mature market
- Low-risk procedures
- Excellent outcomes from existing stent technology
- Dominated by three companies: Medtronic, Boston Scientific, Abbott

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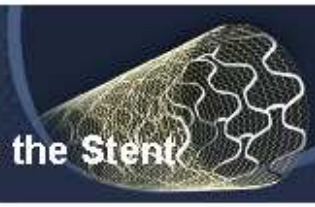
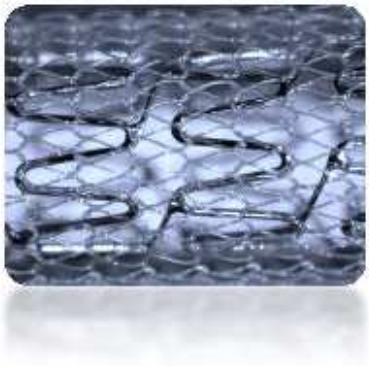
InspireMD's MGuard



Patent-Pending Mesh Net Technology that Wraps the Stent

- **Embolic protection**
  - Safer procedures by filtering plaque and debris
- **Spreads struts pressure**
  - Reduces injury
- **Identical deliverability to other stents**
- **Excellent endothelization**



Growing acceptance by physicians

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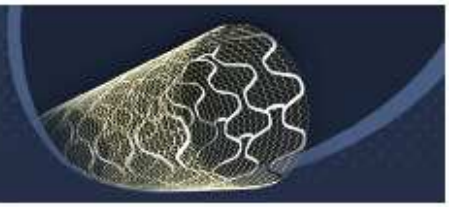
MGuard Historical Trials



Author/PI	No. of patients / Population		End Points
✓ **MAGICAL, Dariusz Dudek, Poland**	**60**	**STEMI**	**BLUSH, TIMI, MACE at 30 d, 6M, 1 YR**
✓ **Federico Piscione, Italy**	**100**	**STEMI**	**ST Resolution, BLUSH,**
✓ **Jain Ajay, Roshan Weerackody, UK**	**51**	**STEMI**	**TIMI, ST resolution, 1 YR MACE**
✓ **iMOS Registry, GB Danzi, Italy**	**203**	**STEMI**	**TIMI, Blush, MACE at 30d**
• First in Man, Eberhard Grube, Germany	41	Stable Angina, SVG	MACE at 30d, 6M
• Alexandre Abizaid, São Paulo, Brazil	30	SVG, ACS	MACE, TVR, at 30d, 1 YR
• Eugenio Martuscelli, Italy	22	SVG	TIMI
• Hana Vaknin-Assa, Ran Kornowski , Israel	41	SVG	TIMI, MACE at 30d, 6 months
• Varshitzky, Boguslavsky, Hadasaah, Israel	38	STEMI, SVG	TIMI

MGUARD:

- **586 patients under trials**
- **414 STEMI patients under trials**

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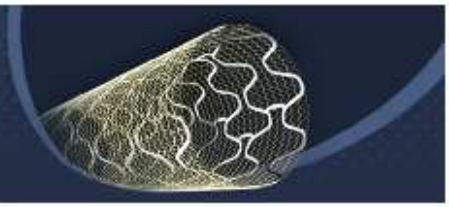
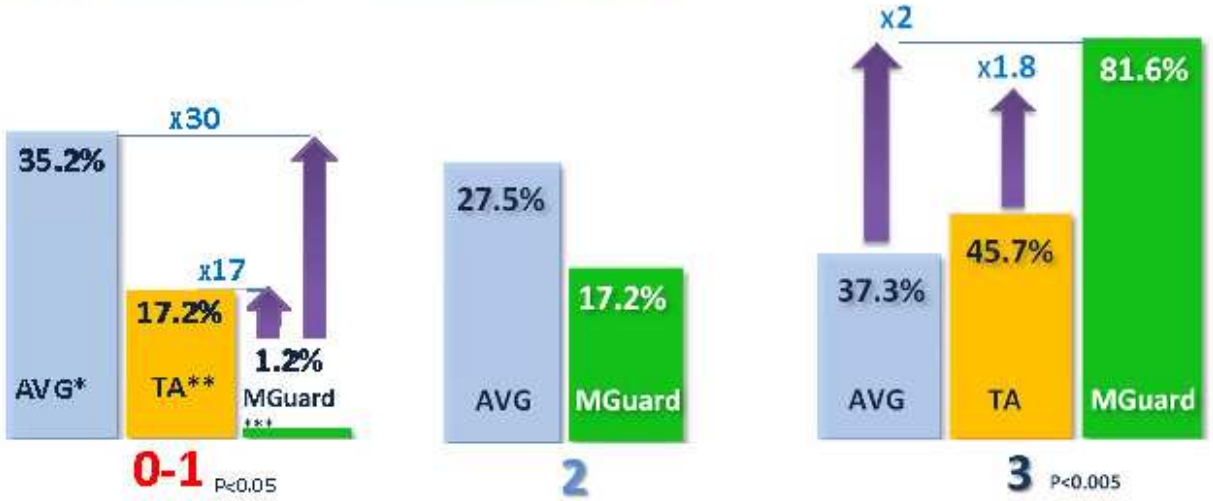
Blush Grade: MGuard Outperforms BMS/DES



MGuard 414 Acute MI/STEMI patients vs.
BMS/DES/Aspiration in ~5000 AMI patients in historical trials



Blush Grade "A strong predictor for adverse events"

* CONTROL, AVG 6 Trials, N=5124, CADILLAC, HORIZONS, TAPAS, EXPORT, EXPIRA, REMEDIA Trials
** TA, TAPAS Aspiration arm, N=535
*** MGuard, N=414, meta-analysis Company and investigator sponsored trials

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MGuard advantage in all Major Adverse Cardiac Events

Major Adverse Cardiac Events

- CONTROL, AVG 6 Trials, N=5124
-- Horizons Trial DES ARM, N=2257
--- Horizons Trial (AVG BMS & DES Outcome)
--- MGuard, N=414, , **meta-analysis Company and investigator sponsored trials**

MACE: Cardiac Death, Myocardial Infarction (heart attack) and TLR

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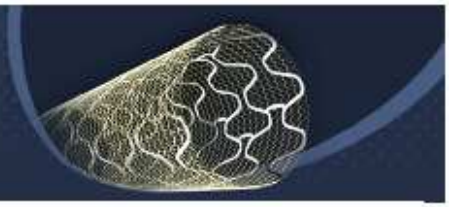
Establishing MGuard Superiority



	MASTER TRIAL	FDA
Enrollment Start-End	Q3/2011 – Q2/2012	Q2/2012 – Q3/2013
Objective	**Superiority** over **BMS** and **DES** in achieving better myocardial reperfusion	**Superiority** over **BMS** in better myocardial reperfusion
Primary End Points	**21% increase** in frequency of complete **ST resolution** from 60% to 73%	**30% increase** in **BLUSH Grade3** from 40% to 51%, non inferiority in TVF
Secondary End Points	Blush, TIMI, 30d; MACE at 6M; 1YR	MACE at 1YR
Follow Up	12 months	12 months
Population	**432**, **STEMI**, Randomized 1:1 vs. **BMS/DES**	**654**, **STEMI** Randomized 2:1 vs. **VISION stent (BMS)**
Chairman, PIs	Chairman: Gregg W. Stone (Columbia University, USA), PIs: Alexandre Abizaid (Brazil), Dariusz Dudek (Poland), Sigmund Silber, (Germany)	Chairman: Donald Cutlip Harvard Clinical Research Institute (HCRI)
Status	Enrolling	Protocol approval pending

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Inspire Intellectual Property

10 Patents (pending)

- First patent priority date: **May 2005**
- Initial filing: PCT, US,
- Stent Platform has US **freedom to operate legal opinion**

IP protects key attributes of mesh technology:

Anchoring	Snow shoe effect	Drug delivery	Macro structure	Minimal fiber width for excellent endotilization

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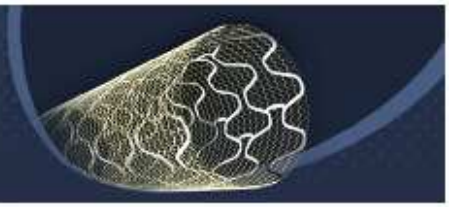
MGuard Positioning



- ✓ **Price: ~Drug Eluding Stent**
- ✓ **Majority of cases: Acute Coronary Syndromes**
- ✓ **MGuard is becoming a 3rd Tool Creates viable stent option for heart attacks**

Actual European catheter lab cabinet and stent inventory

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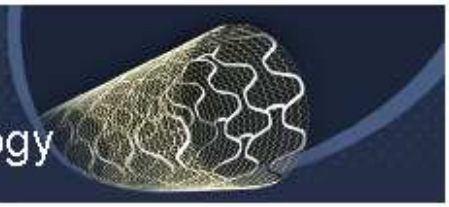
Product Pipeline

Building on InspireMD's Platform Technology



Product Candidate	Addressable Market	Approval Stage
MGuard + MGuard Prime	$2.3B	Launched in Europe, South America, Canada, Australia →
Carotid MGuard	$3.0B	→ CE Mark by Q1/2012 →
Peripheral MGuard	$1.0B	→
Drug Eluding Mesh	$5.5B	→
Cerebral Aneurisms	$1.0B	→

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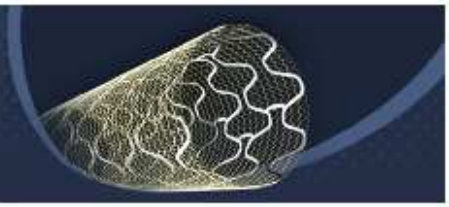
InspireMD Timeline



- **Initial** Clinical validation
- Initial sales

US public listing NSPR.OB

Filed NASDAQ Listing

US LAUNCH

Sales Inflection point

IDE meeting (FDA)

PMA filing

2005-2009 | 2010 | 2011 | 2012 | 2013 | 2014

Initiate MASTER Trial

Carotid CE Mark

MASTER trial Primary endpoint

Complete FDA clinical study

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Executive Management

CEO
Ofir Paz, MSEE/MBA

- Proven entrepreneur with strong track record of creating shareholder value
- CEO and Founder of Peach Networks, acquired by Microsoft in 2000
- Headed Microsoft TV Platform Group in Israel from 2000 - 2002
- Director of several high tech and medical startup companies since 2002
- Officer in Israeli Defense Force

President
Asher Holzer, PhD

- Over 25 years of experience in advanced medical devices
- Johnson & Johnson's Worldwide Carto System Manager
- Leadership roles with Biosense and Kevex Corporation
- CEO and founder of Adar Medical, an investment firm specializing in medical device startups.
- Led investments in Cyber Stent, Vasculogix, NVR, and Theracoat.
- Officer in Israeli Defense Force

CTO if InspireMD, Ltd.
Eli Bar, BSc

- Over 15 years experience in medical device product development, including top-level executive positions
- Expertise in building complete R&D infrastructure & team management
- Numerous inventions including a synthetic vascular graft for femoral and coronary artery replacement, a covered stent, and a fully implantable VAD

CFO
Craig Shore, MBA

- Over 25 years experience in financial management in the USA, Europe and Israel
- Served in various senior financial and general management roles at Pfizer, Bristol Myers Squibb, and Dunn and Bradstreet
- Experience includes raising capital both in the private and public markets
- Former CFO of RIT Technologies (NASDAQ)

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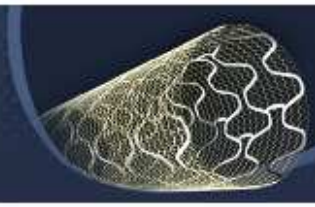
Financial Summary



- **NSPR.OB common stock listed on OTCBB**
- **Private Placement Mar-Apr 2011**
  - 7.4 MM shares at $1.50
  - 3.7 MM warrants at $1.80 exercise price
- **$8.4 MM cash balance***
- **64.2MM shares outstanding****

*As of June 30, 2011
**Fully diluted share count is 81.1 MM including warrants

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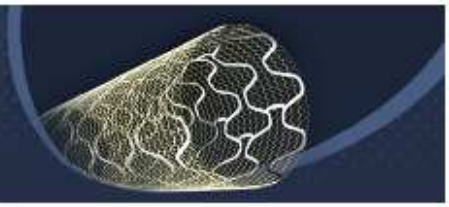
MGuard Highlights



- **Addressing the $2.3B Acute MI Market**
  - ~2M patients/yr, high risk, un-met need,
  - limited competition
  - Favorable demographics for growth
- **Great Adaptation**
  - CE Mark Approved
  - ~20,000 (Q2/2011) stents sold, ~15,000 deployed in First World countries
  - Encouraging outcomes compared to the industry
- **Path to Global Distribution**
  - Pursuing FDA approval by 2014
  - Partnered with Harvard Clinical Research Institute for the FDA

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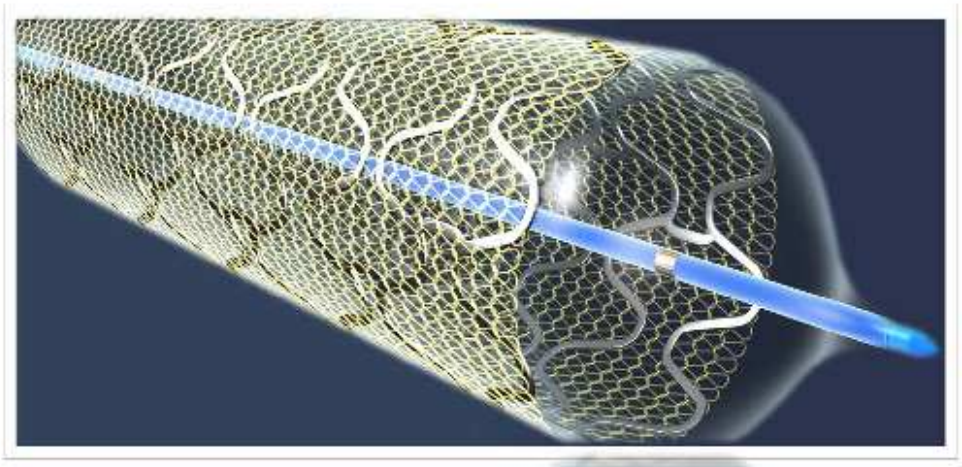
Thank You



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