INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 05/23/13 for the Period Ending 05/23/13

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CIK	0001433607
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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 23, 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 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. (the "Company") will present on May 23, 2013 at EuroPCR, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions, at the Palais Des Congrès in Paris.

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 (the "Exchange Act"), 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On May 23, 2013, the Company issued a press release announcing six-month results from the MASTER (MGuard for Acute ST Elevation Reperfusion) trial of its MGuard™ Embolic Protection Stent. The results will be presented on May 23, 2013 at EuroPCR. The results will also be presented through a conference call and webcast on the same date.

A copy of the press release is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	EuroPCR Presentation
99.2	Press Release dated May 23, 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 23, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	EuroPCR Presentation
99.2	Press Release dated May 23, 2013

Exhibit 99.1

InspireMD

MASTER Trial Update & 6 Month Results

Prof. Dr. Sigmund Silber

FESC, FACC, FAHA

Heart Center at the Isar, Munich, Germany

on behalf of the MASTER study group

MGUARD: DESIGNED FOR EMBOLIC PROTECTION

DESIGN

- Bare metal stent wrapped with an expandable 20µm MicroNet mesh
- Polyethylene Terephthalate (PET) fiber
- Pore size when deployed: 180µm
- Pores are expandable for side branch access
- Attached to proximal and distal edges of the stent

ADVANTAGES

- Deploys exactly like a typical balloon expandable stent
- Standard dilatation pressures
- **Mesh reduces the risk of distal embolization providing protection during and post procedure**

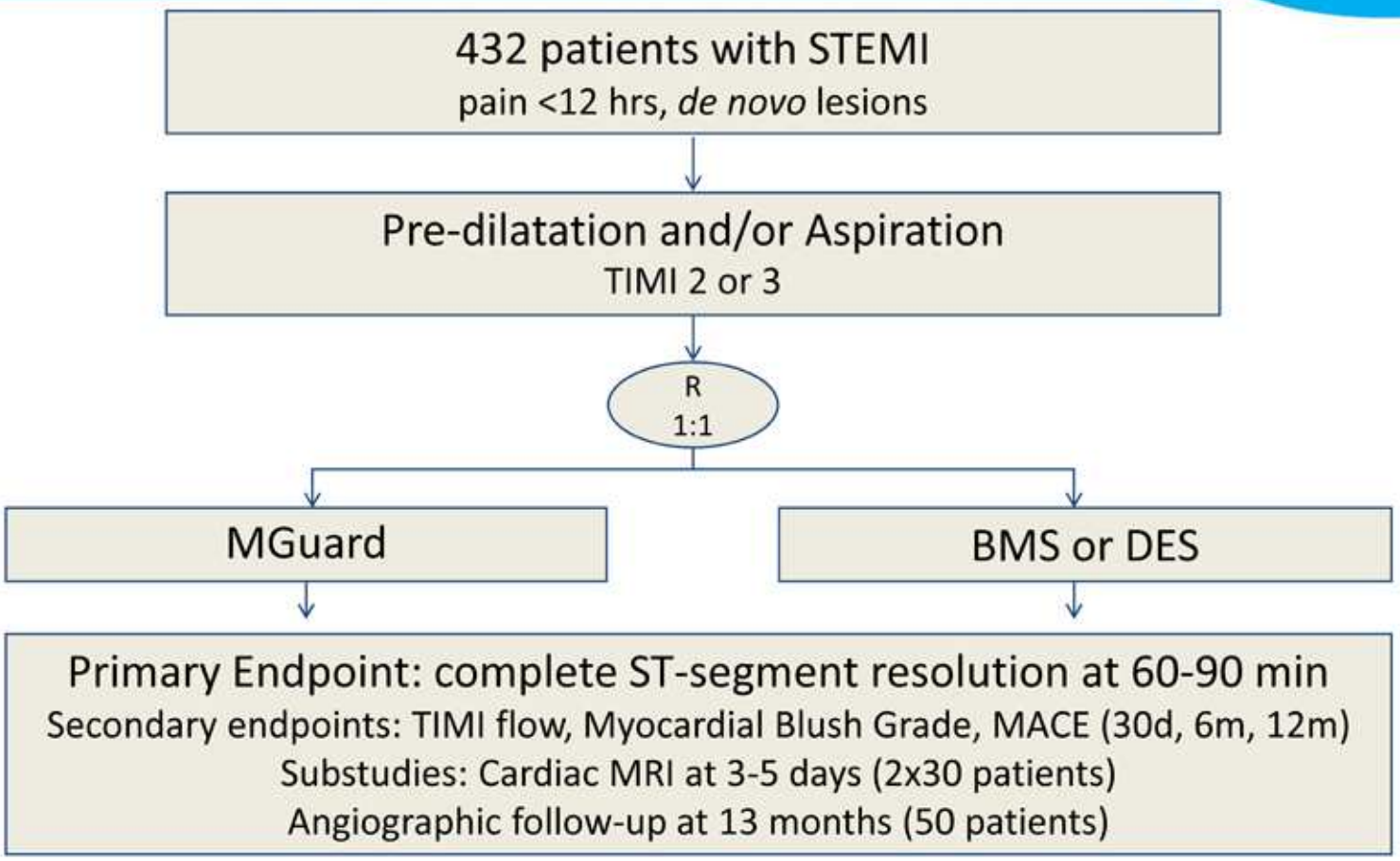
InspireMD

MGUARD & MGUARD PRIME

STENT		
	MGuard 	**MGuard Prime** 
MATERIAL	Stainless steel	Cobalt chromium
STRUT THICKNESS	100µm	80µm
CROSSING PROFILE	1.1-1.3mm	1.0 - 1.2mm
MICRONET		
MATERIAL	PET	
FIBER DIAMETER	20µM	

InspireMD

MASTER TRIAL DESIGN



STUDY ORGANIZATION

PRINCIPAL INVESTIGATORS	» Alexandre Abizaid » Dariusz Dudek » Sigmund Silber
STUDY CHAIRMAN	» Gregg Stone
DATA ANALYSIS	» CRF, New York
CEC EVENT ADJUDICATION	» CRC, Brazil
ECG and MRI CORELAB	» CRF, New York
ANGIO CORELABS	» CRC, Brazil » CRF, New York
DSMB	» 3 members, independent

ENROLLMENT IN PARTICIPATING COUNTRIES

July 22, 2011 - May 29, 2012
433 patients
50 sites, 9 countries

TOP 12 ENROLLING SITES

Prof. Bela Merkely	Semmelweis University	Hungary	37
Prof. Dariusz Dudek	The University Hospital in Krakow	Poland	33
Prof. Ran Kornowski	Rabin Hospital	Israel	31
Dr. Roman Wojdyła	Krakow Center of Invasive Cardiology	Poland	23
Dr. Dezső Apró	State Hospital for Cardiology Balatonfüred	Hungary	19
Prof. Haim Danenberg	Hadassah University Medical Center	Israel	19
Dr. Itzhak Herz	Laniado Hospital	Israel	18
Dr. Jan Horak	General University Hospital	Czech Rep.	17
Dr. Bogdan Januś	The E. Szczeklik Specialized Hospital in Tarnow	Poland	16
Dr. Marc Ohlow	Zentralklinik Bad Berka	Germany	15
Prof. Krystrof Żmudka	The John Paul II Hospital	Poland	15
Dr. Jacek Legutko	INTERCARD, Nowy Targ	Poland	15

MAIN INCLUSION / EXCLUSION CRITERIA

INCLUSION CRITERIA

- Symptoms consistent with STEMI within 12 hours of symptom onset
- ≥ 2 mm of ST-segment elevation in ≥2 contiguous leads
- PCI of a single de novo lesion with RVD ≥ 3.0 to ≤ 4.0 mm
- length ≤ 33 mm

EXCLUSION CRITERIA

- LBBB, paced rhythm, etc.
- Prior PCI within 6 months or prior CABG
- LVEF ≤ 20%, cardiogenic shock or CPR
- ≥ 50% left main stenosis present
- Infarct lesion ostial
- Bifurcation with ≥ 2.0 mm sidebranch
- Target vessel or infarct lesion excessively tortuous, angulated or with moderate to heavy calcification
- Prior stent proximal or w/i 10 mm distal to the target

BASELINE CHARACTERISTICS

	MGUARD (N=217)	CONTROL BMS / DES (N=216)
Age (years)	60 [52, 68]	58 [51, 67]
Male	75.1%	76.9%
Hypertension	42.3%	47.4%
Hyperlipidemia	27.4%	27.1%
Diabetes mellitus	12.0%	18.1%
Cigarette smoking	55.3%	46.8%
Prior MI	3.7%	8.8%
Prior PCI	3.7%	5.6%
Symptoms to device, mins	207 [156, 308]	240 [140, 383]
Infarct artery = LAD	40.1%	40.3%
Baseline TIMI flow = 0/1	66.5%	74.0%
Baseline RVD, mm	3.15 [2.87, 3.38]	3.06 [2.87, 3.40]
Baseline DS %	100 [85, 100]	100 [88, 100]

Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

PROCEDURAL MEDICATIONS

	MGUARD (N=217)	CONTROL STENT BMS / DES (N=216)	P
Anti-platelet agents, peri-procedural			
Aspirin	98.6%	99.1%	1.0
ADP antagonists	95.4%	95.8%	0.82
Clopidogrel	72.9%	70.0%	0.51
Ticlopidine	0.5%	0.0%	1.0
Prasugrel	21.7%	20.8%	0.81
Ticagrelor	4.8%	9.2%	0.08
Anticoagulation, peri-procedural			
Unfractionated heparin	96.8%	96.3%	0.79
Glycoprotein inhibitor	82.9%	83.3%	0.92
Bivalirudin	11.1%	12.5%	0.64

Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

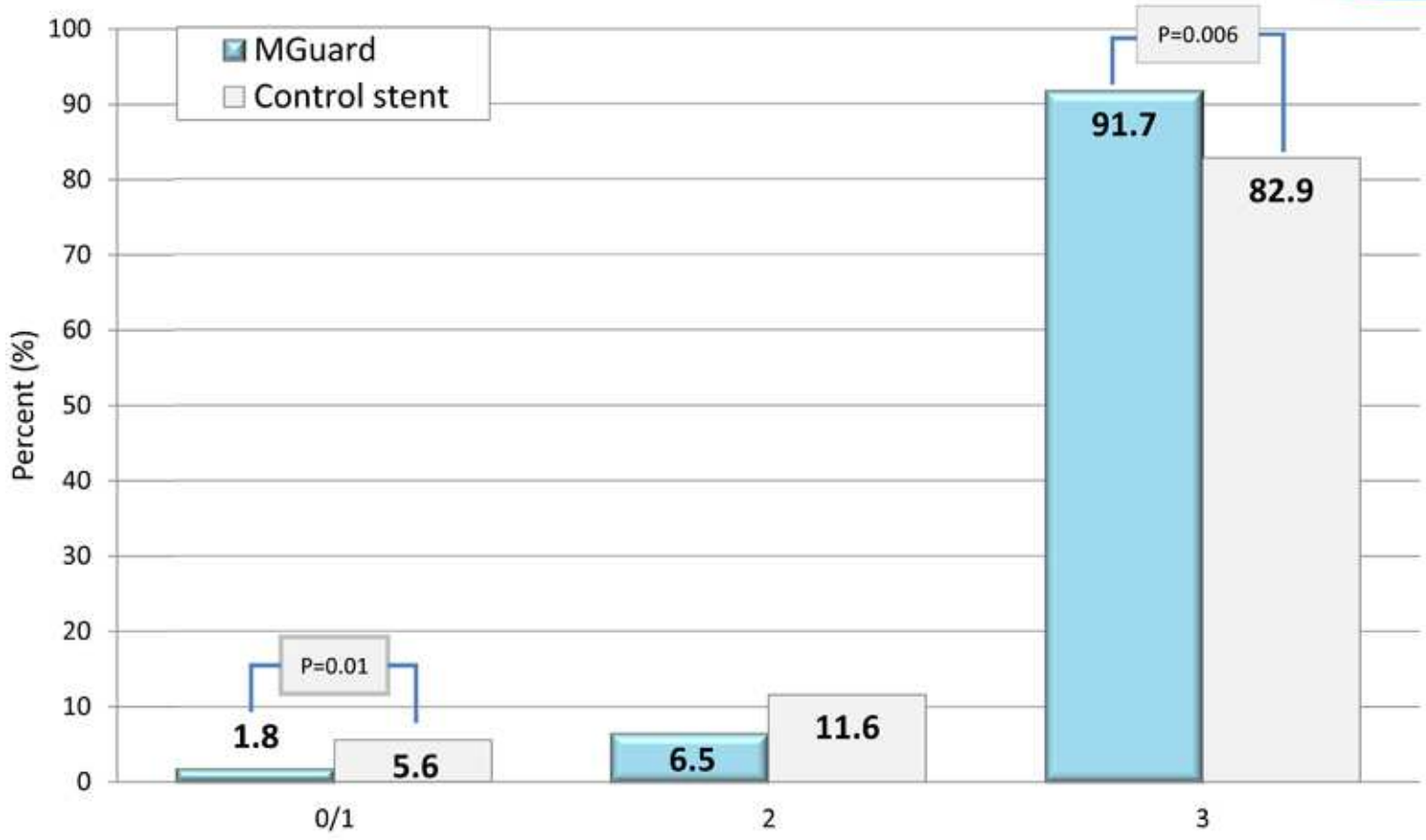
PROCEDURAL CHARACTERISTICS

	MGUARD (N=217)	CONTROL BMS / DES (N=216)	P
Aspiration performed	65.9%	67.1%	0.79
Balloon pre-dilatation performed	50.2%	44.9%	0.27
Direct stenting	12.0%	10.6%	0.66
≥1 stent implanted	99.5%	100.0%	1.0
Stent type			
MGuard	96.3%(*)	0.5%	<0.0001
Bare metal stent	1.4%	59.7%	<0.0001
Drug-eluting stent	2.3%	39.8%	<0.0001
Total stent length, mm	19 [15, 24]	20 [15, 24]	0.64
Post stent dilatation performed	36.4%	30.6%	0.20
Maximal device size, mm	3.5 [3.0, 3.5]	3.5 [3.0, 3.5]	0.78
Maximal dilatation pressure, atm	16 [14, 18]	16 [14, 18]	0.02

* Out of 217 patients, 26 were treated with the MGuard Prime

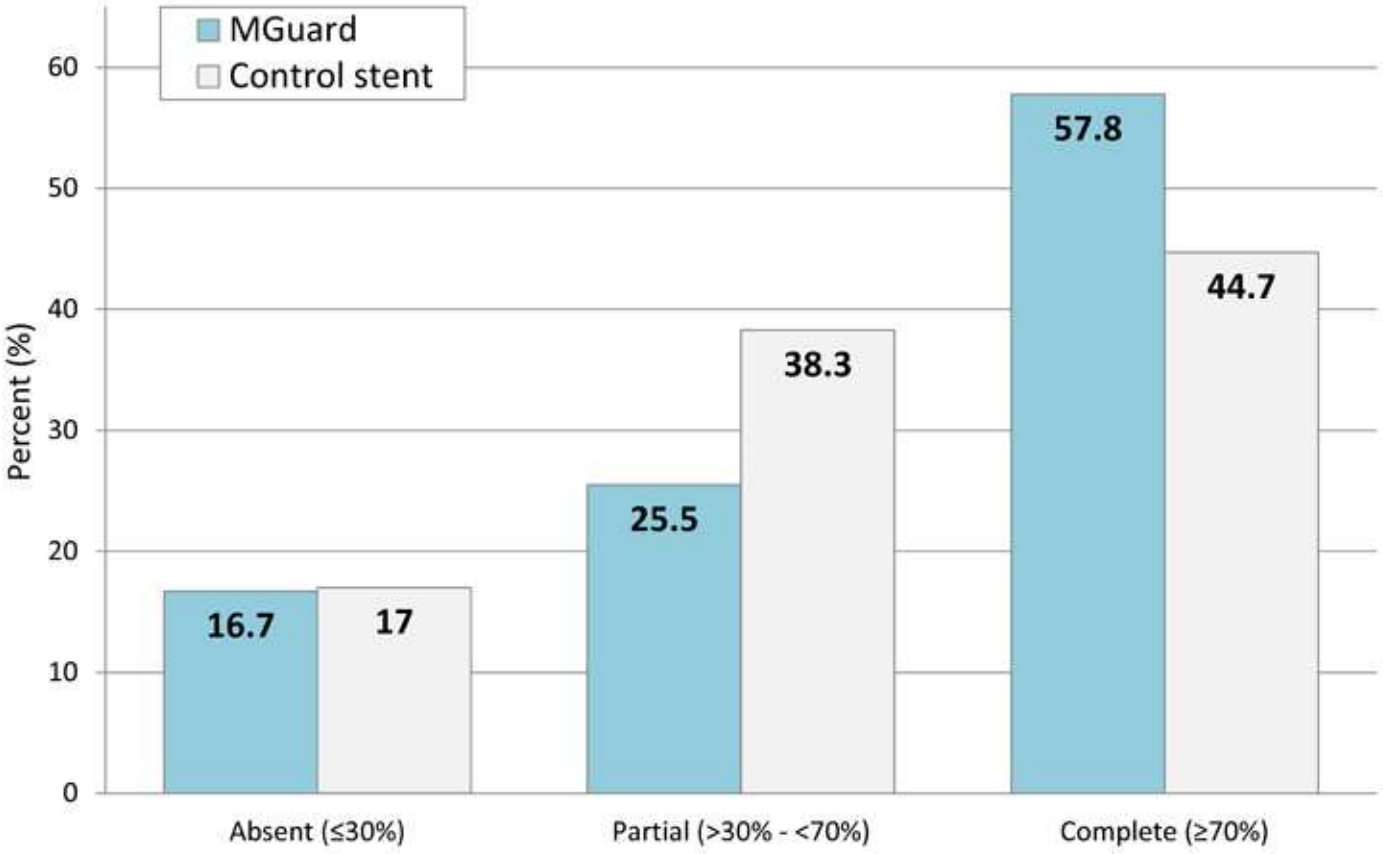
Stone et. al, *J Am Coll Cardiol.* 2012;60:1975-1984.

MGUARD SUPERIOR IN TIMI FLOW



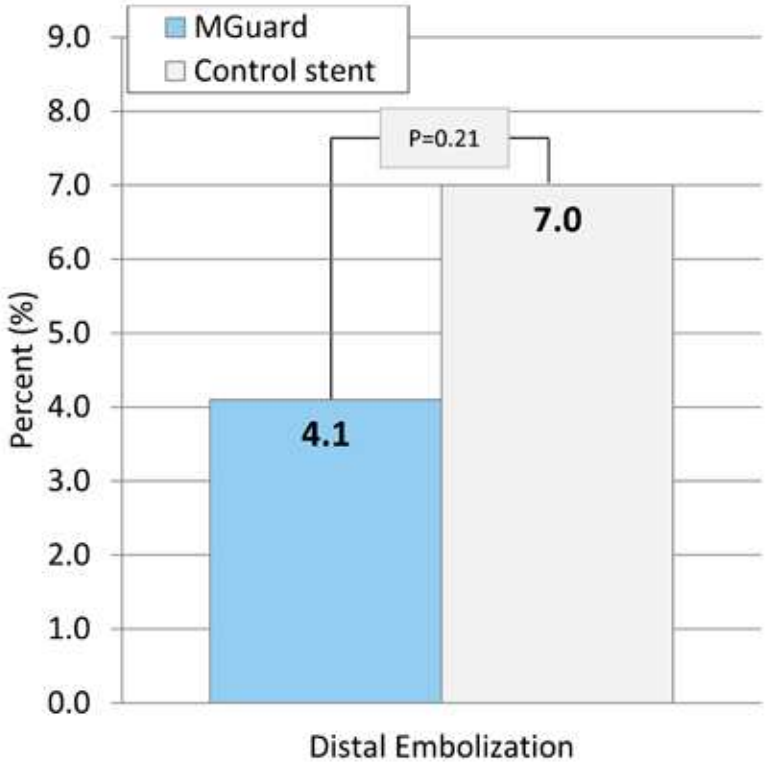
Stone et. al, *J Am Coll Cardiol.* 2012;60:1975-1984.

MGUARD SUPERIOR IN ST SEGMENT RESOLUTION



Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

DISTAL EMBOLIZATION



Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

CARDIAC MRI AT 3-5 DAYS

	MGUARD (N=30)	CONTROL BMS / DES (N=29)	P
Total LV myocardial mass, g	141 [117, 163]	147 [118, 174]	0.41
Infarct mass, g	17.1 [10.0, 30.0]	22.3 [15.7, 30.1]	0.27
Infarct mass (% total LV mass)	13.3 [7.9, 25.0]	16.6 [10.0, 22.6]	0.48
Total MVO, g	0.3 [0.0, 1.6]	1.0 [0.2, 2.8]	0.14
MVO (% total LV mass)	0.4 [0.0, 1.4]	0.8 [0.2, 1.9]	0.39
Abnormal wall motion score	22.5 [20.0, 26.0]	25.0 [21.0, 27.0]	0.48
LVEF (%)	48.3 [44.5, 52.3]	47.3 [42.0, 54.5]	0.79

Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

30 DAYS CLINICAL RESULTS*

	MGUARD (N=217)	CONTROL BMS / DES (N=216)	P
MACE	4 (1.8%)	5 (2.3%)	0.75
All cause mortality	0 (0.0%)	4 (1.9%)	0.06
Cardiac death	0 (0.0%)	4 (1.9%)	0.06
Reinfarction	3 (1.4%)	2 (0.9%)	1.00
TLR, ischemia-driven	4 (1.8%)	1 (0.5%)	0.37
TVR, ischemia-driven	5 (2.3%)	1 (0.5%)	0.10
Stent Thrombosis			
Definite or Probable	3 (1.4%)	2 (0.9%)	0.67
Definite	3 (1.4%)	1 (0.5%)	0.62
Stroke	1 (0.5%)	0 (0.0%)	1.00
TIMI Bleeding			
Major or Minor	4 (1.9%)	4 (1.9%)	0.75
Major	3 (1.4%)	2 (0.9%)	1.00

* Secondary endpoint

Stone et. al, *J Am Coll Cardiol*. 2012;60:1975-1984.

6 MONTHS CLINICAL RESULTS*

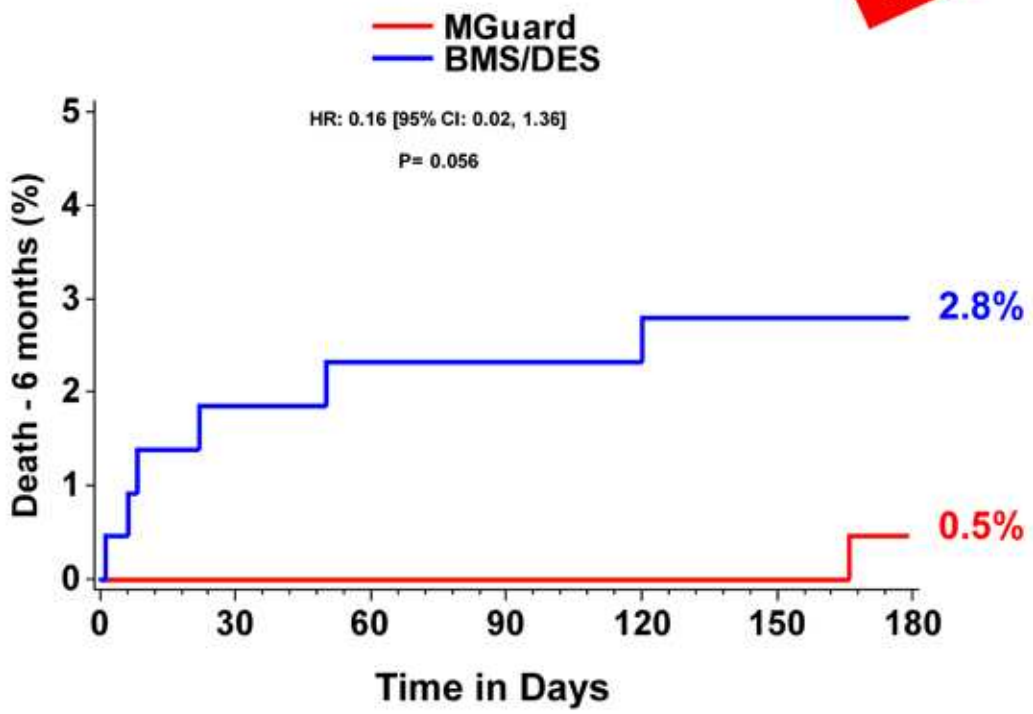
New Data

	MGUARD (N=217)	CONTROL BMS / DES (N=216)	P
MACE	11 (5.2%)	7 (3.4%)	0.34
All cause mortality	1 (0.5%)	6 (2.8%)	0.06
Cardiac death	1 (0.5%)	5 (2.3%)	0.10
Reinfarction	3 (1.4%)	2 (0.9%)	0.66
TLR, ischemia-driven	10 (4.8%)	2 (1.0%)	0.02
TVR, ischemia-driven	13 (6.2%)	2 (1.0%)	<0.01
Stent Thrombosis			
Definite or Probable	4 (1.8%)	2 (0.9%)	0.42
Definite	4 (1.8%)	1 (0.5%)	0.18
Stroke	1 (0.5%)	0 (0.0%)	0.32
TIMI Bleeding			
Major or Minor	5 (2.30%)	5 (2.3%)	0.99
Major	4 (1.8%)	4 (1.3%)	0.71

* Secondary endpoint

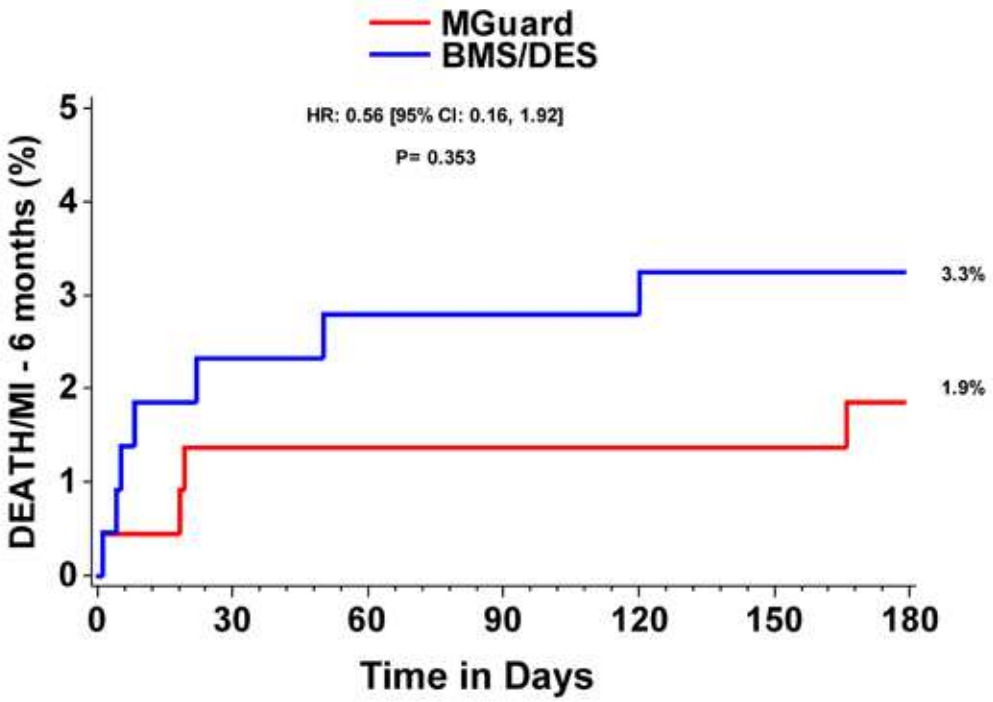
ALL CAUSE MORTALITY AT 6 MONTHS

New Data



Number at risk:				
MGuard	217	213	213	165
BMS/DES	216	209	208	171

DEATH AND MI AT 6 MONTHS



Number at risk:				
MGuard	217	211	211	163
BMS/DES	216	208	207	170

CONCLUSIONS

CONCLUSIONS

Among patients with STEMI undergoing emergent PCI, the MGuard embolic protection stent resulted in superior rates of epicardial coronary flow and complete ST-segment resolution.

A positive trend toward reduced mortality is persistent even after 6.

The 6-month TLR rates in the MGuard arm are similar to those expected from a BMS, and as expected, higher than in the control arm which contained a mixture of DES and BMS

Final 12 month follow-up data will be reported at TCT 2013

Backup slides

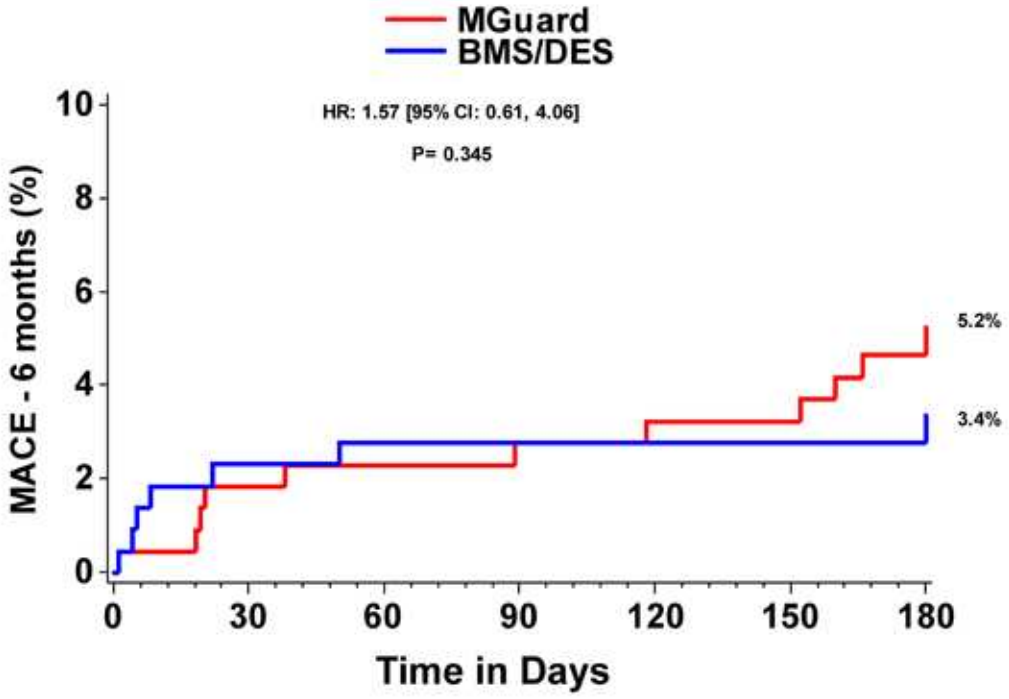
Primary Endpoint: Complete ST-segment resolution

Multivariable predictors

	OR (95%CI)	P value
MGuard vs. control	1.73 (1.14 - 2.62)	0.01
Age (yrs)	1.03 (1.00 - 1.05)	0.02
Male	0.42 (0.25 - 0.71)	0.001
Current smoking	2.07 (1.31 - 3.27)	0.002

Variables: age, male, BMI, hypertension, hyperlipidemia, diabetes, current smoking, congestive heart failure, prior angina, prior MI, prior PCI, randomized group

MACE AT 6 MONTHS



Number at risk:				
MGuard	217	209	207	159
BMS/DES	216	208	208	171

FOR IMMEDIATE RELEASE

InspireMD's MGuard Embolic Protection Stent (EPS) Shows Lower Mortality Rate in STEMI Patients at Six Months Compared to Control Group

- Company to Host Conference Call Today at 8:00am ET, 2:00pm CET -

PARIS, France, MAY 23, 2013 -- InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), the leader in embolic protection stents, today announced new 6-month results from the MASTER (**M** Guard for **A** cute **ST E** levation **R** eperfusion) trial demonstrating that the MGuard Embolic Protection Stent (EPS) outperformed bare metal and drug eluting stents in all-cause mortality in ST segment elevation myocardial infarction (STEMI) patients. Results from the trial were presented at the InspireMD STEMI Symposium at EuroPCR, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions (EAPCI) taking place in Paris from May 21-24, 2013.

In addition to the symposium, the Company reported that another fourteen presentations and three abstracts highlighting the MGuard EPS technology were presented over the 4-day conference.

With its proprietary micro-net mesh sleeve, MGuard EPS addresses an unmet need by preventing unstable arterial plaque and thrombus (clots) that cause heart attack blockage from breaking off and exacerbating damage.

The MASTER trial achieved its primary endpoint (p value = 0.008), in complete ST-segment resolution at 60-90 min post-procedure (a strong predictor of mortality). Secondary endpoint clinical outcomes continue to show a lower mortality rate with MGuard EPS compared to control (0.5% vs. 2.8%, P=0.06) at 6 months. These findings corroborate the previously announced 30-day results showing that all-cause mortality with MGuard EPS was lower than bare metal and drug eluting stents used as a control (0% vs. 1.9%, P=0.06). Additional 6-month results are available at www.inspiremd.com .

"The initial MASTER trial results published in the Journal of the *American College of Cardiology* [1] in October 2012 demonstrated the acute benefits of the embolic protection stent, as MGuard EPS outperformed drug-eluting and bare metal stents in complete ST-segment resolution," said Professor Dr. Sigmund Silber, Director of the Heart Center at the Isar Academic Teaching Site of the University of Munich. "The six-month MASTER results highlight the enduring benefits of the MGuard EPS, with a consistent trend in lower mortality."

In the MASTER trial, a total of 433 patients with STEMI presenting within 12 hours of symptom onset undergoing percutaneous coronary intervention were randomized at 50 sites in 9 countries to the MGuard EPS (n = 217) or commercially available bare metal or drug-eluting stents (n = 216).

“The body of positive clinical evidence supporting the use of the MGuardEPS continues to grow,” said Alan Milinazzo, President and Chief Executive Officer of InspireMD. “Both the 6-month data and the subgroup analysis presented this week at EuroPCR in Paris, suggest that our technology offers improved embolic protection over the current generation of bare metal and drug eluting stents for the STEMI patient. Advancing embolic protection without requiring physicians to increase procedure time or dramatically change their technique is a major benefit of the MGuard EPS.”

Conference Call and Webcast Details

InspireMD will host a conference call and webcast to review 6-month MASTER trial data on Thursday May 23, 2013 at 8:00 ET, 14:00 CET. To access the call, participants should dial the following numbers:

- U.S. and Canada: +1-888-417-8516
- Paris: +33-08-00-90-26-40
- International: +1-719-325-2144

The webcast will be available at www.InspireMD.com . An archived webcast will be available for 30 days.

About Stenting and MGuard EPS

Standard stents were not engineered exclusively for heart attack patients. They were also designed for treating stable angina patients whose occlusion contains thrombotic material.

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 integrates a precisely engineered micro net mesh designed to prevent 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’s mission is to utilize its proprietary MGuard technology to make its products the industry standard for stents and to provide a superior solution to the key clinical issues of current stenting: embolic showers, restenosis and late stent thrombosis.

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.

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[1] Stone GW, Abizaid A, Silber S, Dizon JM, Merkely B, Costa RA, Kornowski R, Abizaid A, Wojdyła R, Maehara A, Dressler O, Brener SJ, Bar E, Dudek D.Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh-Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction: The MASTER Trial. *J Am Coll Cardiol* . 2012;60(19):1975-1984