INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 07/11/12 for the Period Ending 07/05/12

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): July 5, 2012

InspireMD, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	000-54335	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4 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.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that InspireMD, Inc. will present at the JMP Securities Healthcare Conference in New York on Thursday, July 12, 2012.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On July 5, 2012, InspireMD, Inc. issued a press release announcing that it will present at the JMP Securities Healthcare Conference in New York on Thursday, July 12, 2012. A copy of this press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Investor Presentation
99.2	Press Release dated July 5, 2012.

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: July 11, 2012

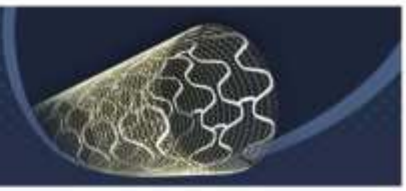
By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Investor Presentation
99.2	Press Release dated July 5, 2012.

July 2012

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 Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at 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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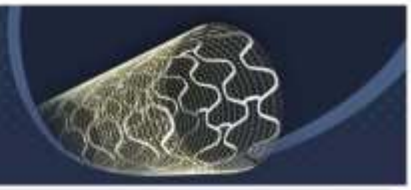
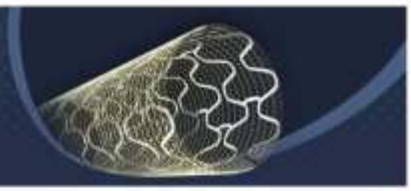
Company Highlights



Novel Technology Platform	• MGuard™ designed to transform the current standard of care • 25,000 stents sold; Physician driven • Data to date compares favorably to published standard of care data
Significant Market Opportunity	• $1.7B market, addressing unmet need • Favorable demographics for growth
Commercial Stage, Global Distribution	• Currently selling in 30 countries; CE Mark clearance 2007 & 2010 • ~$6 million in Revenue in 2011
Intellectual Property	• 1 patent granted, 8 pending, covering all key aspects of core technology • Freedom to Operate legal opinion
Experienced Management	• Proven track record • Sol Barer, Chairman of the Board, former Chairman and CEO of Celgene
Near Term Clinical Trials	• Completed enrollment of MASTER trial (Randomized study) - Top line data in 2H 2012 • FDA trial to begin enrollment in Q4 2012 - PMA filing in 2016
Well-Known Principal Investigators	• Dr. Gregg Stone of Columbia is lead PI for MASTER and FDA trials • Dr. Donald Cutlip of Harvard Clinical Research Institute is Chairman for the FDA trial

Company Vision



To become a global leader in the development and commercialization of innovative and breakthrough technologies in vascular disease treatment

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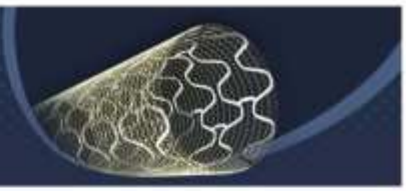
Addressing a Major Unmet Medical Need



Coronary Stent Market

* Source: Health Research International, (June 2012)

Acute MI: MGuard's Target Market - $1.7B

- Inadequate outcomes, as current stents designed primarily for Stable Angina population
- Majority of AMI market is ex-US, commercialization initiated in 30 countries
- Additional potential upside of $0.3B in SVG (Saphenous Vein Graft) market

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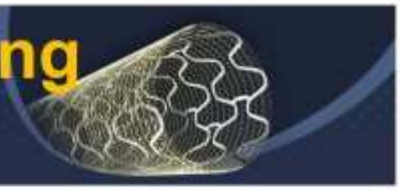
Standard of Care in Treating Acute MI is Suboptimal



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 "Downstream Embolization"

Leading To:

Major Adverse Cardiac Event (MACE)

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MicroNet™ Technology

Proprietary design, flexible structure and construction leads to profound biological implications

- Minimal inflammation
- Minimal foreign body reaction
- Does not promote thrombosis

- Targeted Drug Delivery
- ✓ Filter Emboli
- Seal Aneurysms
- Perforations
- Orthopedics

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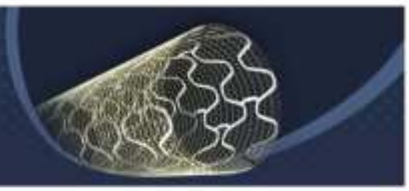
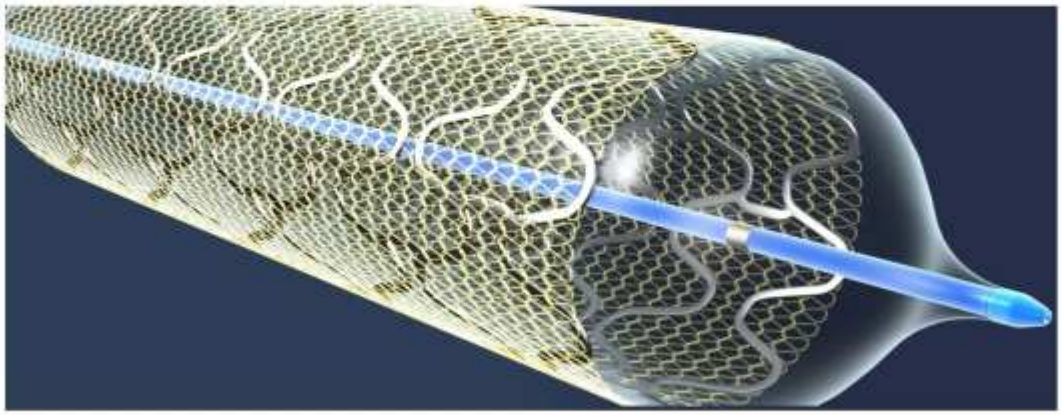
MGuard™

Addressing the Acute MI Market



MicroNet™ Technology Encasing a Stent

Proprietary design attributes allow for the capture of debris and prevention of embolization downstream



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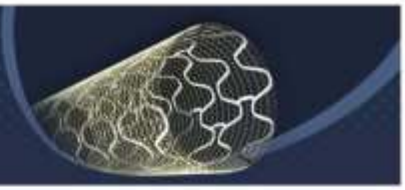
InspireMD's MGuard™

Design Highlights



Embolic Protection

Safer procedures by filtering plaque and debris

Spreads Struts Pressure

Reduces arterial injury

Identical Deliverability to Other Stents

No learning curve

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InspireMD's MGuard™

MicroNet™ Technology Integrated with Stent

Euro PCR Symposium, 2011

Online Video of InspireMD's MGuard

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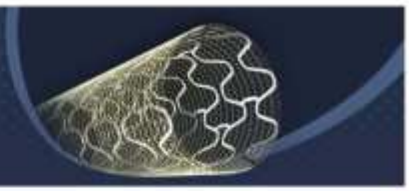
MGuard™ Performance



11 Single-Arm Trials, 630 Patients

458 Acute MI/ST Segment Elevation Myocardial Infarction (STEMI) Patients*

Major Parameters Tested

- Blush Grade
- ST Segment Resolution
- Major Adverse Cardiac Events (MACE)

- Reflect amount of reperfusion to the heart muscle
- Predictors of MACE

Pooled Data Analysis Method

Results compared with historical trials and data

* MAGICAL, Dariusz Dudek, Poland, 60 patients - BLUSH, ST Resolution, TIMI, MACE at 30D, 6M, 1YR
Federico Piscione, Italy, 100 patients - BLUSH, ST Resolution, MACE 30, 1YR, 2YR, 3YR
Jain Ajay, Roshan Weerackody, UK, 51 patients - TIMI, 1 YR MACE
iMOS Registry, GB Danzi, Italy, 203 patients - BLUSH, TIMI, 30D MACE
Dante Lindefjeld, Chile, 20 patients - BLUSH, TIMI, cTFC ; Gaul, Austria, 24 patients - BLUSH, TIMI

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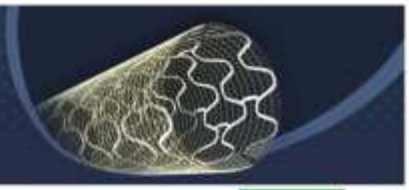
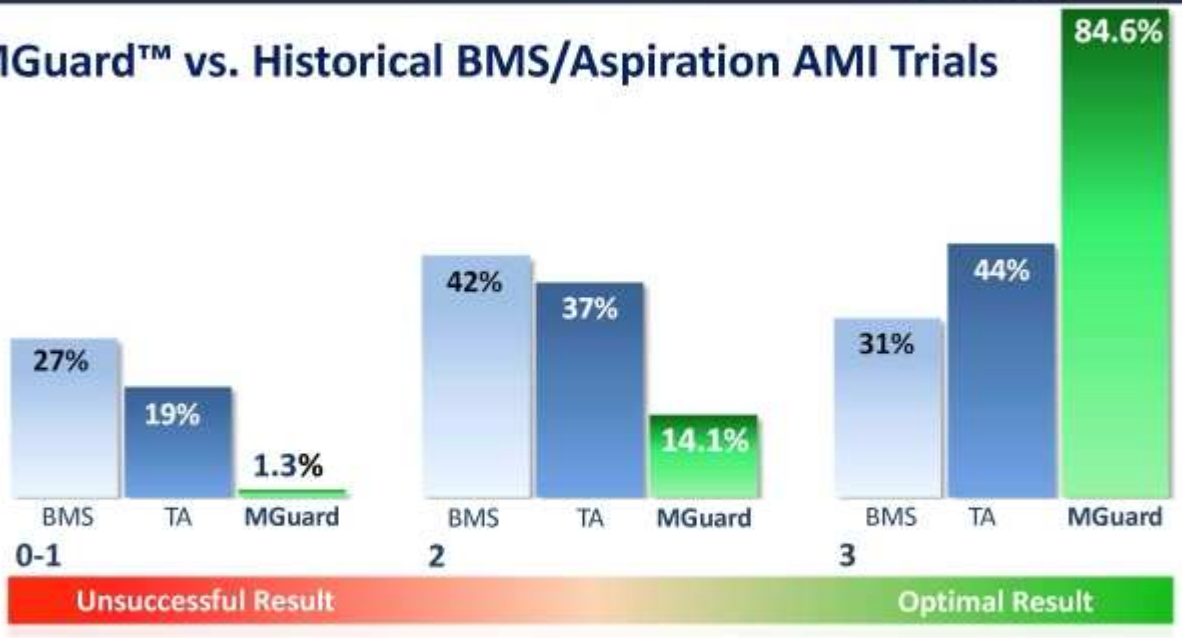
Blush Grade

A Predictor for Adverse Events



MGuard™ vs. Historical BMS/Aspiration AMI Trials



Data on this slide for BMS, TA and MGuard are derived from different sources. Please note a head to head study has not been conducted.

BMS (N=665, TAPAS & EXPORT Trials)
TA (N=655, TAPAS & EXPORT Trial Aspiration arm)
MGuard (N=234, MAGICAL, Piscione, iMOS, Lindefjeld, Gaul)

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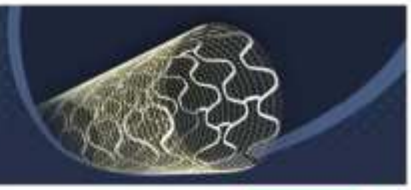
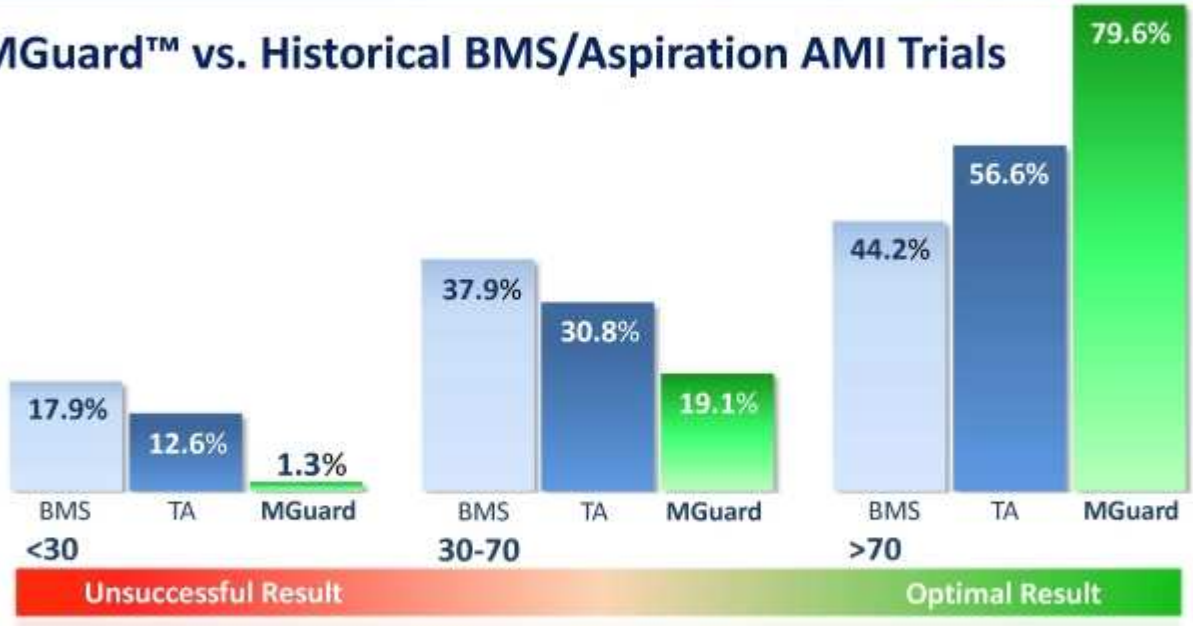
ST Resolution

A Predictor for Adverse Events



MGuard™ vs. Historical BMS/Aspiration AMI Trials



Data on this slide for BMS, TA and MGuard are derived from different sources. Please note a head to head study has not been conducted.

13

BMS (N=665, TAPAS & EXPORT Trials)
TA (N=655, TAPAS & EXPORT Trial Aspiration arm)
MGuard (N=157, MAGICAL, Piscione)

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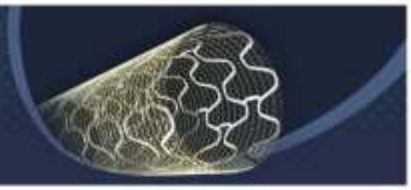
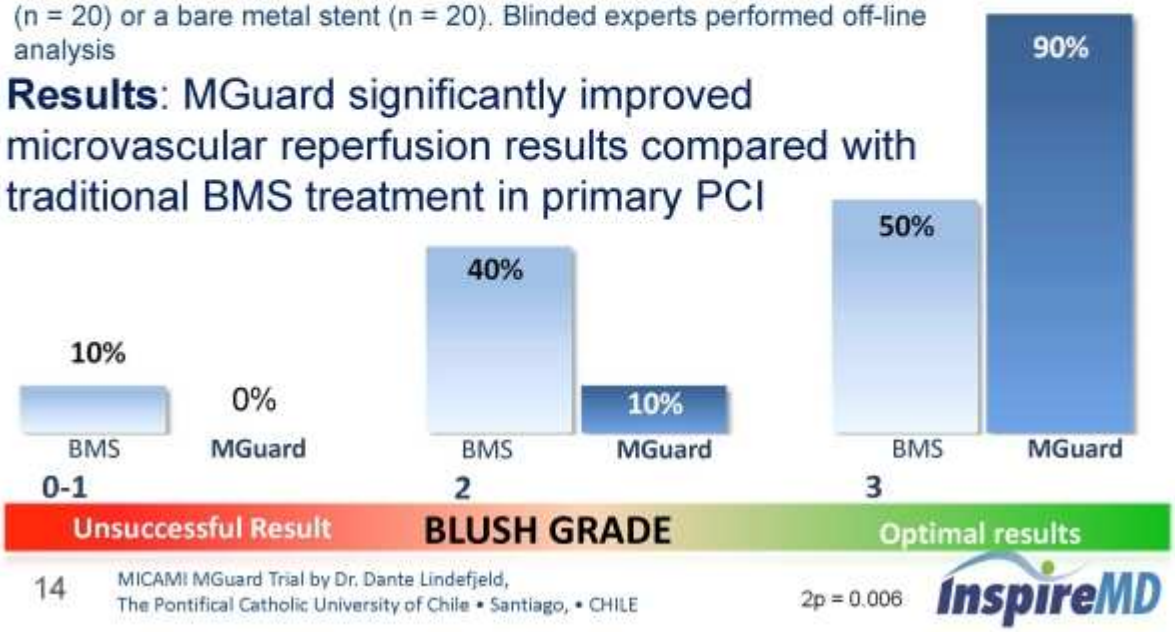
MGuard™
First Randomized Trial Results



Objective: To assess the efficacy of MGuard in microvascular reperfusion impairment during primary PCI, compared with bare metal stents (BMS).

Method: STEMI patients in 3 Chilean centers, randomized for MGuard (n = 20) or a bare metal stent (n = 20). Blinded experts performed off-line analysis

Results: MGuard significantly improved microvascular reperfusion results compared with traditional BMS treatment in primary PCI



MICAMI MGuard Trial by Dr. Dante Lindefjeld,
The Pontifical Catholic University of Chile • Santiago, • CHILE

2p = 0.006

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MGuard™ Data Support Reduction in MACE in AMI

Data on this slide for BMS, TA and MGuard are derived from different sources. Please note a head to head study has not been conducted.

MACE = Cardiac death, MI, and TLR
BMS, HORIZONS AMI trial BMS arm
DES, HORIZONS AMI trial DES arm

MGuard, Magical, Piscione, Weerackody, iMOS
N= 414 (30D,1Y), N=89 (2Y,3Y) OS

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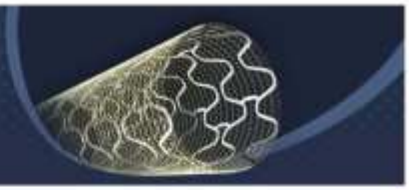
MASTER

Post Marketing Trial, Ex US



Enrollment	**Start:** Q3/2011, **End:** Q2/2012
Objective	Evaluate MGuard compared to BMS and DES in achieving better myocardial reperfusion
Primary End Point	Increase in frequency of complete ST resolution
Secondary End Point	Blush, TIMI, and MACE at 30 days, 6 months, 1 year
Population	432, STEMI, Randomized 1:1, MGuard ™ vs. BMS/DES
Chairman, PI's	**Chairman**: Dr. Gregg W. Stone (Columbia University, USA) **PIs:** Dr. Alexandre Abizaid (Brazil), Dr. Dariusz Dudek (Poland), Dr. Sigmund Silber, (Germany)
Status	***Enrollment Completed (432)***

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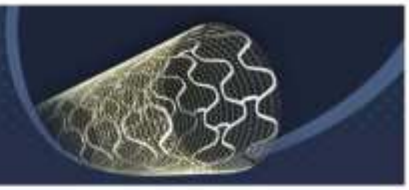
FDA
Registration Trial



Enrollment	**Start:** Q4 2012, **End:** H1 2014
Objective	Evaluate safety and efficacy of MGuard vs. BMS in STEMI/AMI
Co-primary End Points	**Efficacy:** Superiority in myocardial reperfusion: Increase in BLUSH Grade 3 (MBG3) **Safety:** Non inferiority in TVF (Target Vessel Failure)
Secondary End Point	MACE at 1 year, TIMI, and ST segment resolution
Population	880, STEMI Randomized 2:1 vs. VISION stent (BMS)
Chairman, PI's	**Chairman**: Dr. Donald Cutlip, Harvard Clinical Research Institute **PI**: Gregg Stone, Columbia University
Status	Protocol approval pending

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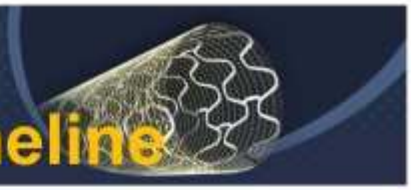
MGuard™ Clinical Development Timeline



MASTER, Marketing Trial

- 432 patients, Randomized 1:1 vs. BMS/DES
- Primary end point – ST Segment resolution

FDA PMA Trial

- 880 patients (pending), Randomized 2:1 vs. BMS
- Co-primary end points – Superiority in MBG3, Non-inferiority in TVF

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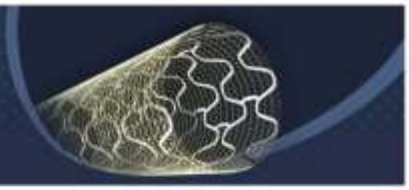
Highly Leveragable Platform Technology



* Planned product

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Product Pipeline

Building on InspireMD's Platform Technology

Product	Addressable Market	Product Stage
MGuard + MGuard Prime	$1.7B*	Sold in Europe, S.America, India, Australia
Carotid MGuard	$3.0B	CE Mark in 2012
Peripheral MGuard	$1.0B	CE Mark in 2012
Drug Eluting MGuard	$4.2B*	Planned Product
Cerebral Aneurysms	$1.0B	Planned Product

* Source: Health Research International, (January 2012)

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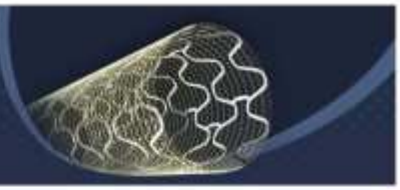
Intellectual Property



- Patents Filed in US and overseas
- 9 Patents (1 granted, 8 pending)
- Stent platform: US Freedom to Operate legal opinion
- IP Counsel: Wilson, Sonsini, Goodrich & Rosati

IP protects Key Attributes of MicroNet™ Technology

Anchoring	"Snow Shoe Effect"	Drug Delivery	Macro Structure	Fiber Width

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Experienced Management Team

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

Ofir Paz, MSEE/MBA
CEO
Previous experience:
- Founder, Peach Networks
- Microsoft
- IDF Officer

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

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

Robert Ratini, MSc
VP Sales & Marketing
- Orbusneich Medical Hoevelaken
- Biosensors International
- Abbott Vascular
- Boston Scientific
- Haemonetics

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Board of Directors

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

Ofir Paz, MSEE/MBA
Co-Founder & CEO
- Founder, Peach Networks
- Microsoft
- IDF Officer

Asher Holzer, PhD
Co-Founder
- Johnson & Johnson's Worldwide Carto System Manager
- Biosense, Adar Medical & Kevex Corporation

James Barry
- EVP and COO, Arsenal Medical

Previous experience
- Vice President, Corporate Research and Advanced Technology Development at Boston Scientific
- Howmedica Division of Pfizer

Paul Stuka
- Managing Dir. Of Osiris Partners

Previous experience:
- Longwood Partners
- State Street Research

Eyal Weinstein, CPA
- CEO, Leorex

Previous experience:
- Better Online Solutions (NASD: BOSC)
- Exseed

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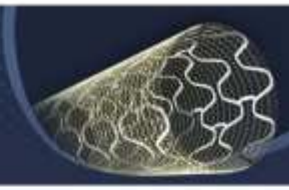
Scientific Advisory Board



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

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

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
- Associate professor of the Jagiellonian University, Krakow, Poland

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)

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

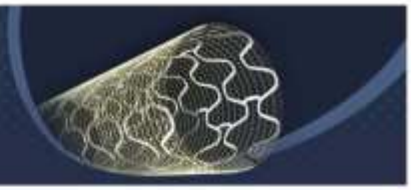
Dr. Edo Kaluski, MD, FACC, FESC
- Director of Cardiac Catheterization Laboratories and Invasive Cardiology at the University Hospital in Newark, New Jersey
- Co-founder of InspireMD

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

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

Financial Highlights
NSPR.OB



$ in Thousands	3 Months Ended		Year Ended December 31,	
	2012	2011	2011	2010
Income Statement				
Total Revenue	1,138	1,686	6,004	4,949
Cost of Revenues	574	899	3,011	2,696
Expenses				
Research and Development	1,349	343	2,474	1,338
Sales and Marketing	445	428	1,973	1,236
General and Administrative	1,896	1,186	12,275	2,898
Total Operating Expenses	3,690	1,957	16,722	5,472
Other	14	725	936	201
Net (loss) Income	(3,140)	(1,895)	(14,665)	(3,420)
EBITDA excluding share based compensation	(1,904)	(760)	(4,050)	(1,508)

11.4 MM cash balance*
$1.7 MM burn rate for Q1 2012
68.2 MM shares outstanding**

* As of May 15, 2012
** Fully diluted share count is 100 MM including options and warrants outstanding

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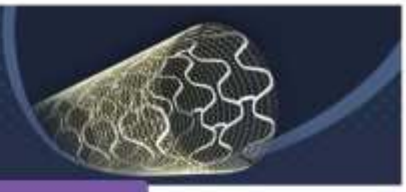
Summary



Novel Stent Technology

Core technology aim to change standard of care, 25k sold to date

Opportunity

$1.7B dollar initial market, potential to be standard of care

Distribution Infrastructure

30 countries, physician driven

Intellectual Property

Patents filed covering all relevant aspects, Freedom to Operate

Leadership

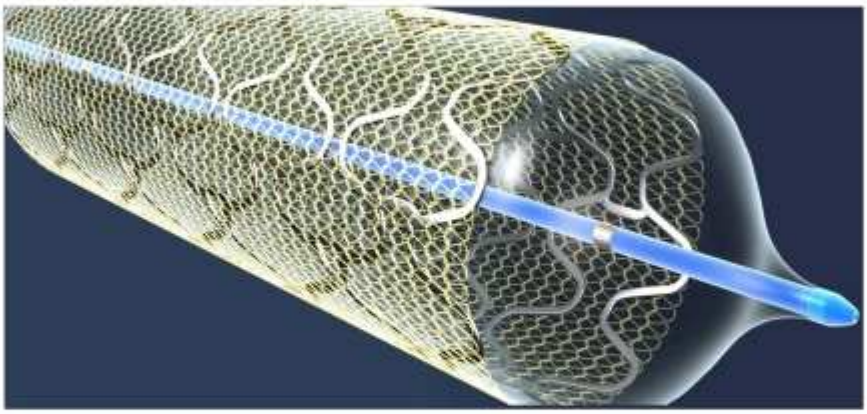
- Prior expertise with Microsoft, Boston Scientific, Abbott Vascular, Biosensors, Pfizer, Bristol Myers Squibb and General Electric
- Entrepreneurship, experience & track record

Near Term Clinical Trials Led by Well-Known PIs

- Enrollment completed in MASTER trial, headed by Dr. Gregg Stone of Columbia University
- Beginning FDA trial enrollment later this year, headed by Dr. Gregg Stone and Dr. Donald Cutlip of Harvard

InspireMD

Thank You



InspireMD

FOR IMMEDIATE RELEASE

INSPIREMD TO PRESENT AT JMP SECURITIES HEALTHCARE CONFERENCE ON JULY 12 TH IN NEW YORK

Tel Aviv, Israel – July 5, 2012 – InspireMD, Inc. (OTC BB: NSPR) (the "Company" or "InspireMD"), a medical device company focusing on the development and commercialization of its proprietary stent platform technology for use in patients with Acute Myocardial Infarctions, announced today that Craig Shore, Chief Financial Officer, will present at the 7th Annual JMP Securities Healthcare Conference on July 12th in New York City.

Presentation Details

- Date: Thursday, July 12, 2012
- Time: 3 PM
- Location: Chelsea Room, The Peninsula Hotel, 700 5th Avenue, New York, NY.

About the JMP Healthcare Conference

The 7 th Annual JMP Securities Healthcare Conference will take place at the Peninsula Hotel in New York, July 12 th – 13 th . This institutional investor forum will feature more than 100 publicly traded and privately held companies in the life sciences field.

JMP Securities is a full-service investment bank that provides equity research, institutional brokerage and investment banking services to growth companies and their investors. The firm specializes in four broad growth industries: Technology, Healthcare, Financial Services and Real Estate. JMP's research department covers primarily small and mid-cap public companies

Attendance at this event is restricted to clients of JMP Securities. For full event details and registration information, please click here: http://www.jmpg.com/jmpsecurities/about/conferences/ .

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 listed on the OTC BB under the ticker symbol "NSPR".

About MGuard™ Coronary Stent

MGuard™ combines a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer micron net that is integrated with the stent. The MGuard™ is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard™ is CE Mark approved. Mesh-based protection is now recommended for use in the recent Guidelines of the Task force of Myocardial Revascularization of the European Society of Cardiology (ESC).

MGuard™ is currently being investigated in the multi-center international MASTER (MGuard™ for Acute ST Elevation Reperfusion) trial. This study has been designed to evaluate the MGuard™ stent compared to commercially-approved BMS or DES products in STEMI patients undergoing primary angioplasty. The trial is fully enrolled and preliminary top line results are expected in the third quarter of 2012. Plans for a registration study in the US are also at an advanced stage.

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, including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at 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.

Investor Contact:
Michael Rice
Office Phone: (646) 597-6979
Email: mrice@lifesciadvisors.com

Corporate Contact:
Jonina Ohayon
Marketing Director
Email: jonina@inspire-md.com
OTC BB: NSPR
www.inspire-md.com

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