# INSPIREMD, INC.

## FORM 8-K
(Current report filing)

Filed 05/08/13 for the Period Ending 05/08/13

| | |
|---|---|
| Address | 321 COLUMBUS AVENUE<br>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): May 8, 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.) |

| 4 Menorat Hamaor St.<br>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 2.02 Results of Operations and Financial Condition.**

On May 8, 2013, InspireMD, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2013. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 7.01 Regulation FD Disclosure.**

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 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, which is furnished pursuant to Item 2.02, and Exhibit 99.2, which is furnished pursuant to Item 7.01, shall not be deemed to be "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, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Earnings release dated May 8, 2013. |
| 99.2 | Investor slide show presentation dated May 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: May 8, 2013

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

**EXHIBIT INDEX**

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**InspireMD Reports Financial Results For Period Ended March 31, 2013**

***- Revenue increased 33% over prior year -***
***- Several key milestones achieved -***

**BOSTON and TEL AVIV, MAY 8, 2013** — InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection stents, today announced financial results for the three month period ended March 31, 2013, the third quarter of its 2013 fiscal year.

Revenue for the period increased by 33% over the March 31, 2012 quarter, reflecting the impact of several new marketing initiatives leveraging positive validation from the MASTER I trial of the Company's MGuard™ Embolic Protection Stent (EPS™) published in the November 6, 2012 edition of the peer-reviewed *Journal of American College of Cardiology (JACC)*, Vol. 60, No. 19. Authors of the study concluded that, "among patients with acute STEMI ( **ST** Segment **E** levation **M** yocardial **I** nfarction) undergoing emergent PCI enrolled in the present multicenter, randomized, controlled trial, the MGuard Embolic Protection Stent (EPS) compared to standard metallic stents resulted in superior rates of epicardial coronary flow and complete STR, with trends present toward reduced microvascular obstruction, infarct size and mortality."

Alan Milinazzo, President and CEO of InspireMD, said, "Since joining the Company on January 3 rd , we have made significant progress in key strategic areas of the business. In addition to a solid increase in quarterly revenues, we obtained the CE Mark for our carotid stent and we strengthened our board and executive management team. Momentum continued in April as we re-capitalized the Company, uplisted to the NYSE MKT and received regulatory approval to begin enrolling patients in our MASTER II clinical trial. These achievements represent a very good start to 2013 and we expect to continue to deliver strong results on multiple fronts throughout the year."

**Financial Highlights for the Quarter Ended March 31, 2013**

—Revenue for the quarter ended March 31, 2013 totaled $1.5 million, an increase of 33% over the $1.1 million recorded in the same period in 2012. The increase was the result of improved selling activities in key European countries.

—Gross profit for the March 31, 2013 period increased 49% to $840,000, compared to $564,000 for the March 31, 2012 period. The increase was due to higher revenue and gross margins, which increased from 50% to 55% due to a higher average selling price and lower cost per unit sold.

—Total operating expenses for the March 31, 2013 period were $4.1 million, compared to $3.7 million in the March 31, 2012 period, an increase of $400,000. With enrollment for the MASTER I trial completed, as well as a timing gap between the pre-clinical phase and the start of the recruitment phase of the FDA trial, R&D expenses for the March 31, 2013 period decreased by approximately $500,000, or 33%, compared to the March 31, 2012 period. This decrease was offset by an 81% increase in sales and marketing expenses as we expanded our sales activities worldwide, and a 23% increase in G&A expenses due mainly to an increase in share-based compensation and salary expenses.

—The loss from operations for the March 31, 2013 period was $3.2 million, compared to $3.1 million for the March 31, 2012 period.

—The net loss for the period ended March 31, 2013 totaled $4.9 million, or $0.27 per basic and diluted share, compared to a net loss of $3.1 million, or $0.18 per basic and diluted share in the period ended March 31, 2012. The increased net loss for the quarter just ended resulted primarily from a roughly $400,000 increase in operating expenses, and $1.7 million in financial expenses related to debenture amortization costs and anti-dilution rights expenses. The weighted average number of shares of common stock used in computing net loss per share (basic and diluted) was 18.2 million for the quarter ended March 31, 2013, and 17 million for the quarter ended March 31, 2012.

—At March 31, 2013, cash and cash equivalents was approximately $2.5 million, compared to $10.3 million at June 30, 2012. On April 16, 2013, the Company completed an underwritten public stock offering, providing net proceeds of approximately $22.6 million.

**Key Activities; March 31, 2013 Period**

Alan Milinazzo, a 15-year veteran of the interventional cardiology industry, joined InspireMD on January 3 rd as President, Chief Executive Officer and a member of the board. Mr. Milinazzo was instrumental in the launch of ENDEAVOR , Medtronic, Inc.'s first drug eluting stent platform which has since generated more than $1 billion in revenue. He previously spent 12 years in executive positions at Boston Scientific Corporation, another major stent producer, serving as Vice President of Marketing at its $200 million SCIMED European unit, responsible for product launches, clinical programs and regulatory strategies. Most recently he served as President and Chief Executive Officer of Nasdaq-listed Orthofix International N.V., a position he was promoted to in 2006 after being hired a year earlier as Chief Operating Officer. During his tenure at Orthofix, he transformed it into a category leader in novel spine and orthopedic stem cell therapy. Total company revenue grew from $300 million to $580 million and profits nearly doubled.

Since joining InspireMD, he has been instrumental in completing a $25 million equity raise, and in leading the creation of new sales, marketing and corporate strategies; goals and programs intended to position the Company for near and long-term growth as a leader in the worldwide stent market.

—The Company continues to strengthen its commercial activities with an expanded sales and marketing organization and new distributor relationships, in order to leverage the MASTER I trial's initial outcomes, MGuard EPS product line expansions and new regulatory approvals.

—Michael Berman, a former Group President and Executive Committee member of Boston Scientific, joined InspireMD's board of directors in February. Since leaving Boston Scientific, he co-founded or was a founding director of seven medical technology companies, three of which sold for more than $350 million, plus $100 million in contingent payments.

—The Company received CE Mark approval for its self-expanding Nitinol carotid EPS, further validating the MGuard MicroNet technology and strengthening its distributor and partnership strategy in the near term.

**Recent Events**

—On April 16, the Company completed an underwritten public offering of 12.5 million common shares, raising net proceeds of approximately $22.6 million. A portion of the proceeds were used in connection with the retirement of the Company's outstanding debentures and the Company intends to use the balance of the proceeds to support the worldwide commercialization of the MGuard EPS, to pursue FDA approval in the U.S. of the MGuard EPS and for general corporate purposes. Concurrent with this funding, the Company's shares commenced trading on the NYSE MKT.

—On April 19, Gwen K. Bame joined the Company as Vice President of Corporate Development, a new position created to strengthen the Company's focus on executing strategic programs and partnerships designed to meet the Company's ambitious global growth objectives. Ms. Bame, who previously held executive positions with Boston Scientific and Covidien, is expected to identify and negotiate in/out licensing agreements, analyze strategic partnerships and structure joint ventures worldwide.

—On April 23, the Company announced it received approval with conditions from the FDA to commence a pivotal trial in support of its IDE application. An approval with conditions indicates the FDA concurs with the overall trial design and, while minor details are being finalized, it allows the Company to initiate enrollment in the randomized MASTER II IDE trial of patients suffering from ST Elevation Myocardial Infraction (STEMI). The principal investigators for the 1,114-patient trial, which will be conducted at 70 sites in the U.S. and Europe, will be Gregg Stone, MD, of the Cardiovascular Research Foundation in New York and Jose P.S. Henriques, MD, of the Academic Medical Center Amsterdam in The Netherlands.

**Upcoming Events**

InspireMD will host a symposium with key opinion leaders to review six month follow up data from the Company's multi-center MASTER trial of the MGuard Embolic Protection Stent. The meeting will take place at the EuroPCR meeting in Paris, France on Thursday, May 23 rd at 12:00pm Paris time.

**About Stenting and MGuard™ EPS™**

Standard stents were not engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

The MGuard EPS is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

While offering superior performance relative to standard stents in STEMI patients with regard to ST segment resolution, the MGuard EPS requires no change in current physician practice - an important factor in promoting acceptance and general use in time-critical emergency settings.

**About InspireMD, Inc.**

InspireMD is a medical device company focusing on the development and commercialization of its proprietary stent system technology, MGuard. InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

MGuard EPS is CE Mark approved. It is not approved for sale in the U.S. by the Food and Drug Administration (FDA) at this time.

**Forward-looking Statements:**

This press release 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, 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 (xii) 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 Transition Report on Form 10-K/T 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.

# # #

Financial Tables Follow

**CONSOLIDATED STATEMENTS OF OPERATIONS** [(1)]
(U.S. dollars in thousands, except per share data)

| | Three months ended March 31, | | Nine months ended March 31, | |
|---|---|---|---|---|
| | **2013** | **2012** | **2013** | **2012** |
| **Revenues** | $ 1,514 | $ 1,138 | $ 3,373 | $ 4,416 |
| Cost of Revenues | 674 | 574 | 1,451 | 2,046 |
| **Gross Profit** | 840 | 564 | 1,922 | 2,370 |
| Operating Expenses: | | | | |
| Royalties buyout expenses | | | 918 | |
| Other research and development expenses | 907 | 1,349 | 3,109 | 2,730 |
| Selling and marketing | 804 | 445 | 2,412 | 1,373 |
| General and administrative | 2,340 | 1,896 | 6,341 | 11,780 |
| Total operating expenses | 4,051 | 3,690 | 12,780 | 15,883 |
| Loss from Operations | (3,211) | (3,126) | (10,858) | (13,513) |
| Expenses related to revaluation of contingently redeemable warrants and others, net | 402 | | 106 | |
| Expenses related to interest on convertible loan and other financial expenses (income) | 1,290 | (11) | 3,316 | 136 |
| Loss before tax expenses (income) | (4,903) | (3,115) | (14,280) | (13,649) |
| Tax Expenses (income) | (18) | 25 | 31 | 7 |
| **Net Loss** | $ (4,885) | $ (3,140) | $ (14,311) | $ (13,656) |
| Net loss per share – basic and diluted | $ (0.27) | $ (0.18) | $ (0.81) | $ (0.82) |
| Weighted average number of shares of common stock used in computing net loss per share – basic and diluted | 18,196,083 | 17,044,737 | 17,662,175 | 16,596,379 |

**CONSOLIDATED BALANCE SHEETS** [(2)]
(U.S. dollars in thousands)

| | March 31, 2013 | June 30, 2012 |
|---|---|---|
| **ASSETS** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 2,514 | $ 10,284 |
| Restricted cash | 91 | 37 |
| Accounts receivable: | | |
| Trade | 2,146 | 1,824 |
| Other | 278 | 264 |
| Prepaid expenses | 91 | 93 |
| Inventory: | | |
| On hand | 1,982 | 1,744 |
| On consignment | | 63 |
| **Total current assets** | 7,102 | 14,309 |
| Property, plant and equipment, net of accumulated depreciation and amortization | 467 | 462 |
| Other non-current assets: | | |
| Deferred issuance costs | 951 | 961 |
| Funds in respect of employee rights upon retirement | 380 | 282 |
| Royalties buyout | 897 | |
| **Total other non-current assets** | 2,228 | 1,243 |
| **Total assets** | $ 9,797 | $ 16,014 |

| | March 31, 2013 | June 30, 2012 |
|---|---|---|
| **LIABILITIES AND EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accruals: | | |
| Trade | $ 416 | $ 441 |
| Other | 2,885 | 2,925 |
| Advanced payment from customers | 177 | 174 |
| Deferred revenues | 10 | 10 |
| Convertible loan | 7,385 | |
| **Total current liabilities** | 10,873 | 3,550 |
| Long-term liabilities: | | |
| Liability for employees rights upon retirement | 495 | 354 |
| Convertible loan | | 5,018 |
| Contingently redeemable warrants and others | 1,832 | 1,706 |
| **Total long-term liabilities** | 2,327 | 7,078 |
| **Total liabilities** | 13,200 | 10,628 |
| Equity (capital deficiency): | | |
| Common stock, par value $0.0001 per share; 125,000,000 shares authorized; 18,204,796 and 17,040,040 shares issued and outstanding at March 31, 2013 and June 30, 2012. | 2 | 2 |
| Additional paid-in capital | 54,628 | 49,106 |
| Accumulated deficit | (58,033) | (43,722) |
| **Total equity (capital deficiency)** | (3,403) | 5,386 |
| **Total liabilities and equity (less capital deficiency)** | $ 9,797 | $ 16,014 |

(1) All 2013 financial information is derived from the Company's 2013 unaudited financial statements and all 2012 financial information is derived from the Company's 2012 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 7, 2013.

(2) All March 31, 2013 financial information is derived from the Company's 2013 unaudited financial statements and all June 30, 2012 financial information is derived from the Company's 2012 audited financial statements, as disclosed in the Company's Transition Report on Form 10-KT, filed with the Securities and Exchange Commission on September 11, 2012.

**For additional information:**

InspireMD Desk

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InspireMD
May 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

# Company Overview

## Company Description

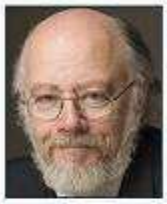
- InspireMD is a medical device company developing and commercializing its MicroNet technology for interventional cardiology and other vascular procedures
- Currently commercializing the MGuard™ Coronary Embolic Protection Stent (EPS) for the treatment of acute coronary syndromes, namely Acute Myocardial Infarctions (AMI)

## Corporate Highlights

- **Ticker:** NSPR (NYSE MKT)
- **Corporate Headquarters:** Boston, MA
- **International Headquarters:** Tel Aviv, Israel
- **Fully Diluted Shares Outstanding:** 40.9 million
- **Fully Diluted Market Cap (as of 5/1/2013):** $114.52 million

InspireMD

# Experienced Leadership Team



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

**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

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

**Gwen Bame**
**VP Corporate Development**
- Covidien
- Aspect Medical Systems
- Boston Scientific

**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

**Robert Ratini, MSc**
**VP Sales & Marketing**
- Orbusneich Medical
- Biosensors Int'l
- Abbott Vascular
- Boston Scientific
- CardiacAssist
- Haemonetics

# 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.)

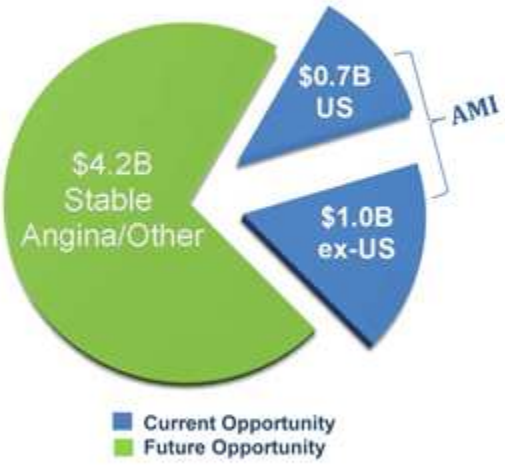
**Prof. Eberhard Grube**
- Professor of Medicine, Chief of the Department of Cardiology and Angiology at Siegburg Heart Centre, Germany

**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

# Addressing a Major Unmet Medical Need

**Coronary Stent Market***




**Worldwide AMI Market of $1.7B**

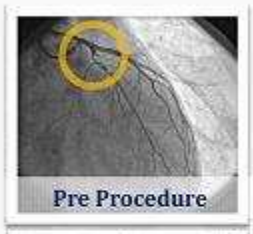
- Inadequate outcomes, as current stents designed primarily for Stable Angina population
- Distal embolization occurs in up to 73% of cases**
- Majority of AMI market is outside of the U.S. (~60%)

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

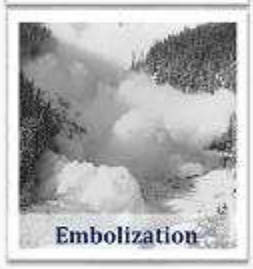


InspireMD

# Standard of Care in Treating AMI is Suboptimal



Pre Procedure



Embolization

Post Procedure

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

**Causes:**

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

**Leading To:**

**Major Adverse Cardiac Event (MACE)**

InspireMD

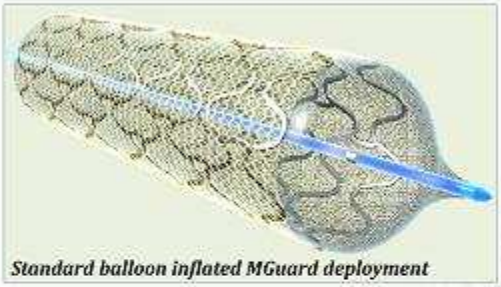
# MGuard™ Embolic Protection Stent

## Addressing the AMI Market

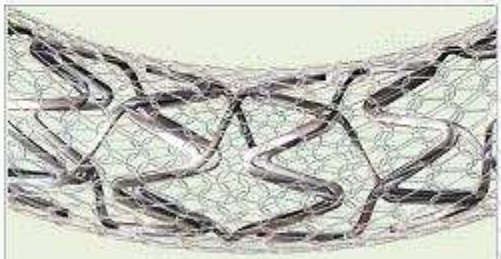
MGuard™ Coronary combines InspireMD's proprietary MicroNet™ technology, secured to proximal and distal edges of conventional stent.

### MGuard™ Highlights

- Prevent distal embolization
- Stabilize ruptured plaque
- Improve safety outcome
- Maintain standard stenting procedure
  - No learning curve
  - First class deliverability



***Standard balloon inflated MGuard deployment***



***MicroNet Technology;*** *CoCr Stent | Highly Flexible | Thin Struts | Low Crossing Profile*

InspireMD

# MicroNet™ Technology

Proprietary circular knitted mesh, made of a single fiber from a biocompatible polymer, widely used in medical implantations

Advantages of technology:

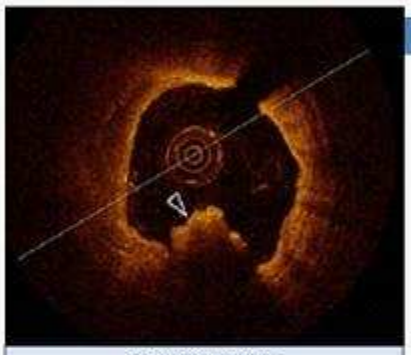
- Flexible structure
- Minimal foreign body reaction
- Does not promote thrombosis

**Potential Applications of Core Technology**

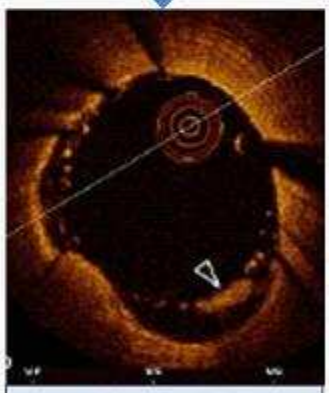

InspireMD

# MGuard™ Coronary Prevents Embolization

...could lead to embolization when treated with BMS/DES, but with MGuard™...



**Before Stenting**
Residual thrombus following aspiration



**After MGuard™**
Thrombus trapped behind mesh

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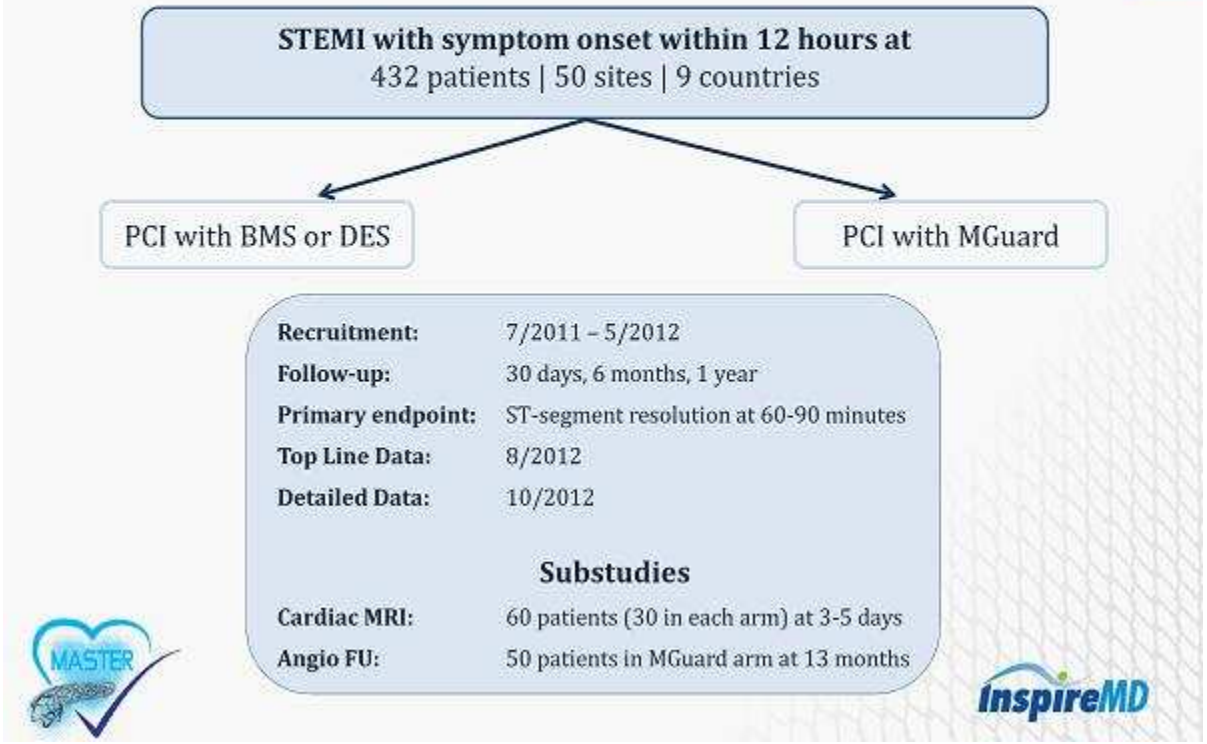
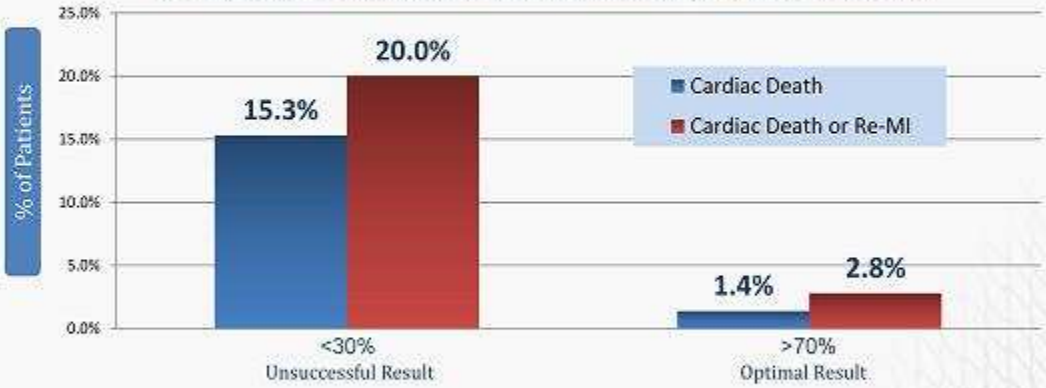
# The MASTER Trial

## MGuard™ for Acute ST Elevation Reperfusion



# Clinical Significance of ST Segment Resolution

**TAPAS:** Thrombus Aspiration During Primary Percutaneous Coronary Intervention




**In STEMI, occurrence of major clinical events at 1 year is significantly related to ST resolution***

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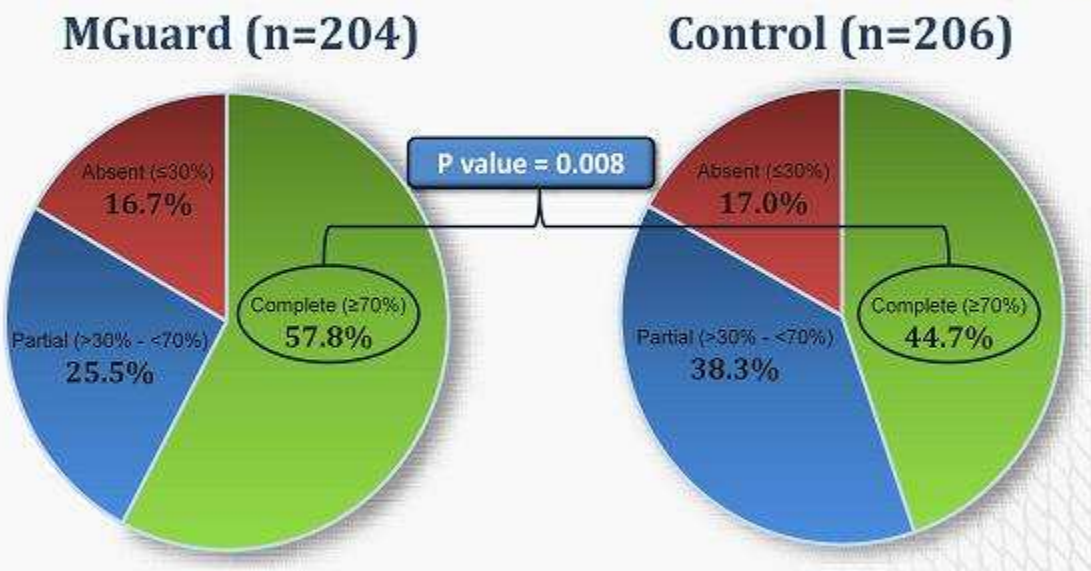
* TAPAS, Pieter J Vlaar, Lancet 2008; 371: 1915–20

# Master Trial - Primary Endpoint

## Complete ST Segment Resolution




**Relative Improvement: 29.3% (absolute – 13.2%)**

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# MASTER Trial Summary

## Achieved Primary End Point

- Superiority in TIMI Flow – 91.7% vs. 82.9%
- Superiority in ST Resolution – 57.8% vs. 44.7%
- MRI - Smaller Infarct Size - 17.1 gm vs. 22.3 gm

**Mortality at 30 days occurred in 0/217 (0%) patients in the treatment arm and in 4/216 (1.9%) patients in the control arm.**

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# MGuard™ Commercial Strategy

- Establish Embolic Protection Stent (EPS) as new stent category
- Promote MGuard™ EPS as the preferred solution for STEMI patients
- Utilize positive MASTER Trial results to push adoption and get premium reimbursement in key markets
- Develop sales infrastructure to support a focused and phased selling approach in select high-volume markets



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# Focused Commercial Activities

- **Tier 1**
  - Mix of direct sales 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 Strategics
  - Scaling global reach and frequency
- **Tier 3**
  - USA



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# Proposed USA IDE Trial Strategy

| | |
|---|---|
| **Status** | Approval with conditions to commence recruitment |
| **Objective** | Evaluate safety and efficacy of MGuard™ Prime Coronary vs. BMS and DES in STEMI |
| **Co-primary End Points** | **Efficacy:** Superiority in complete ST Resolution<br>**Safety:** Non inferiority in death and Target Vessel MI |
| **Population** | 1,100, STEMI Randomized 1:1 vs. FDA approved BMS or DES |
| **Chairman, PIs** | **PI**: Gregg Stone, M.D. FACC, Columbia University |

# Highly Leverageable

## Received CE Mark for Coronary


* Planned product

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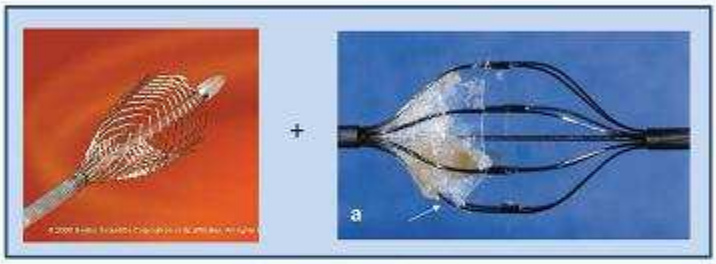
# MGuard™ Carotid

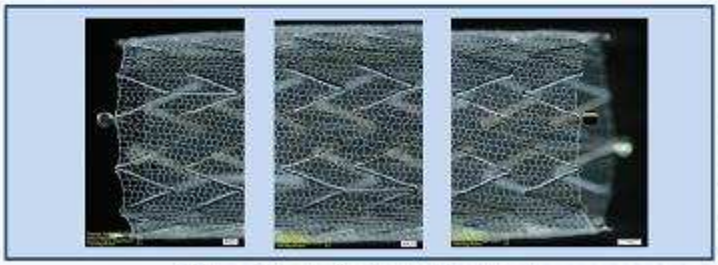
## CE Mark Approved; Q1 2013

**Current Market Solution:**




**Stent + Filter Device**

**MGuard™ Carotid Solution:**



**MGuard Embolic Protection Stent During and Post Procedure**

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# 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**


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# MGuard™ Manufacturing Facility

- Use of proceeds from offering to support manufacturing expansion, global launch
- Facility has completed requisite EMA inspections
- Implementation of Good Manufacturing Practice (GMP) facility in process
- Platform technology 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

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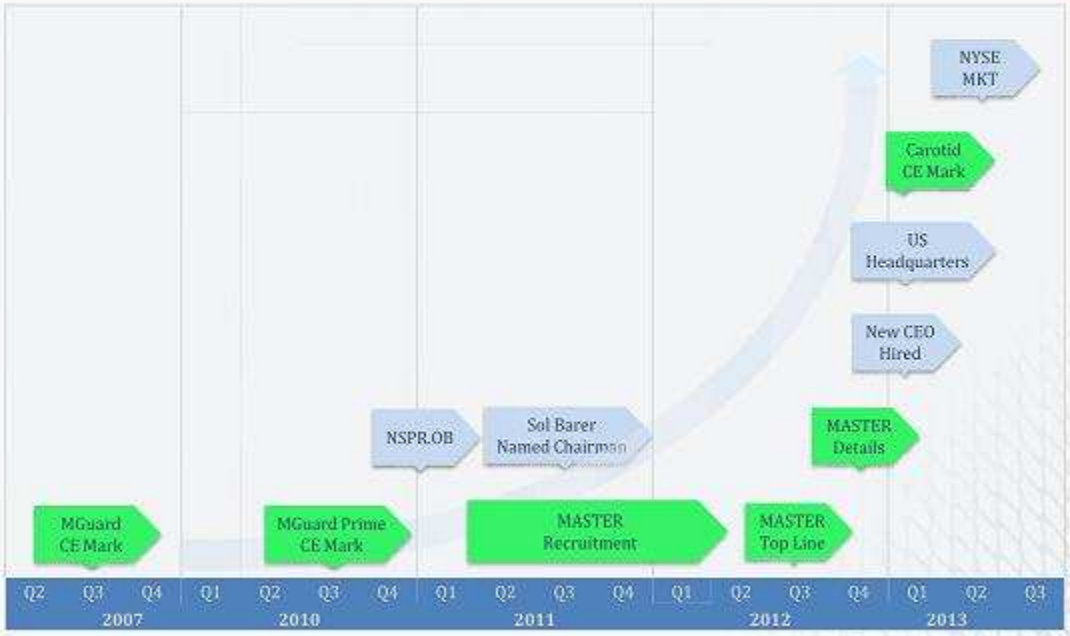
# Milestones To-Date

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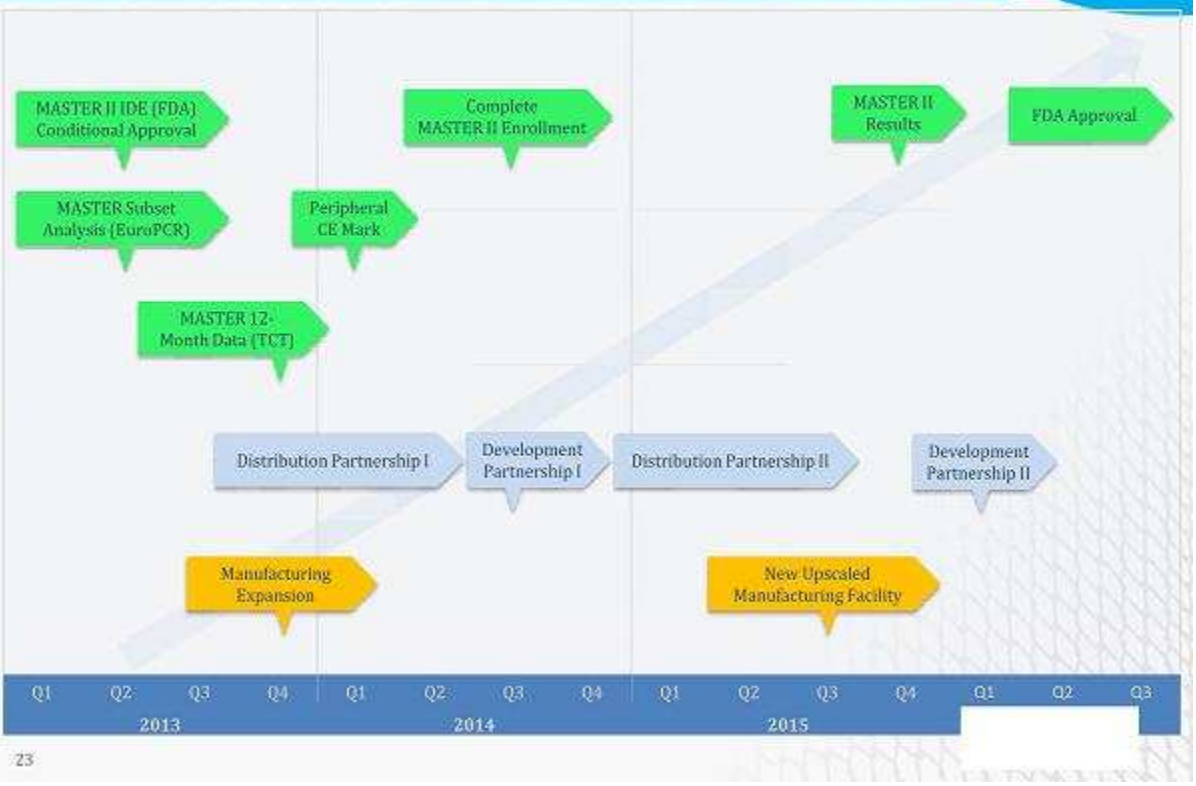
# Anticipated Future Milestones



# Financial Highlights
## NSPR (NYSE MKT)

| | |
|---|---|
| Basic Shares Outstanding | 34 million |
| Warrants, Options and Convertible Loan Shares | 6.9 million |
| Fully Diluted Shares Outstanding | 40.9 million |
| Stock Price (5/1/2013) | $2.80 |
| Fully Diluted Market Capitalization (5/1/2013) | $114.52 million |
| Revenue Growth | Q2 – $1.4M / Q1 – $0.5M (Up 165%) |

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# Company Highlights

| | |
|---|---|
| **Unmet Clinical Need** | • MGuard™ Coronary Embolic Protection Stent designed to transform the standard of care for AMI<br>• Initial focus is STEMI patient population<br>• AMI market value $1.7B |
| **Strong Clinical Evidence** | • MASTER Trial (randomized study)<br>• Primary Endpoint: Statistical significance achieved with superior results<br>• Chairman: Dr. Gregg Stone of the Cardiovascular Research Foundation |
| **Regulatory Status** | • CE Mark approved, currently active in 24 countries<br>• FDA USA IDE trial recruitment approved with conditions<br>• Lead PI: Dr. Gregg Stone |
| **Intellectual Property** | • 6 patents granted<br>• 31 patents pending<br>• Key aspects of core technology covered |

# Appendix

# MGuard™
## Clinical Results Summary

| Clinical Trials | ST Resolution | Death | | MACE | |
|---|---|---|---|---|---|
| | >70% | 30 days | 1 year | 30 days | 1 year |
| MAGICAL | 61.00% | 0.00% | 1.80% | 0.00% | 1.80% |
| Piscione | 90.00% | 2.20% | 4.50% | N/A | 5.60% |
| Weerakody | N/A | 0.00% | 0.00% | N/A | 6.00% |
| iMOS | N/A | 2.00% | N/A | 2.80% | 6.80% |
| Gaul | 58.00% | N/A | N/A | N/A | N/A |
| MICAMI | N/A | 0.00% | N/A | 0.00% | N/A |
| MASTER | 57.8% | 0.00% | N/A | 1.8% | N/A |

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# MASTER Trial
## Detailed Analysis

**MASTER, *although not powered for non primary endpoint measurements*, showed statistical significance and positive trends for key measurements.**

### Clinical Events at 30 Days

| | MGuard (n=217) | Control (n=216) |
|---|---|---|
| MACE | 4 (1.8%) | 5 (2.3%) |
| -Cardiac mortality[1] | 0 (0.0%) | 4 (1.9%) |
| -Reinfarction | 3 (1.4%) | 2 (0.9%) |
| -TLR, ischemia-driven | 4 (1.8%) | 1 (0.5%) |

### 3-5 Day MRI Substudy Results

| | MGuard (n=30) | Control (n=29) |
|---|---|---|
| Infarct mass, grams | **17.1 [10.0,30.0]** | **22.3 [15.7,30.1]** |
| Infarct mass (% total LV mass) | **13.3 [7.9,25.0]** | **16.6 [10.0,22.6]** |
| Total MVO, grams | **0.3 [0.0,1.6]** | **1.0 [0.2, 2.8]** |
| MVO (% total LV mass)[2] | 0.4 [0.0,1.4] | 0.8 [0.2,1.9] |
| LVEF (%) | 48.3 [44.5,52.3] | 47.3 [42.0,54.5] |

### Measurement of Blood Flow

| | MGuard (n=217[4]) | Control (n=216) |
|---|---|---|
| Aspiration Performed | 65.9% | 67.1% |
| Stent Type | | |
| - BMS | | 59.7% |
| - DES | | 39.8% |
| TIMI Flow = 3[3] | 91.7% | 82.9% |
| TIMI Flow = 2[3] | 6.5% | 11.6% |
| TIMI Flow = 0/1[3] | 1.8% | 5.6% |
| Myocardial Blush = 2/3 | 83.9% | 84.7% |

(1) Data showing a positive trend
(2) MVO = microvascular obstruction
(3) Data is statistically significant
(4) 191 MGuard, 26 MGuard Prime

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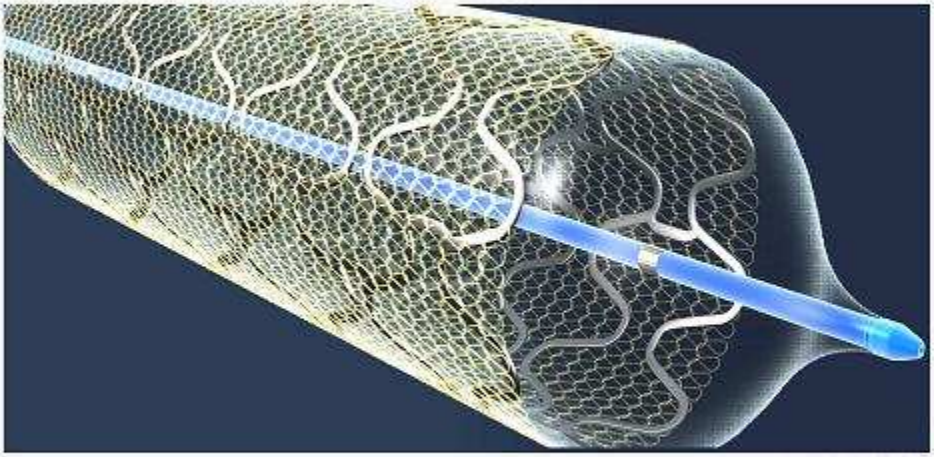
## Thank You



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