INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 09/16/14 for the Period Ending 09/16/14

Address	321 COLUMBUS AVENUE 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): September 16, 2014

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.)

321 Columbus Avenue Boston, Massachusetts	02116
(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 Joachim Schofer, MD, will present on September 16, 2014, at the Transcatheter Cardiovascular Therapeutics (TCT) Conference, at the Walter E. Washington Convention Center in Washington, D.C., with respect to the results of InspireMD, Inc.'s CARENET (***CAR*** *otid* ***E*** *mbolic protection using micro* ***NET***) 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 September 16, 2014, InspireMD, Inc. issued a press release announcing the results of InspireMD, Inc.'s CARENET 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	2014 TCT Presentation
99.2	Press Release dated September 16, 2014

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INSPIREMD, INC.

Date: September 16, 2014

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

Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial

(CARotid Embolic protection using microNET)

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

Joachim Schofer, MD,PhD, Hamburg University CardiovascularCenter, Hamburg Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany

tct2014 In Partnership with the ACC

Columbia University Medical Center
NewYork-Presbyterian

Disclosure Statement of Financial Interest

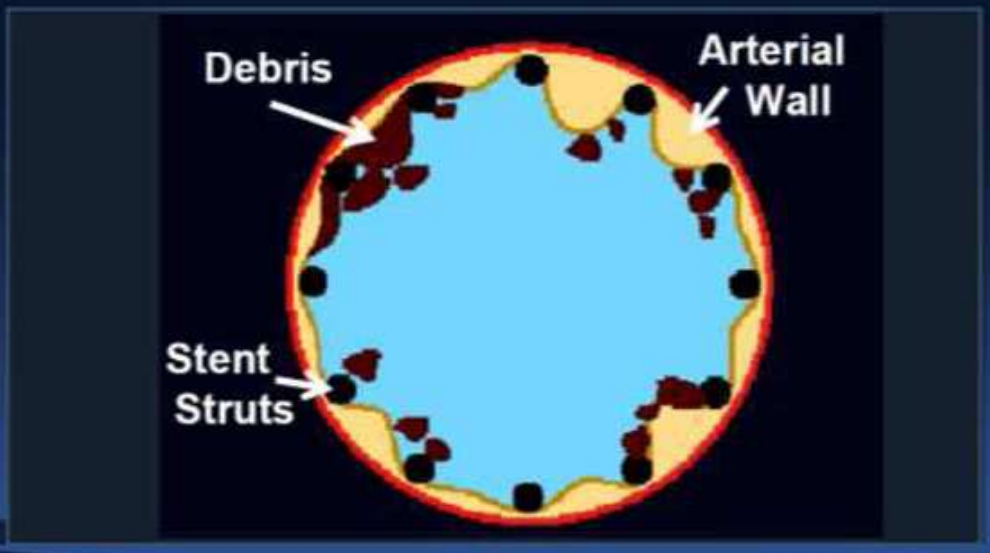
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• InspireMD

Rationale of Technology

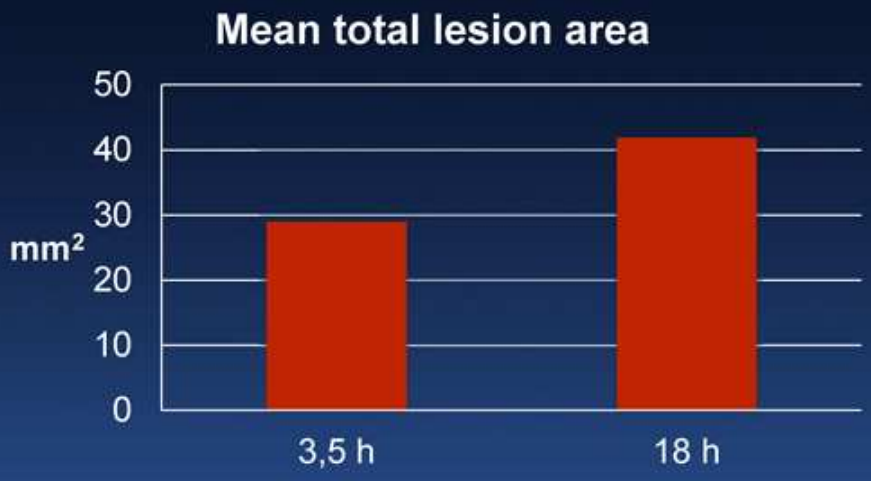
Conventional Carotid Stent

Plaque protrusion may lead to early and late distal embolization



Late Embolization

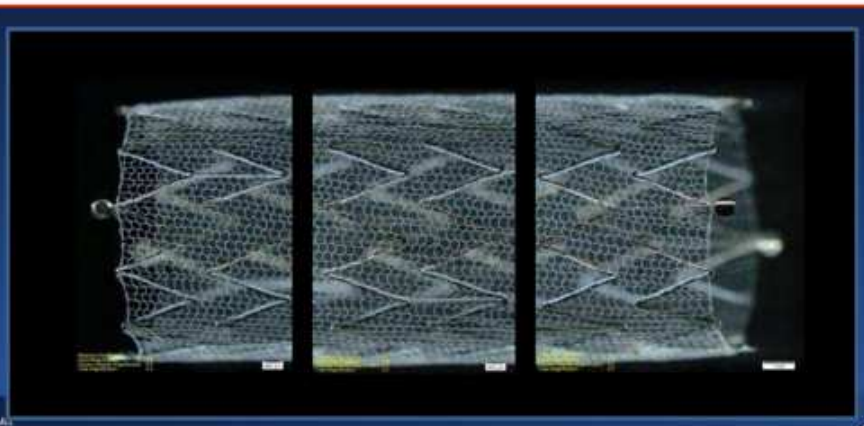
DW-MRI post CAS



Schofer J et al, JACC Cardiovasc interv 2008

CGuard™ Carotid Embolic Prevention System Specifications

Device Features	
Stent type	Nitinol Self-Expanding
MicroNet Aperture Size	150-180μ
Guidewire	0.014"
Foreshortening	<10%
Sizes	Diameter(6mm-10mm) x Length (20mm – 60mm)
Delivery System (OD)	6F (2.1mm)



tct2014

Columbia University Medical Center

NewYork-Presbyterian

CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design

- **Study Design:**
  - Prospective, multi-center, multi-specialty, international, open label, single arm, non-randomized clinical trial in patients with symptomatic and asymptomatic carotid artery stenosis
- **Objectives:**
  - To evaluate the periprocedural safety and efficacy of the CGuard™ system in the treatment of carotid lesions in 30 consecutive patients suitable for carotid artery stenting (CAS)
- **Sites:**
  - Hamburg University CardiovascularCenter, Hamburg Germany, Joachim Schofer
  - Jagiellonian University MedicalCollege at JohnPaul II Hospital, Krakow Poland, Piotr Musialek
  - Cardiovascular Center Frankfurt, Frankfurt Germany, Horst Seivert
  - Augusta Hospital, Dusseldorf Germany, Ralf Kolvenbach

CGuard™ CARENET (CARotid Embolic protection using microNET) Trial Design

- **Study Population:**
  - Symptomatic pts (w/ history of a transient ischemic attack, stroke, or amaurosis fugax within the last 6 mos on the ipsilateral side) w/carotid stenosis ≥ 50%
  - Asymptomatic pts w/ carotid stenosis ≥ 80% both as diagnosed by angiography using NASCET methodology
- **Primary Endpoint:**
  - 30 day MACE (death, stroke, MI)
- **Key secondary Endpoints:**
  - Technical success
  - Periprocedural complications (including device-related)
  - Incidence, number and volume of new lesions assessed by DW MRI during pre-procedure, 24-48 hours post-procedure, and at 30 days (+/- 3 days)
  - Peak systolic velocity (PSV) and end diastolic velocity (EDV) assessment by ultrasound examination at 30 days, 6 mos, and 1 year

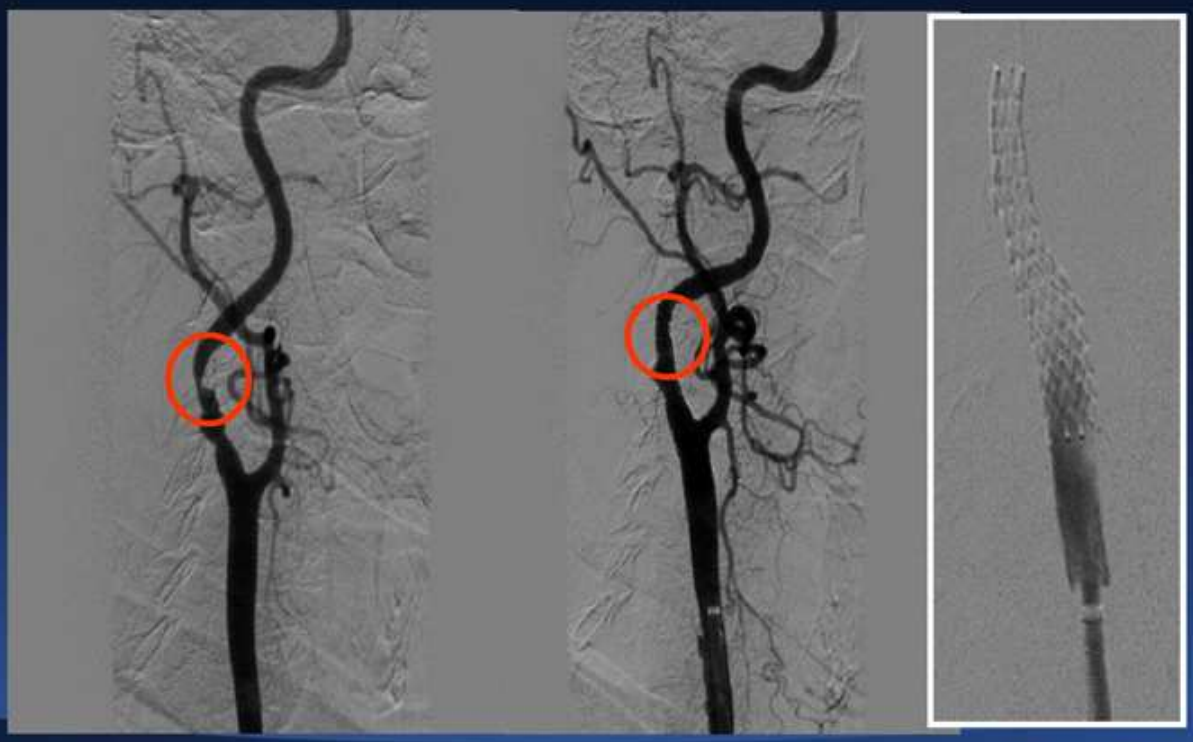
Baseline Characteristics
(n=30)

Age	71.6 ±7.6
Male	63.4%
Symptomatic	33.3% (10)
BMI (kg/m^2)	26.4 ± 3.9
Hypertension	83.3% (25)
Dyslipidemia	90% (27)
Diabetics	23.3% (7)
Smoker: Current Former	 13.4% (4) 36.6% (11)
Prior MI	26.7% (8)
Prior TIA	13.3% (4)

Procedure Results

Femoral access	100% (30)
Target vessel Left ICA Right ICA	 33.3% (10) 66.6% (20)
Protection used Distal protection Proximal protection	100% 96.6% (29) 3.4% (1)
Pre dilatation	70.9% (22)
Post dilatation	77.4% (24)
Post dilatation Pressure (ATM)	13.6 ±4.5
Device success	100% (30)
Stent deployed	100% (30)
Stent diameter (Mean)	8.23mm ± 0.8
Stent length (Mean)	34.8 mm ± 5.0
Second stent used	3.33% (1)

Pre & Post Procedure Carotid Angiogram in Patient with right ICA Stenosis



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Clinical Outcomes

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

Angiographic Assessment

	Baseline	Final
Lesion location (internal)	100%	NA
Lesion length (mm)	16.94±4.7	NA
RVD (mm)	6.18	5.89
MLD (mm)	1.25	4.82
Diameter stenosis (%)	79.9%±5.0%	16.9%±6.5% (in stent)
ECA stenosis (%)	18.0%	22.1%
TIMI flow in ECA		
Normal	100.0%	100.0%

CARENET with Distal Protection
DW-MRI @ 24-48 hrs

	CARENET CGuard with only Distal EPD (N=26*)
Incidence of New Lesions	46%
Lesions (per patient)	1.62 ±2.68
Volume (per patient)	0.061 ±0.11 cm^3

- **3 pts unable to undergo MRI (1 = pacemaker; 2 = claustrophobia)*
- *1 pt with proximal protection had 78 new lesions. New ischemic lesions had no clinical or neurological impact, all lesions been resolved at 30 days.*

CARENET Comparison
DW-MRI @ 24-48 hrs

	CARENET (Filter group) N=26	PROFI[1] (Filter group) N=31	ICSS[2] (Filter group) N=37
Incidencs of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm^3	0.59 cm^3	NA

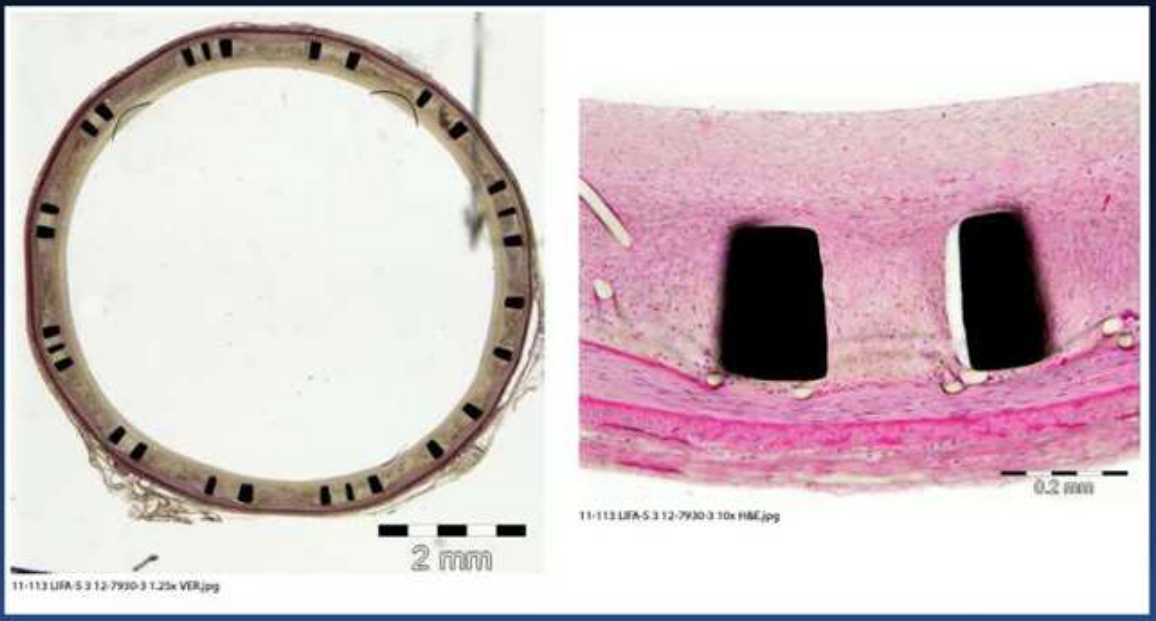
[1] *JACC, April 2012*
[2] *Lancet, March 2010*

Conclusions

- CARENET trial demonstrated the safety of the CGuard™ Technology with zero MACCE at 30 days
- The procedural success was 100%
- Compared to published DW-MRI data of non-mesh covered carotid stents, the incidence of new ischemic lesions was reduced by almost 50% and the average lesion volume per patient 10 times smaller
- These initial clinical results suggest that the MicroNet™ covered CGuard™ offers unique clinical benefits for patients undergoing CAS

- **Back up slides**

Histopathology in Pig Carotid Artery

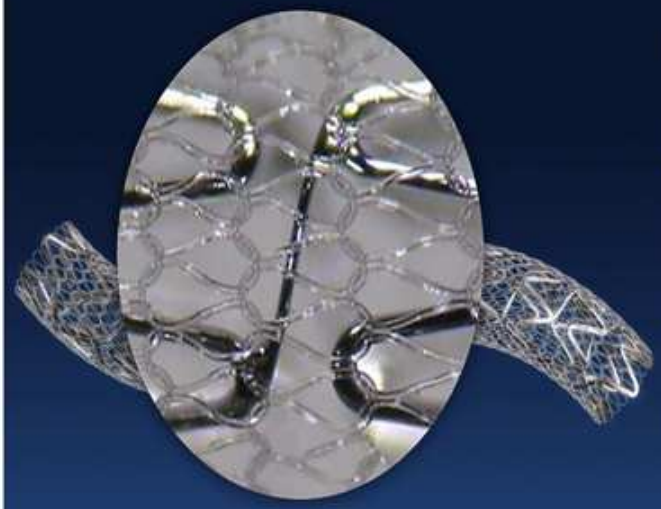


Ischemic Lesions (Pre, 48hr Post, 30 day Post)

	Preprocedure MRI	48-Hr MRI	30-Day MRI
Subjects with Lesions	2 (8.0%)	11 (46.0%)	2 (8.32%)
Number of new lesions	12	42	2
Avg. Lesions (per patient)	0.5±1.72	1.71 ±4.77	0.08±0.28
Total Lesion Volume (cm^3)	0.33 ± 1.4	0.16± 0.31	0.13 ± 0.54

History - MGuard™ Prime EPS

DESIGNED FOR EMBOLIC PROTECTION

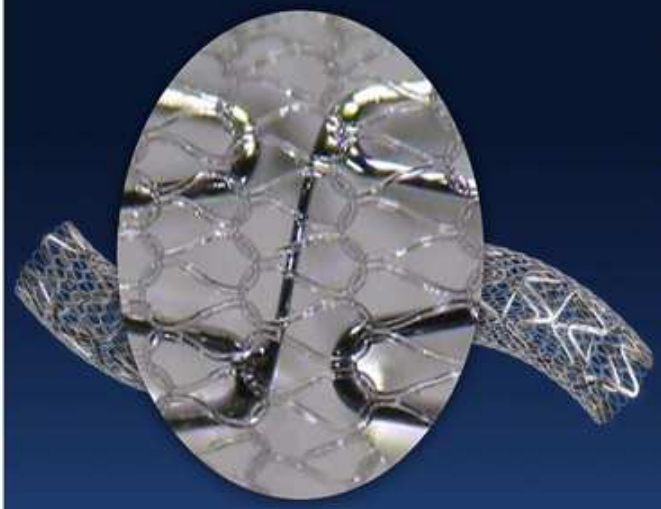


- Co-Cr Bare metal stent wrapped with an expandable MicroNet™
- Single strand Polyethylene Terephthalate (PET) fiber
- Attached only to proximal and distal crowns of the stent
- Deploys exactly like a typical balloon expandable stent
- Thousand's of MGuard™ coronary embolic protection systems have been implanted for AMI / STEMI indications

CE Mark and commercial (coronary indication) throughout world (Not available for sale in US)

History - MGuard™ Prime EPS

DESIGNED FOR EMBOLIC PROTECTION



Mesh (pore size 150-180 µ) reduces the risk of distal embolization providing protection during and post procedure

- Co-Cr Bare metal stent wrapped with an expandable MicroNet™
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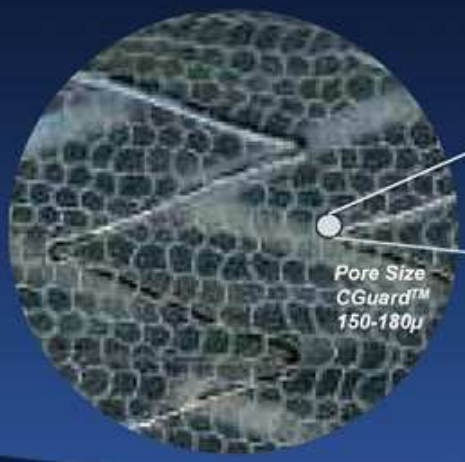
Aperture Size

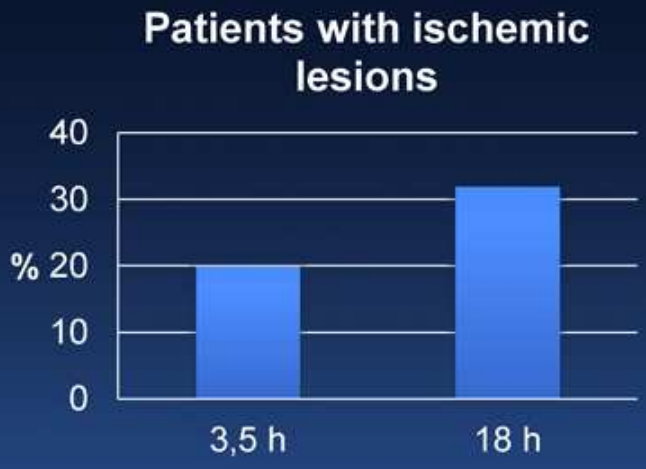


Other Mesh covered carotid stent technology 375-500 microns

CGuard™ 150-180 microns

Late Embolization

DW-MRI post CAS



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DW-MRI @ 24-48 hrs

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Incidence of New Lesions	46%
Lesions (per patient)	1.62 ±2.68
Number of new lesion	42
Volume (per patient)	0.061 ±0.11 cm^3

- **3 pts unable to undergo MRI (1 = pacemaker; 2 = claustrophobia)*
- *1 pt with proximal protection had 78 new lesions. New ischemic lesions had no clinical or neurological impact, all lesions been resolved at 30 days.*

Conclusions

- CARENET trial met primary endpoint of zero MACE (no death, stroke, and MI) at 30 days
- The procedural success was 100%
- Compared to published historical control groups of non-mesh covered carotid stents, in the CARENET trial the incidence of new ischemic lesions as assessed by DW-MRI was reduced by almost 50% and the average lesion volume per patient was 10 times smaller
- These initial clinical results suggest that the MicroNet™ covered CGuard™ offers unique clinical benefits for patients undergoing CAS

Exhibit 99.2

InspireMD Announces Positive Results from CGuard™ CARENET Trial with 0% MACE reported at 30 Days

- - -

Achieved Primary 30 Day Endpoint

Patients in CARENET Trial had significantly lower incidence of new ischemic lesions compared to historical control groups of non-mesh covered carotid stents

BOSTON, MA – September 16, 2014 — InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced positive results from the CARENET (**CAR** otid **E** mbolic protection study using micro **NET**) Trial for its CGuard ™ EPS. This trial demonstrates that the MicroNet ™ covered CGuard may offer important clinical benefits for patients undergoing carotid artery stenting (CAS).

CARENET was a multi-specialty trial that assessed the peri-procedural safety and efficacy of CGuard systems in the treatment of carotid lesions. The CARENET trial recruited a total of 30 patients and achieved its primary endpoint with 0% MACE (meaning no death, stroke or myocardial infarction) at 30 days. Additionally, compared to published historical control groups of non-mesh covered carotid stents, the incidence of new ischemic lesions as assessed by Diffusion Weighted Magnetic Resonance Imaging (DW-MRI) after carotid artery stenting was reduced by almost 50%. The CARENET trial also reported an average lesion volume per patient that was 10 times smaller than these historical control groups. The reduction in both the number of new ischemic lesions and the volume of those lesions indicates therapeutic benefits of the MicroNet technology in this patient cohort.

"The very positive data from the CARENET trial indicates that the CGuard EPS, with InspireMD's proprietary MicroNet technology, may provide patients an improved treatment for carotid artery disease," stated Alan Milinazzo, President and Chief Executive Officer of InspireMD. "Given the positive results from the trial, we plan to immediately initiate a limited market release of the CGuard in Europe through our direct sales organization in anticipation of a full market release in early 2015."

"This CARENET study shows that the CGuard reduces the incidence, as well as the total volume of ischemic lesions," stated Professor Joachim Schofer, MD, a Principal Investigator for the CARENET study, from the Hamburg University Cardiovascular Center, in Hamburg, Germany. "The results from this study seem to confirm that the small pore size of the MicroNet technology allows excellent blood flow while trapping potentially harmful plaque debris and thrombus. The DW-MRI follow up data confirmed that the MicroNet covered CGuard offers unique benefits for patients undergoing a CAS procedure."

Professor Piotr Musialek, Co- Principal Investigator for the CARENET study, from Jagiellonian University Medical College at John Paul II Hospital, in Krakow, Poland, commented, "My experience using the CGuard device has been extremely positive. The CARENET study involved an all-comer spectrum of patients and lesion types, making it truly reflective of the CAS population we treat today. While compatible with all types of embolic protection devices, the CGuard may provide an increase in the safety of carotid artery stenting irrespective of the type of protection used due to the ability of the MicroNet to prevent plaque protrusion and late embolization. I have seen the benefit of this device past 30-days, when the carotid stent can safely heal, in absence of any plaque protrusion through the stent struts. The 50 percent decrease in the incidence of new ischemic lesions as compared to traditional carotid non-mesh covered stents was impressive. I look forward to the continued use of the CGuard in my daily practice."

TCT Innovation Session on Late Breaking Early Human Clinical Studies
Comprehensive results from the CARENET trial are being presented by Professor Joachim Schofer, MD, from the Hamburg University Cardiovascular Center, at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in Washington, D.C. today, September 16, 2014. The detailed findings are being presented at 4:01 p.m. ET at the TCT 2014 Innovation Session: Late Breaking Early Human Clinical Studies under the title " Evaluation of a PET Mesh Covered Stent in Patients with Carotid Artery Disease: Results of the First in Man CARENET Trial."

To view the CARENET trial results presentation please visit InspireMD's website at www.inspire-md.com

About CGuard EPS
The proprietary CGuard EPS uses the same MicroNet technology featured on the MGuard™ and MGuard Prime™ coronary embolic protection systems. The MicroNet technology is a single fiber knitted mesh wrapped on an open cell stent platform designed to trap debris that can dislodge and travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect patients from plaque debris and blood clots breaking off and which can lead to life threatening strokes. The size, or aperture, of the MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus within the carotid artery.

CGuard EPS is CE Mark approved. CGuard EPS, however, is not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ technology to make its products the industry standard for embolic protection 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 MicroNet technology in coronary, carotid (CGuard ™) and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

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) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) 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 (xiii) 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-KT 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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