INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 09/12/17 for the Period Ending 09/12/17

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): September 12, 2017

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	6744832
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (888) 776-6804

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 7.01 Regulation FD Disclosure.

InspireMD, Inc. (the " ***Company*** ") intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and other conferences a slide presentation, which is attached hereto as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the " ***Exchange Act*** "), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Slide Presentation of InspireMD, Inc. dated September 2017.

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 12, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Investor Presentation

NYSE MKT: NSPR

September 2017

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 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 payors 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 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.

About InspireMD

InspireMD is a commercial-stage medical device company with proprietary and innovative embolic prevention systems (EPS)/thrombus management technologies and neurovascular devices that seek to overcome the harmful consequences of conventional stenting.

COMPANY

NYSE MKT:	NSPR
Founded:	2005
Employees:	37
Headquarters:	Tel Aviv
Manufacturing Facility:	Tel Aviv

TECHNOLOGY

Proprietary MicroNet™ technology in multiple products providing a superior solution for the treatment of complex vascular and coronary disease

PRODUCTS

Commercial:

CGuard™ Carotid EPS

MGuard™ Coronary EPS

Pipeline:

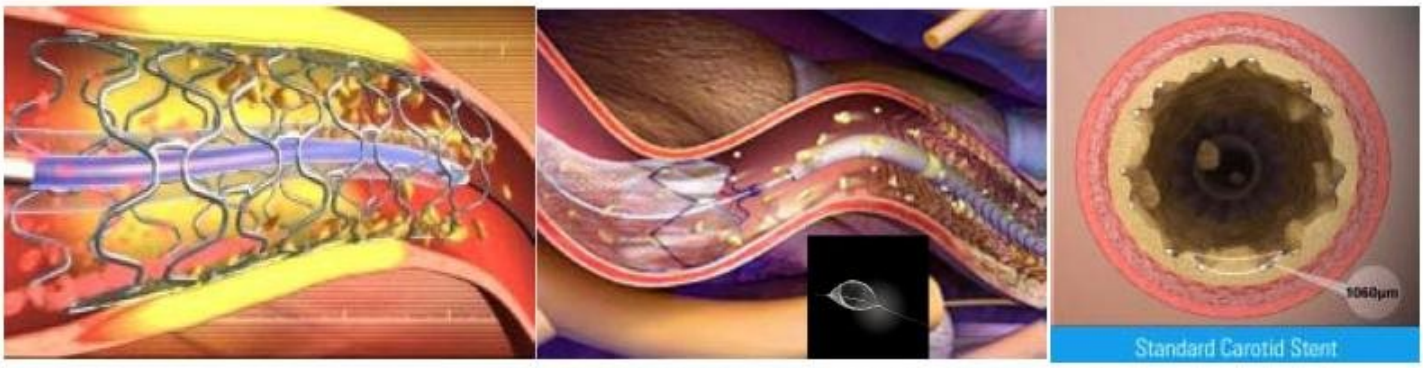
Next Gen CGuard™ - 5F

NGuard™

PVGuard™

Embolization Following Carotid Artery Stenting

"Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents in relation to plaque morphology/symptomatic status and stent type, providing a mechanism for post carotid artery stenting (CAS) cerebral embolization, either directly or via additional thrombus formation."*

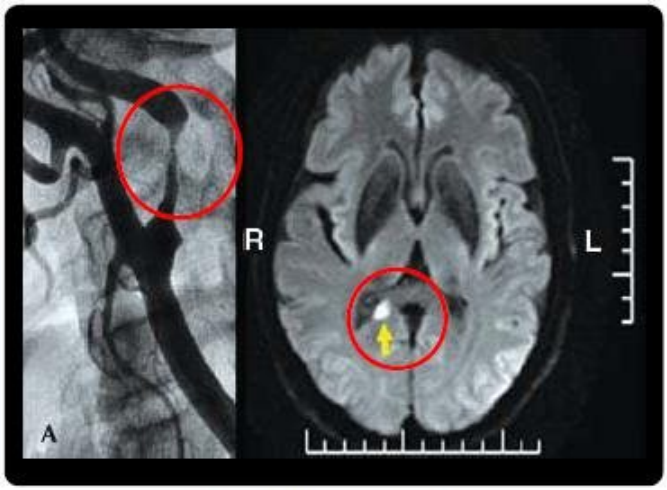


https://biotextiles2015.wordpress.com/embolic-protection-device/

2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

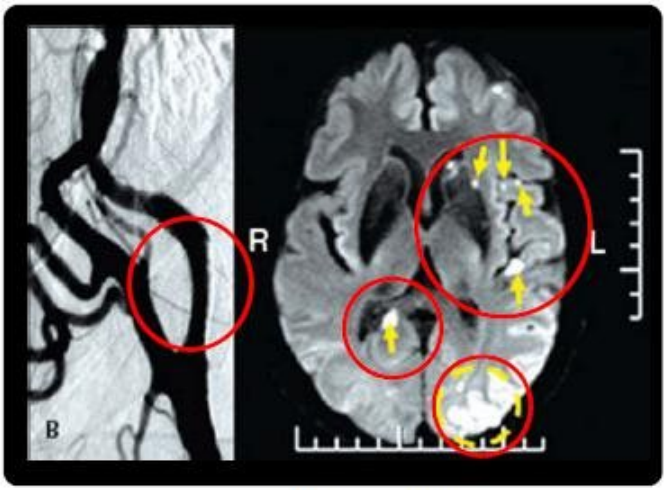
* Muslalek, et.al. EuroInterventions 2016;12 August 2016.
** Boslers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

Consequences Range from Neurological Deficit to Stroke



Pre-Procedure

Pre-intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction).



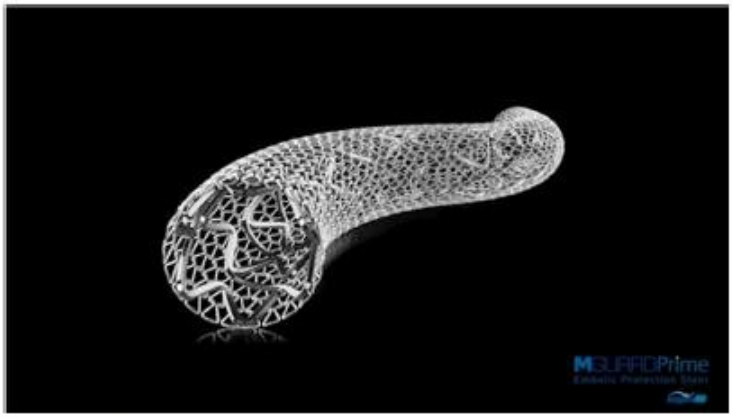
Post-Procedure

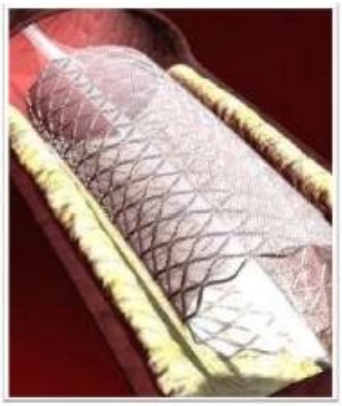
Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

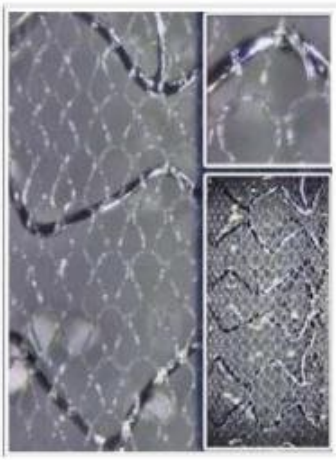
Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.

MicroNet™ Prevents Distal Embolization and Other Vascular Disease Challenges

- Ultrathin PET* mesh provides meaningful clinical benefit versus conventional devices
- Provides revascularization benefit
- MicroNet™ acts as a "safety net" by offering greater vessel area coverage to prevent large plaque protrusion through the scaffold into the vessel lumen
- Made of a single fiber from a biocompatible polymer, widely used in other medical implants
- Stents incorporating MicroNet™ have identical deliverability to other stents





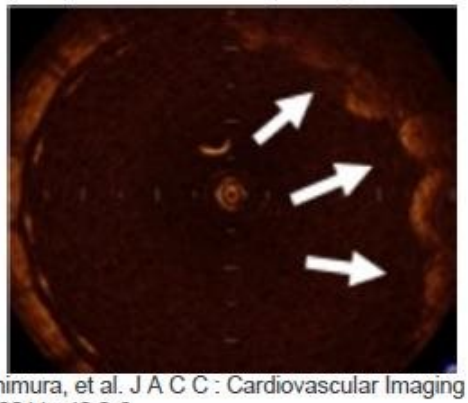


*PET – polyethylene terephthalate

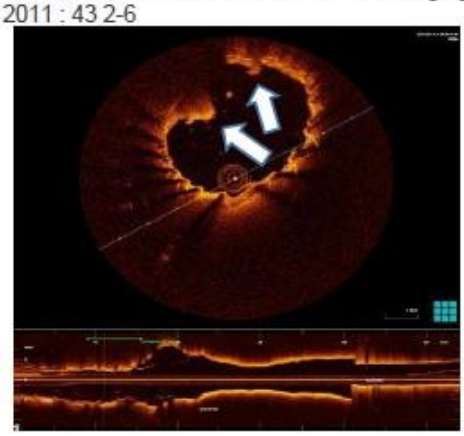
Plaque Coverage in Carotid Stents

Conventional Carotid Stents

No plaque coverage leading to vulnerable plaque protrusions or prolapse

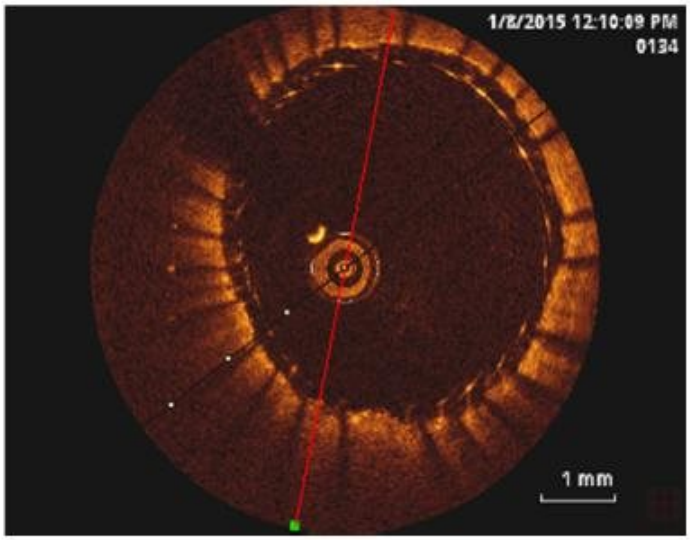


Yoshimura, et al. J A C C : Cardiovascular Imaging 4; 4, 2011 : 43 2-6



CGuard™ EPS

The MicroNet **permanently covers** thrombus that might be present and the plaque and prevents thrombus or "debris" from passing through the mesh and into the vessel lumen



Case reports courtesy Dr. Gianmarco de Donato, Department of Medicine Surgery and Neuroscience Universita degli studi di Siena, Italy.

Plaque Coverage with MicroNet™

jaa

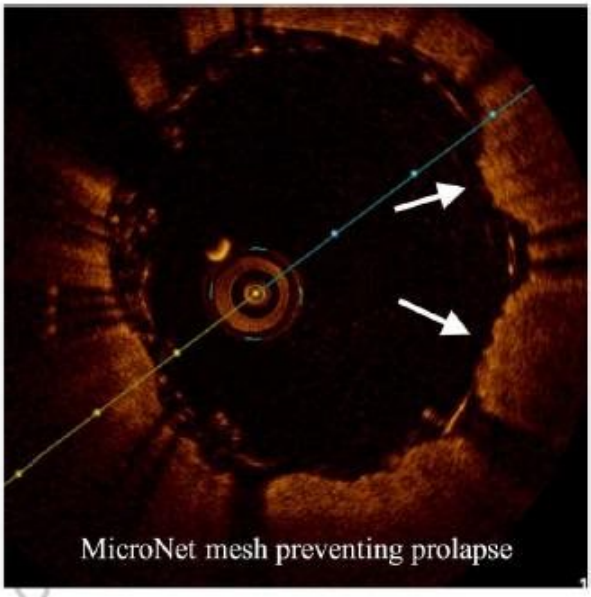
EuroIntervention

Title: Optical Coherence Tomography Assessment of New Generation Mesh-Covered Stents after Carotid Stenting

Authors: Tomoyuki Umemoto, MD; Gianmarco de Donato, MD; Andrea Pacchioni, MD; Bernhard Reimers, MD; Giuseppe Ferrante, MD, PhD; Mitsuaki Isobe, MD, PhD; Carlo Setacci, MD

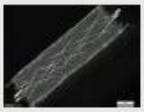
DOI: 10.4244/EIJ-D-16-00866

Citation: Umemoto T, de Donato G, Pacchioni A, Reimers B, Ferrante G, Isobe M, Setacci C. Optical Coherence Tomography Assessment of New Generation Mesh-Covered Stents after Carotid Stenting. *EuroIntervention* 2017; Jaa-192 2017, doi: 10.4244/EIJ-D-16-00866



Tomoyuki, et.al. EuropIntervetnioon 2017

Large & Growing Addressable Market

Embolic Prevention Products		Market Oppty	CE Mark	Focus Area
CGuard™		$500M	✓	Carotid
MGuard™*		$1.7B	✓	Coronary AMI & SVG
NGuard™		$675M	Planned Submission TBD	Neurovascular
PVGuard™		$1.7B	Planned Submission TBD	Peripheral

* MGuard™ global strategy focused on drug eluting stent OEM partnership

* MGuard is a bare metal stent scaffold

Positive CGuard™ Clinical Experience

CARENET Clinical Trial (2014)

- 30 Patient Safety and Efficacy clinical trial
- **Zero major adverse cardiac or cerebral events (MACCE)** at 30 days (Comparative data 5.72%*)
- **50% fewer new ischemic lesions** with lesion volume being 10x times smaller compared to historical non-mesh carotid artery stenting data
- **All new ischemic lesions fully resolved at 30 days** except one
- 3.6% MACCE rate at 6 months (Comparative data 8.09%**)
- **Zero strokes or stroke related deaths at 12 months**

PARADIGM 101 Clinical Trial (2015 and 2016)

- 101 patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)
  - **99.1% device success**
  - **0% MACCE (Death/stroke/MI) @ 48 hr**
  - **0% MACCE @ 30 day**
  - **Zero strokes or stroke related deaths at 12 months**

"CGuard can safely be used on more than 90% of all-comer patients that have carotid artery stenosis."
P. Musialek, MD

* Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVErIC 1+2, MAVErIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS
** Values extrapolated from event curves

Additional Independent Clinical

Independent study conducted in 30 patients with internal carotid artery disease

Clinical results (2016)

- **100% success** in implanting the CGuard™ EPS
- No peri- or post-procedural complications
- **No deaths, major adverse events, minor or major strokes**, or new neurologic symptoms during the six months following the procedure
- All vessels treated with the CGuard™ system remained patent (open) at six months
- DW-MRI performed in 19 of 30 patients found **no new ipsilateral lesions after 30 days and after six months** compared with baseline DW-MRI studies

ENDOVASCULAR THERAPY

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

Christian Wissgott, MD[1], Wolfram Schmidt, PhD[2], Christoph Brandt-Wunderlich, MSc[2], Peter Behrens, MSc[2], and Reimer Andresen, MD[1]

Abstract

Purpose: To report early clinical outcomes with a novel double-layer stent for the internal carotid artery (ICA) and the in vitro investigation of the stent's mechanical properties. **Methods:** A prospective single-center study enrolled 30 consecutive patients (mean age 73.1 ± 6.3 years; 21 male) with symptomatic (n=25) or high-grade (n=5) ICA stenosis treated with the new double-layer carotid CGUARD Embolic Prevention System (EPS) stent, which has an inner open-cell nitinol design with an outer closed-cell polyethylene terephthalate layer. The average stenosis of the treated arteries was 84.15±7.9% with a mean lesion length of 16.6±2.1 mm. In the laboratory, 8×40-mm stents were tested in vitro with respect to their radial force during expansion, the bending stiffness of the stent system and the expanded stent, as well as the collapse pressure in a thin and flexible sheath. The wall adaptation was assessed using fluoroscopy after stent release in a pulsatile and curved vessel model. **Results:** The stent was successfully implanted in all patients. No peri- or postprocedural complications occurred; no minor or major stroke was observed in the 6-month follow-up. The bending stiffness of the expanded stent was 63.1 N·mm² and post unexpectedly was clearly lower than that of the stent system (481.5 N·mm²). The normalized radial force during expansion of the stent to 7.0 mm, consistent with in vivo sizing, was relatively high (0.004 N/mm), which correlates well with the collapse pressure of 0.17 bars. Vessel wall adaptation was harmonic and caused no straightening of the vessel after clinical application. **Conclusion:** Because of its structure, the novel CGUARD EPS stent is characterized by a high flexibility combined with a high radial force and very good plaque coverage. These first clinical results demonstrate a very safe implantation behavior without any stroke up to 6 months after the procedure.

Keywords

carotid artery stent, closed-cell design, double-layer stent, embolic filter, stroke, carotid artery, in vitro testing, mechanical behavior, nitinol, open-cell design, radial force, stenosis, stent

Introduction

Several studies have demonstrated that carotid artery stenting (CAS) of the extracranial internal carotid artery (ICA) is a well-established and equally good option for treating atherosclerotic carotid stenosis in comparison with carotid endarterectomy (CEA).[1–4] Although CAS is still considered the gold standard therapy of carotid stenosis[5] because of a lower risk of procedure-related and postprocedural cerebral striking stroke, stent implantation is a valuable treatment option because of its less invasive character.[6]

Despite the fact that procedure-related events can be caused by brain crossing and post-procedurally,[7,8] particular attention has been focused on the stent design because postprocedure diffusion-weighted magnetic resonance imaging (DW-MRI) lesions were more numerous in patients treated with an open-cell stent vs a closed-cell stent.[9,10]

One problem stents should solve is the plaque bit scissored embolic protection like an ultra closed-cell stent and show high flexibility and conformability like an open-cell stent.[11] The first reports of a closed-cell stent with double stranded layers showed promising clinical results with respect to its implantation behavior based on the closed-cell design.[12,13] This article presents the clinical results

[1] Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westküstenklinikum Heide, Academic Teaching Hospital of the University of Kiel, Lübeck, and Hamburg, Heide, Germany
[2] Institute for Biomedical Engineering, Rostock University Medical Center, Rostock, Germany

Corresponding Author:
Christian Wissgott, Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westküstenklinikum Heide—Academic Teaching Hospital of the Universities of Kiel, Lübeck, and Hamburg, Heide/Holstein 30, 25746, Heide, Germany.
Email: cwissgott@web.de

"CGuard EPS is an important new treatment option for both symptomatic and asymptomatic carotid artery stenosis patients."

C. Wissgott, MD

Wissgott, et.al. J Endovasc Ther 2016.

Additional Independent Clinical Data

The Iron-Guard Registry

- Physician initiated
- 12 large Italian medical centers
- 200 patients


SPECIAL ARTICLES

J CARDIOVASC SURG 2015;56:787-91

Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent: the IRON-Guard registry. Rationale and design

C. SETACCI [1], F. SPEZIALE [2], G. DE DONATO [1], P. SIRIGNANO [2], F. SETACCI [2], L. CAPOCCIA [2], G. GALZERANO [1], W. MANSOUR [2], On behalf of IRON-Guard Study Group.

Clinical Results

- **100% success** in implanting the CGuard EPS
- **No major adverse cerebrovascular cardiac events** at 30 days
- DW-MRI performed in 61 of 200 patients found **only 19% new lesions** between 24-72 hours
  - CARENET reported 37% new lesions in 30 patients
  - PROFI reported 66% new lesions in 62 patients

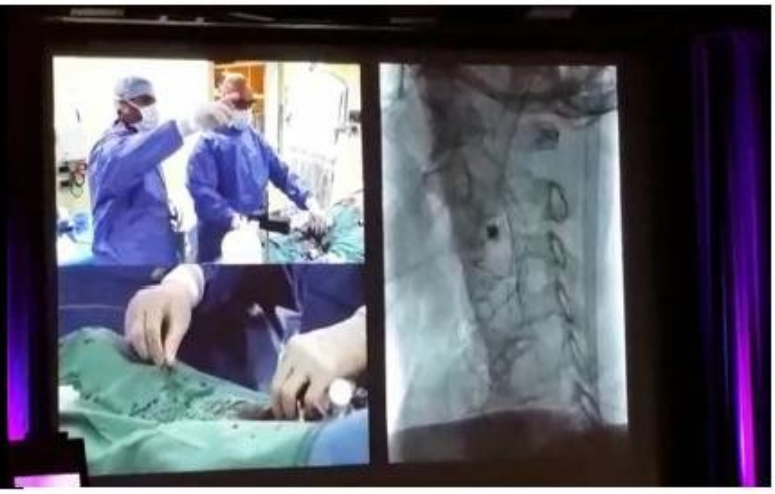
"The IRON-Guard Registry shows promising results in this interim analysis with a low incidence of complications and the lowest reported rate of new MRDWI lesions

F. Spezaile, MD and P. Sirignano, MD

Growing KOL Support Across Europe

Leipzig Interventional Course (LINC) January 2017

PD Dr. Andrej Schmidt and Dr. Sven Bräunlich Department of Angiology, University Hospital Leipzig, Division of Interventional Angiology, Leipzig, Germany, perform a live stent endovascular interventional procedure featuring the CGuard™ EPS



European Association of Percutaneous Cardiovascular Interventions (EuroPCR) May 2017

Dr. Fausto Castriota and Dr. Antonio Micari Interventional Cardiovascular Units at GVM Care and Research, Maria Cecilia Hospital, Cotignola Hospital Cotignola, Pavenna Italy perform a live stent endovascular interventional procedure featuring the CGuard™ EPS

Peripheral Interventions: EuroPCR 2017 Highlights

- "We know that with the prior generation of [carotid] stents a lot of the [distal embolization] events happen after the procedure" (*Prof. Musialek*)
- "Here [with mesh covered stents] we have seen a lot of cases with control of IVUS and really there is no more plaque protrusion…this [mesh covered stents] is clearly a major advantage" *(Prof. Roffi)*

https://www.youtube.com/watch?v=YI16rcFYdHs&feature=dir#t=3m00s
Non-sponsored Video recorded at EuroPCR 2017 – ©Europa Organisation

Impact of Mesh Covered Stents on Long term Stroke Compared to Surgery

InspireMD

Independent Clinical Review Authored by Leading U.S. and European Physicians Supports the Safety and Efficacy of CAS vs. CEA (2017)

Review paper

One swallow does not a summer make but many swallows do: accumulating clinical evidence for nearly-eliminated peri-procedural and 30-day complications with mesh-covered stents transforms the carotid revascularisation field

Data from more than 550 patients: near-elimination of post-procedural events

- Confirmed **no difference between CAS and CEA long term stroke risk**
- **Superior conformability compared to other next generation carotid devices**
- **Maximum protection from protruding plaque**
- Better radial force and open stent design, allow it to **conform effectively to vessel wall**
- No need to make calculations to ensure proper coverage of the lesion

Muslalek, et.al. Adv. Interv. Cardiol 2017

Sales & Marketing Strategy

Former distributor for Europe was primarily focused on the interventional neuroradiology market, their key customer segment

Replaced exclusive European CGuard™ distributor with regional distributors who target all 4 clinical specialties

- Vascular surgery, interventional cardiology, interventional neuroradiology, and interventional radiology

Recent direct distributors - Europe:

- Germany
- Poland
- Switzerland
- Austria
- Belgium
- Netherlands
- Estonia
- Lithuania
- Latvia

Recent distributors - rest of world:

- Russia
- Hong Kong
- Turkey
- Peru
- Ecuador
- Taiwan

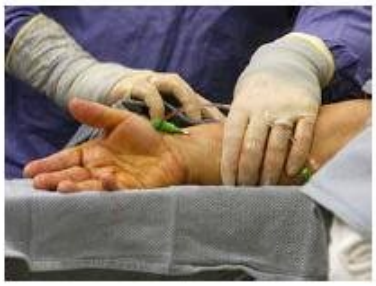
Recent Highlights

- ✓ Completed transition from a single distributor covering 18 European countries, to a direct distribution model with local distributors
- ✓ European distribution network now fully in place
- ✓ Rapidly adding top key opinion leaders across Europe
- ✓ CGuard sales in European countries covered by former distributor increased 122% in Q2 2017 versus the Q1 2017
- ✓ Now focusing efforts on expansion into other markets around the world

CGuard™ Product Development

- US FDA
  - Pre-IDE FDA submission for CGuard™ February 2017
  - Formal FDA meeting held April 2017
  - Planned IDE submission in 2018

- Next generation CGuard™ - 5 French CGuard™



  - Minimally invasive devices trending smaller for broader and easier usage
  - Lower profile system for cases where pre-dilatation could be problematic
  - Competitive advantage in the Asia/Pacific markets
    - Smaller anatomy particularly in the female population
  - Transradial delivery (delivery from the wrist vs. femoral artery) gaining favor among interventionalists

Broad Platform Technology

* Planning & Development Phase

Near Term Growth Strategy

CGuard™

- Engaging distribution partners in countries with current/near-term regulatory approval
- Seeking additional regulatory approvals in countries that accept CE Mark
- Plan to file US FDA IDE in 2018
- Plan to file CE Mark for next generation 5 French CGuard™ in 2018
- Expanding into the Asia Pacific region
  - CAS is the preferred treatment of carotid artery disease in China
  - Pursuing partnership strategy in China
  - Distributors identified and sales have commenced in Hong Kong and Taiwan
  - Identifying distributors/partners for South Korea, Japan, Australia and New Zealand
- Attracting leading KOLs from around the world

MGuard

- Strategy focused on formation of strategic partnerships with stent manufacturers with approved drug eluting stents

Recent/Upcoming Anticipated Milestones

Continued market execution and revenue growth.

Intellectual Property Portfolio

- Proprietary platform technology supported by a robust intellectual property portfolio
- Continue to strengthen and broaden patent protection globally to enable future pipeline products

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	6	0	12
Rest of World	18	2	19

Leadership

Significant track records of success

Dr. James Barry	President and CEO	Boston Scientific, Pfizer
Craig Shore	CFO	Pfizer, GE
Agustin Gago	CCO	Delcath Systems, Inc., angiodynamics, EZ EM
Paul Stuka	Chairman	Osiris, Fidelity Investments
Michael Berman	Director	Boston Scientific, Velocimed, LUTONIX
Dr. Campbell Rogers	Director	HeartFlow, Cordis, Harvard Medical School
Thomas Kester	Director	Kester Search Group, KPMG
Sol Barer, Ph.D.	Special Advisor to the Board	Celgene, Teva Pharmaceutical Industries Ltd.

Investment Highlights

- Multi-billion dollar opportunity for MicroNet™ products for multiple vascular markets
  - Current stents do not adequately address the risk of post-procedural embolization
  - Consistent positive clinical trial results positioning CGuard™ as a potential standard-of-care in treating carotid artery disease
- Revenue growth driven by new commercialization strategy
  - Completed transition from exclusive European distributor (18 countries) to InspireMD managed regional distributor model
  - Expanding CGuard™ users to a greater number of vascular surgeons, interventional cardiologists, and interventional radiologists
- Recent leadership changes focused on sales, marketing and high value pipeline development
- Strategic collaboration outreach expanding for multiple MicroNet™ product applications
- A broad portfolio of patent-protected assets

Financial Snapshot

NYSE MKT: NSPR

Stock Price (9/8/17):	$0.32
Average 3 Month Volume (9/8/17):	241 K
Shares Outstanding (9/8/17):	7.5 M
Shares Outstanding Including full conversion of preferred shares (9/8/17):	17.0M
Market Capitalization including full conversion of preferred shares (9/8/17):	$5.4 M
Total Cash (6/30/2017) :	$6.9 M
Headquarters:	Tel Aviv, Israel
# of Employees (9/8/17)	37

James Barry, Ph.D., President and CEO
888.776.6804
jimb@inspiremd.com

Craig Shore, CFO
888.776.6804
craigs@inspiremd.com