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INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 10/29/13 for the Period Ending 10/29/13

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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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): October 29, 2013

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

800 Bolyston Street, Suite 16041 Boston, MA	02199
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that Professor Dariusz Dudek will present on October 29, 2013 at the Transcatheter Cardiovascular Therapeutics (TCT) Conference, at the Moscone Center in San Francisco, CA, with respect to the 12 month results of InspireMD, Inc.'s MASTER trial.

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 October 29, 2013, InspireMD, Inc. issued a press release announcing the 12 month results of InspireMD, Inc.'s MASTER trial and announcing that it will host a conference call at 8:30 a.m. ET on October 30, 2013 to discuss the results of the MASTER trial. A copy of the press release is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	2013 TCT Presentation
99.2	Press Release dated October 29, 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: October 29, 2013

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

MASTER Trial
12 Month Results

Prof. Dariusz Dudek
Hospital University of Krakow, Poland
on behalf of the MASTER Trial Investigators

tct 25
CARDIOVASCULAR RESEARCH FOUNDATION

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• InspireMD
• Consulting Fees/Honoraria	• No
• Major Stock Shareholder/Equity	• No
• Royalty Income	• No
• Ownership/Founder	• No
• Intellectual Property Rights	• No
• Other Financial Benefit	• No

Background

- Impaired myocardial perfusion after PCI in STEMI is common, and results in increased infarct size, heart failure and mortality.
- PCI-induced distal embolization of thrombus and/or friable atheromatous debris contributes to impaired myocardial perfusion.
- Efforts to improve myocardial perfusion with embolic protection devices have failed.
- Recent results from the INFUSE-AMI and TASTE trials question whether aspiration results in any significant myocardial or clinical benefits.

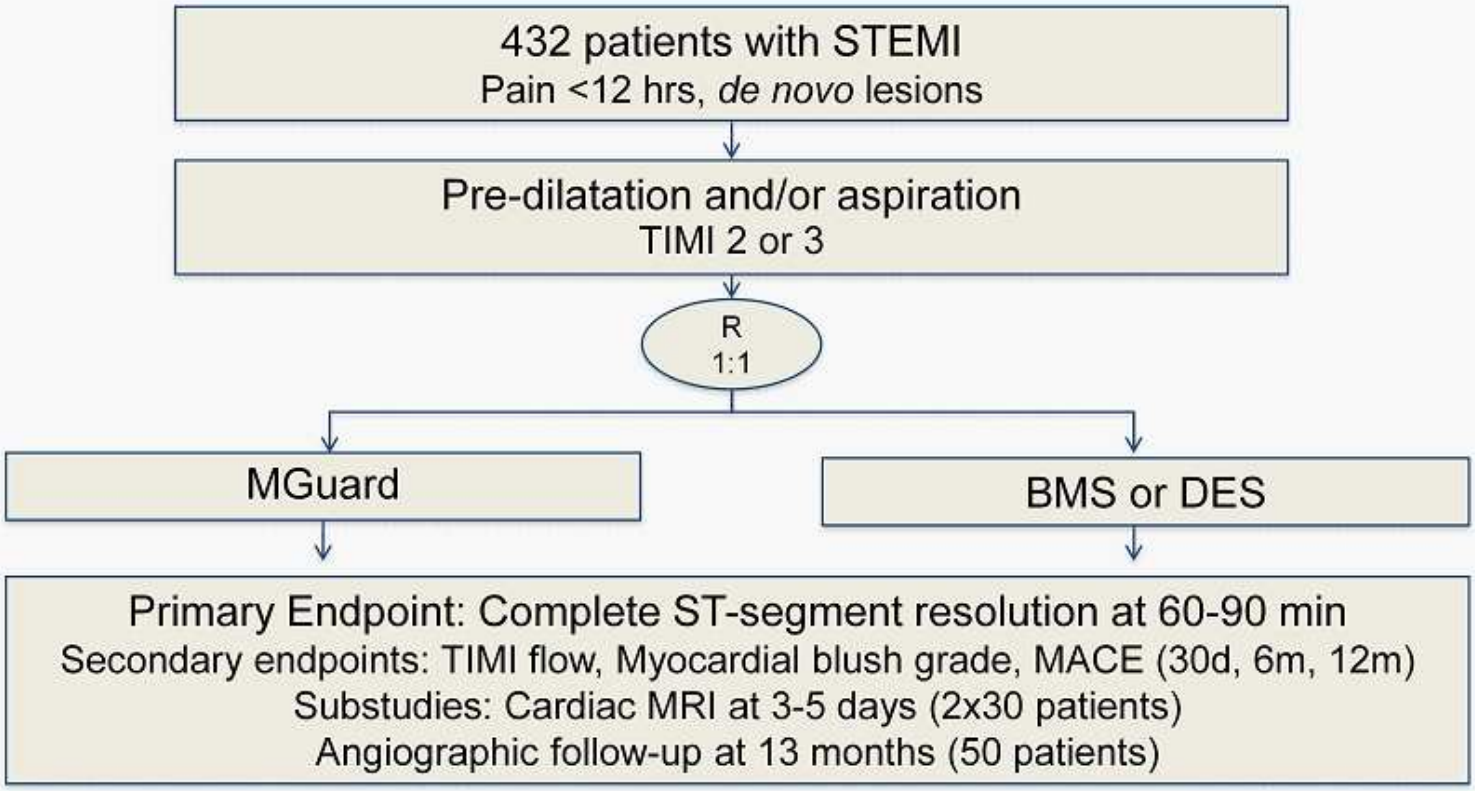
MGuard stent: designed for embolic protection

- MGuard is a thin-strut BMS wrapped with an expandable MicroNet mesh, designed to trap, exclude and secure the thrombus and friable atheromatous debris to prevent distal embolization during and post procedure.
- The mesh is made of a 20μM Polyethylene Terephthalate (PET) fiber.
- The pores expand to 180μm when deployed.
- The mesh is expandable for side branch access.
- The mesh is attached to the proximal and distal edges of the stent only to ensure high flexibility of the stent system.

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	
PORE SIZE	150-180µM	

MASTER Trial design



Enrollment in participating countries

Main Inclusion / exclusion criteria

INCLUSION CRITERIA	» Symptoms consistent with STEMI within 12 hours of symptom onset » ≥2 mm of ST-segment elevation in ≥2 leads » PCI of a single de novo lesion with RVD ≥3.0 to ≤4.0 mm » Lesion length ≤33 mm
EXCLUSION CRITERIA	» LBBB, paced rhythm, etc. (unable to assess ST-segments) » 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 (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 GW et al. *J Am Coll Cardiol.* 2012;60:1975-1984

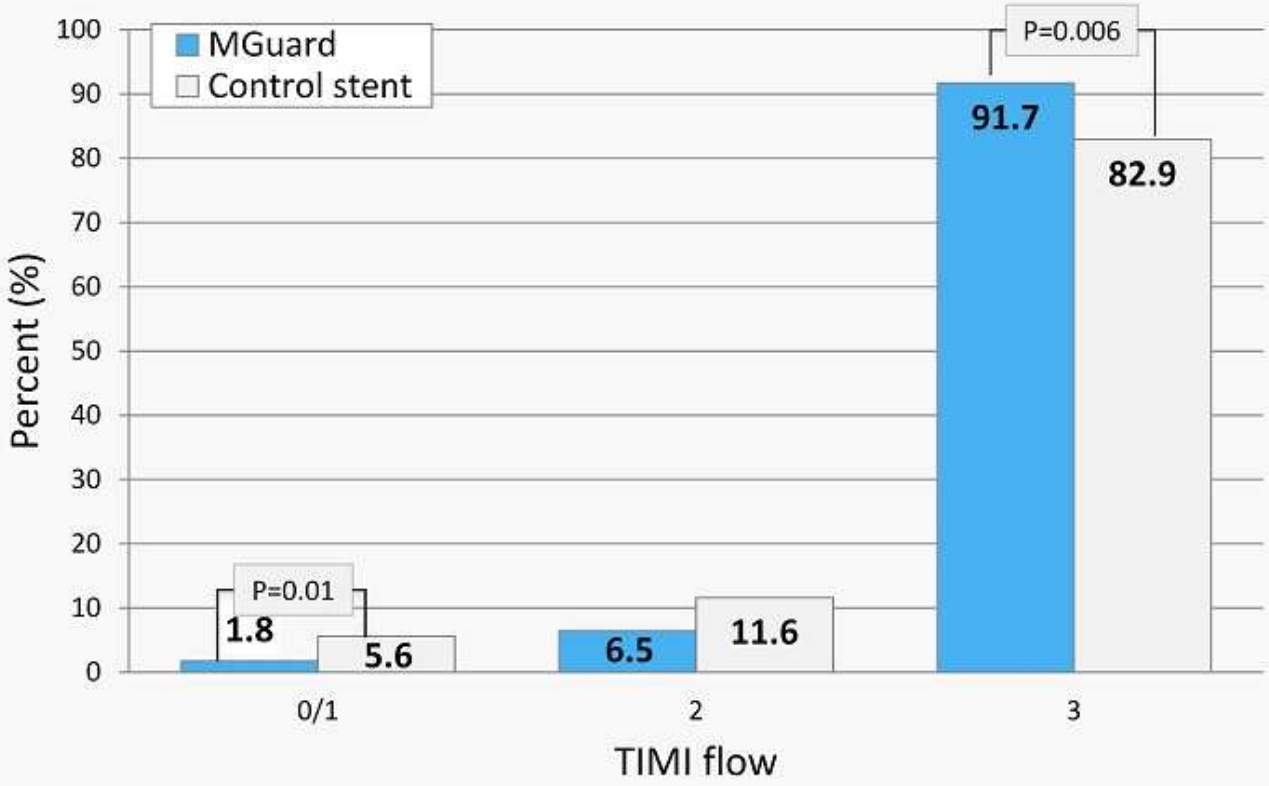
Procedural characteristics

	MGUARD (N=217)	CONTROL (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, 27 were treated with MGuard Prime

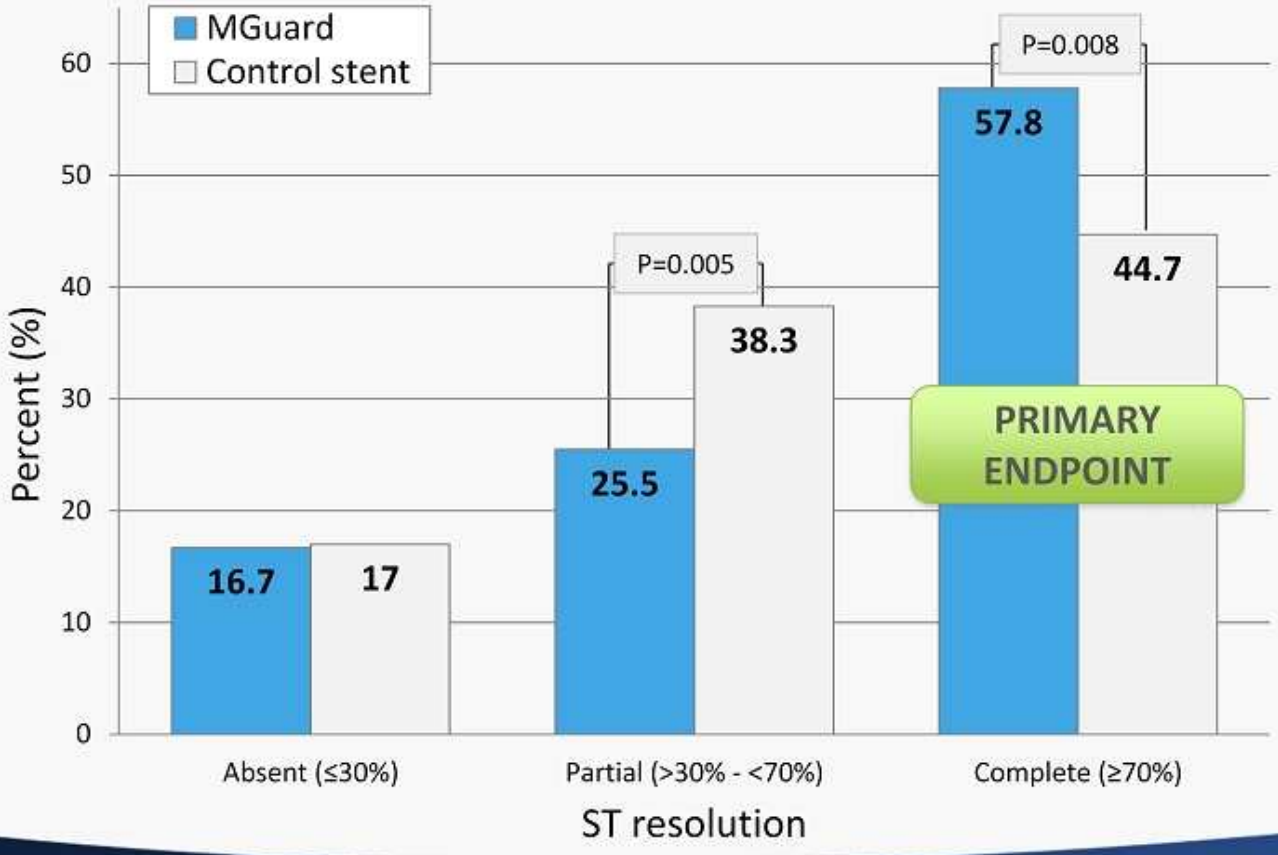
Stone GW et al. *J Am Coll Cardiol*. 2012;60:1975-1984

Epicardial coronary flow



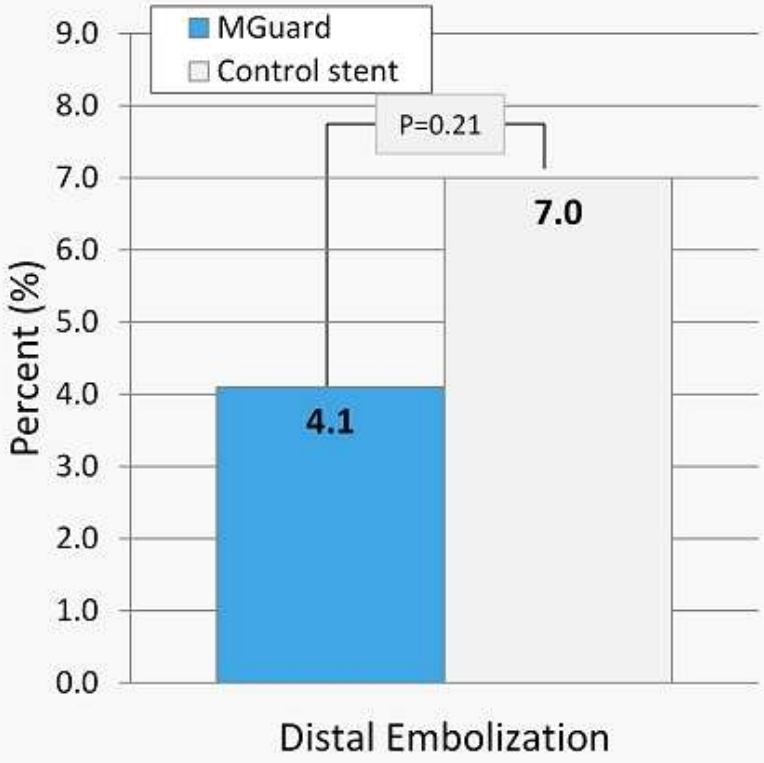
Stone GW et al. *J Am Coll Cardiol*. 2012;60:1975-1984

ST-segment resolution



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

Distal embolization



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

Cardiac MRI sub-study at 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 GW et al. *J Am Coll Cardiol*. 2012;60:1975-1984

30-day clinical results

	MGUARD (N=217)	CONTROL (N=214)	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%)	1.00
Major	3 (1.4%)	2 (0.9%)	1.00

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

12 month clinical results

NEW RESULTS

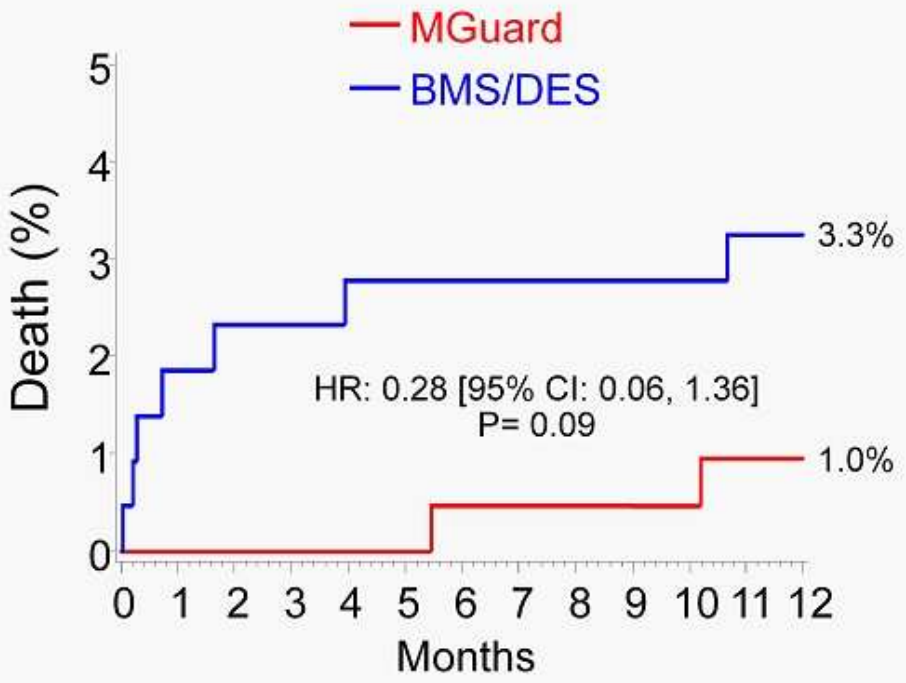
	MGUARD (N=217)	CONTROL (N=216)	P
MACE	9.1% (19)	3.3% (7)	0.02
All cause mortality	1.0% (2)	3.3% (7)	0.09
Cardiac death	0.5% (1)	2.3% (5)	0.10
Reinfarction	1.4% (3)	0.9% (2)	0.66
Death or reinfarction	2.3% (5)	3.7% (8)	0.39
TLR, ischemia-driven	8.6% (18)	0.9% (2)	0.0003
TVR, ischemia-driven	11.0% (23)	0.9% (2)	<0.0001
Stent Thrombosis			
Definite or Probable	2.3% (5)	0.9% (2)	0.26
Definite	2.3% (5)	0.5% (1)	0.10
Stroke	0.5% (1)	1.0% (2)	0.56
TIMI Bleeding			
Major or Minor	1.8% (4)	2.5% (5)	0.73
Major	2.4% (5)	0.9% (2)	0.26

Propensity score *matching (TLR / TVR)*

	HORIZONS-AMI BMS N=443	MASTER MGuard N=191	P
MACE	7.5% (33)	9.2% (17)	0.54
TLR, ischemia-driven	6.0% (26)	8.7% (16)	0.26
TVR, ischemia-driven	6.9% (30)	10.3% (19)	0.18

Propensity Score Adjustment on the following covariates (3 - 1 caliper = 0.35): Age, BMI, Male, Hyperlipidemia, Diabetes, Prior Angina, Prior MI, Symptom to Balloon time, stent length, baseline RVD, LAD vs RCA vs LCX, Baseline TIMI 0/1/2 vs TIMI3

Death Time-to-Event curve

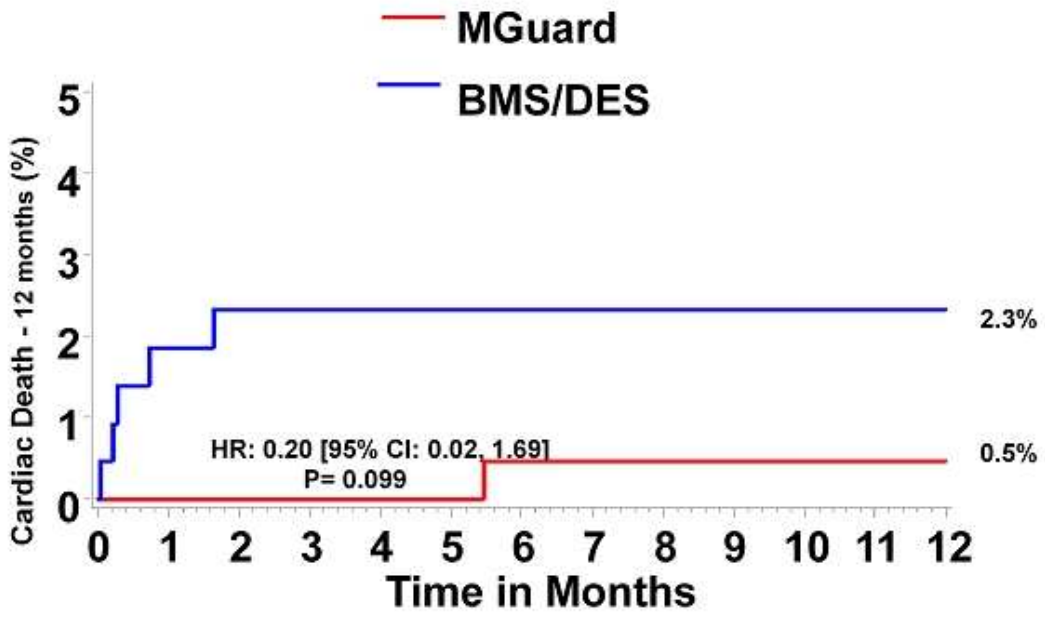


Number at risk:

MGuard	217	214	209	206	126
BMS/DES	216	210	209	207	123

NEW RESULTS

Cardiac Death Time-to-Event curve

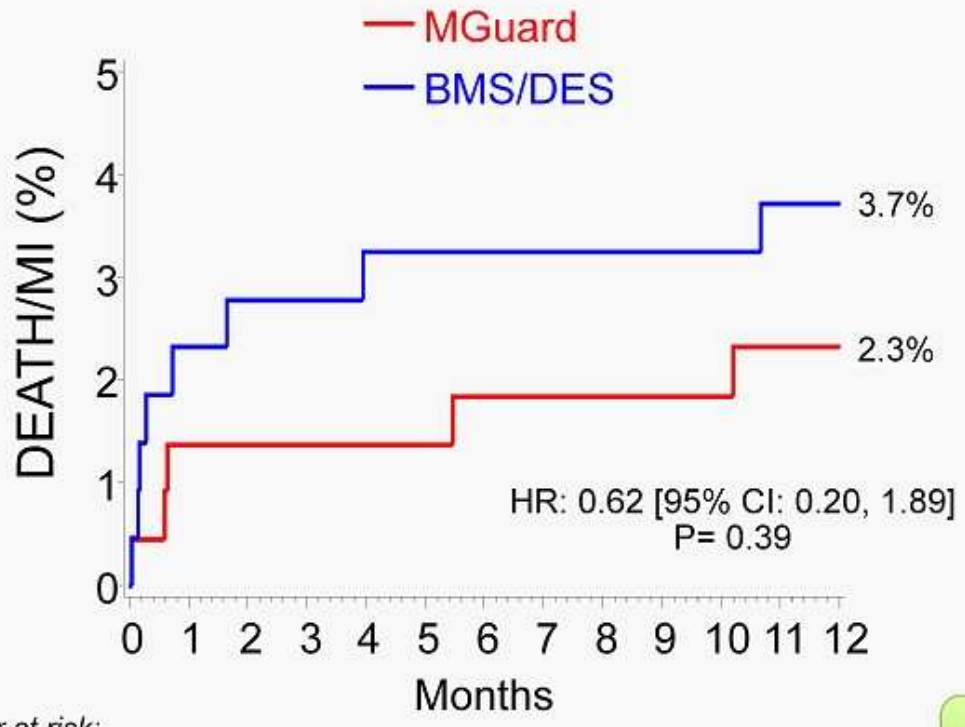


Number at risk:

MGuard	217	214	209	206	126
BMS/DES	216	210	210	207	124

NEW RESULTS

Death or MI Time-to-Event curve



Number at risk:

MGuard	217	212	207	205	125
BMS/DES	216	209	208	206	123

NEW RESULTS

13 Month angiographic sub-study follow-up

- Enrollment into the angiographic sub-study started after the study enrolled 100 patients, and occurred in pre-specified sites.

- 48 consecutively enrolled patients randomized to the MGuard were consented to return at 13 months for an invasive angiographic follow-up.

- 38 patients underwent the angiography (79.2%)
  - 4 patients refused
  - 1 patient was not available during the visit window.
  - 2 patients exited the study before the follow-up period
  - 1 patient died before the follow-up period
  - 1 patient had an illness, and could not have the angiography
  - 1 patient was lost to follow-up

13 Month angiographic sub-study follow-up

	ENTIRE SUBSTUDY COHORT (N=36)*		SINGLE MGUARD STENT (N=31)**	
	Average	**95% CI**	**Average**	**95% CI**
Late loss *(in stent)*	0.99 ± 0.80	[0.73,1.26]	0.88 ± 0.70	[0.63,1.14]
Late loss *(in segment)*	0.82 ± 0.75	[0.57,1.06]	0.72 ± 0.65	[0.48,0.95]
Binary Restenosis *(in stent)*	23.7%	[11.4%, 40.2%]	19.4%	[7.5%, 37.5%]
Binary Restenosis *(in segment)*	31.6%	[17.5%, 48.7%]	29.0%	[14.2%, 48.0%]

NEW RESULTS

tct 25

* Of the 38 patients, 36 lesions were analyzable
** 31 patients were treated with a single MGuard stent

CARDIOVASCULAR RESEARCH FOUNDATION

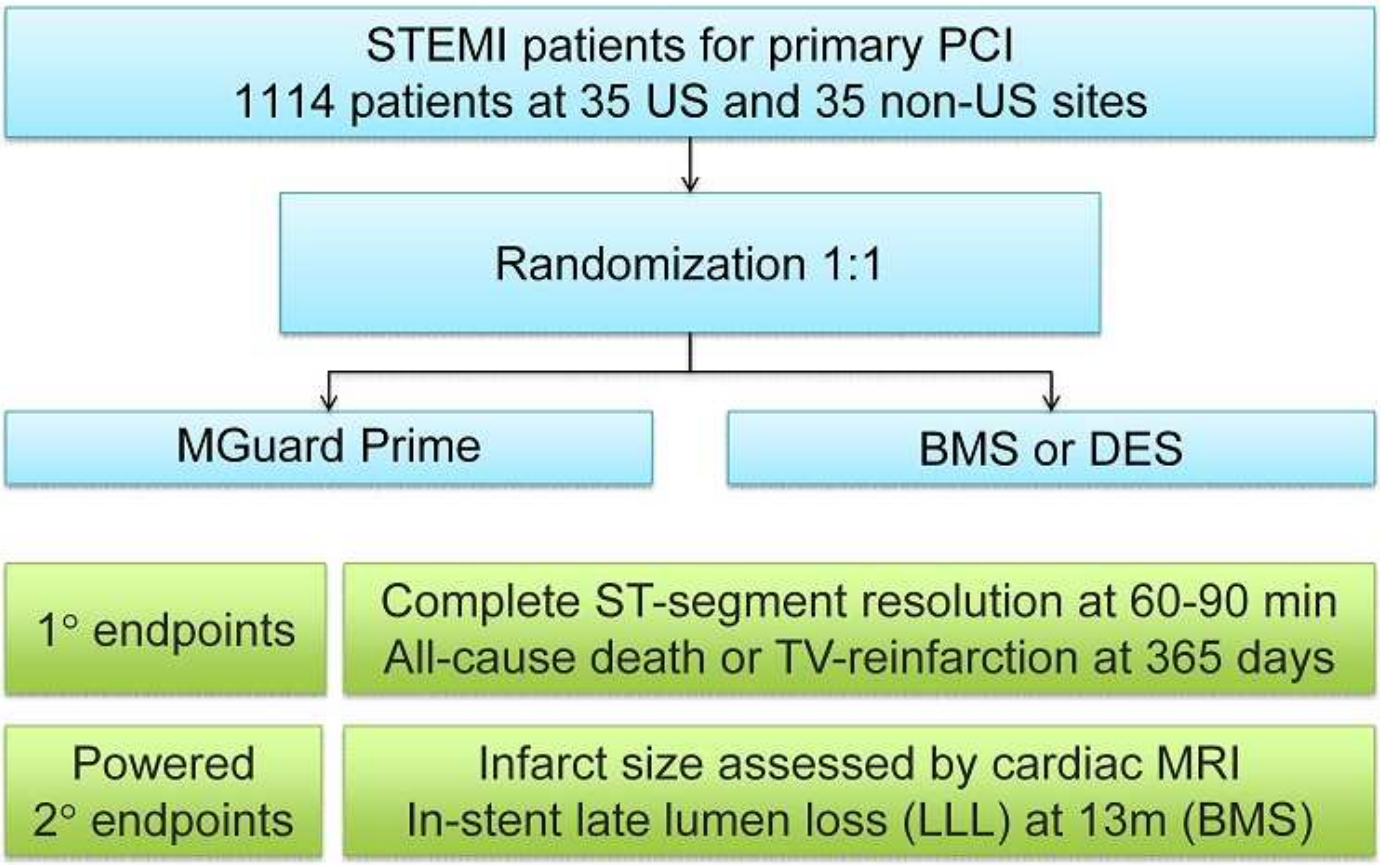
Limitations

- The MASTER trial was powered for ST-segment resolution, and not for infarct size or clinical events.
- Endpoints other than ST-segment resolution should be considered exploratory and hypothesis-generating.
- The control arm in MASTER consisted of a mixture of patients treated with DES and BMS, and randomization was not stratified by stent type.
- The trial was open label, and some degree of bias cannot be excluded.
- Angiographic follow-up was not performed in the control arm.

Conclusions

- Among patients with acute STEMI undergoing emergent PCI, MGuard EPS resulted in superior rates of TIMI3 and complete STR.
- A trend towards reduced mortality was present in the MGuard arm at 30 days, which persisted throughout 12 month follow-up.
- No significant differences in reinfarction or stent thrombosis were present at 12 months between the MGuard and control groups.
- The 12 month TLR rate in the MGuard arm were higher than in the control, but were comparable to those expected from a BMS.
- The 13 month angiographic analysis demonstrates LLL and binary restenosis rates for the MGuard stent which are comparable to other BMS.

MASTER-II IDE study design



InspireMD's MGuard Stent Shows Lower Mortality Rate in STEMI Patients at Twelve Months Compared to Control Group

- - -

Company to Host Conference Call Tomorrow at 5:30 a.m. PT / 8:30 a.m. ET

BOSTON, Ma – October 29, 2013 – InspireMD, Inc. ("InspireMD" or the "Company") (NYSE MKT: NSPR), a leader in embolic protection stents, today announced new 12-month results from the MASTER (**M** Guard for **A** cute **ST E** levation **R** eperfusion) trial demonstrating that the MGuard 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 Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco earlier today.

Additionally, the Company will be holding an evening symposium tomorrow, October 30 th , starting at 6:30 pm PT. Dr. Gregg Stone, Dr. Ori Ben-Yehuda and Dr. Jose Henriques will lead the symposium and will be joined by a panel of medical experts.

The MGuard utilizes the Company's proprietary MicroNet™ technology, which is a circular knitted mesh that wraps around the stent to protect patients from plaque debris flowing downstream upon deployment. This advanced technology allows the MGuard to specifically address the unmet need for STEMI patients, and save the life of those who suffer from heart attacks.

The MASTER trial achieved its primary endpoint (p value = 0.008), in complete ST-segment resolution at 60-90 minutes post-procedure. ST-segment resolution is historically known to be a strong predictor of mortality. Secondary endpoint clinical outcomes continued to show a lower mortality rate with the MGuard EPS compared to the control (1.0% vs. 3.3%, p=0.092) at 12 months. These findings are in line with the previously announced 6 month follow-up results showing that all-cause mortality with MGuard EPS was lower than bare metal and drug eluting stents used as a control (0.5% vs. 2.8%, p=0.056). Additional 12-month results are available at www.inspiremd.com.

"The positive follow-up data presented at TCT suggests that our MGuard EPS offers STEMI patients a higher likelihood of survival at 12 months than standard bare metal and drug eluting stents," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "This data further supports the evidence that positive acute results at the time the patient is treated are associated with improved outcomes at 12 months. Additionally and importantly, the subset data we released on treatment time from symptom onset to reperfusion revealed that MGuard may increase the therapeutic window for physicians treating STEMI patients. This could be a very important factor when physicians assess clinical treatment options for their patients."

"It is very reassuring to see that the 12-month follow up data is consistent with the acute results presented at TCT last year, especially the data that shows the mortality benefit trend of using this unique technology," stated Prof. Dariusz Dudek, Physician-in-Chief, 2nd Department of Clinical Cardiology and Cardiovascular Interventions at the University Hospital in Krakow. "These positive results should give clinicians the confidence to use MGuard technology as a first line of defense against distal embolization for their STEMI patients."

The MASTER trial enrolled 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).

Conference Call and Webcast Details

InspireMD will host a conference call and webcast to review 12-month MASTER trial follow-up data on Wednesday, October 30, 2013 at 8:30 a.m. ET / 5:30 a.m. PT. To access the call, participants should call (877) 842-0788 (United States/Canada) or (317) 468-2947 (International) and request the InspireMD call or provide confirmation code 90920442. A live webcast of the call will be available on the Investor Relations section of the Company's website at http://www.inspire-md.com/site_en/for-investors/ . Please allow 10 minutes prior to the call to visit the site and download any necessary audio software.

A replay of the conference call will be available approximately two hours after completion of the live conference call and will be accessible until 11:59 p.m. ET on November 13, 2013. To listen to the replay, dial (855) 859-2056 (United States/Canada) or (404) 537-3406 (International) and enter code 90920442. The webcast of the event will also be archived for a limited time on the Investor Relations section of the Company's website at http://www.inspire-md.com/site_en/for-investors/ .

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 seeks to utilize its proprietary MGuard™ technology to make its products the industry standard for embolic protection stents and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

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 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, multinational 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 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 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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