# INSPIREMD, INC.

## FORM FWP

(Free Writing Prospectus - Filing under Securities Act Rules 163/433)

Filed 06/27/18

| | |
|---|---|
| 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 |

Issuer Free Writing Prospectus
Filed Pursuant to Rule 433 of the
Securities Act of 1933, as amended
Registration Statement No. 333-225680


# Investor Presentation

This presentation shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities of the company nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

**NYSE MKT: NSPR** **June 2018**

# 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) our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern, (ii) our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests, (iii) our ability to regain compliance with NYSE American listing standards, (iv) our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products, (v) our ability to adequately protect our intellectual property, (vi) our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary, (vii) the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products, (viii) market acceptance of our products, (ix) negative clinical trial results or lengthy product delays in key markets, (x) an inability to secure and maintain regulatory approvals for the sale of our products, (xi) intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do, (xii) entry of new competitors and products and potential technological obsolescence of our products, (xiii) inability to carry out research, development and commercialization plans, (xiv) loss of a key customer or supplier, (xv) technical problems with our research and products and potential product liability claims, (xvi) product malfunctions, (xvii) price increases for supplies and components, (xviii) adverse economic conditions, (xix) insufficient or inadequate reimbursement by governmental and other third-party payers for our products,

# Forward Looking Statements (continued)

(xx) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (xxi) adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions, (xxii) 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, (xxiii) the escalation of hostilities in Israel, which could impair our ability to manufacture our products, and (xxiv) loss or retirement of key executives and research scientists. 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.

# Free Writing Prospectus

This presentation highlights basic information about InspireMD, Inc. and the offering. InspireMD, Inc. has filed a registration statement on Form S-1 (Registration No. 333-225680) (including a prospectus) with the U.S. Securities and Exchange Commission (the "SEC") for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including, among other things, risk factors described therein) and other documents the issuer has filed with the SEC for more complete information about InspireMD, Inc. and this offering. The preliminary prospectus dated June 26, 2018, and subsequent amendments are available at the SEC website: https://www.sec.gov/Archives/edgar/data/1433607/000149315218009230/0001493152-18-009230-index.htm. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. Alternatively, InspireMD, Inc. or any underwriter or any dealer participating in the offering will arrange to send you the prospectus if you request it by contacting H.C. Wainwright & Co., LLC, 430 Park Avenue, 3rd Floor, New York, NY 10022, by calling (646) 975-6996 or emailing placements@hcwco.com.

# About InspireMD

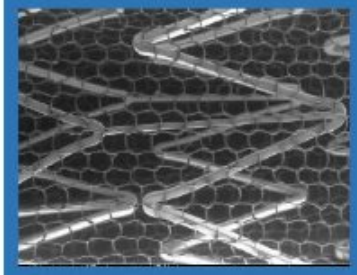
**InspireMD is a commercial-stage medical device company developing and marketing innovative embolic prevention systems (EPS) that can prevent harmful consequences associated with conventional medical device procedures, with a primary focus on preventing stroke in patients with carotid artery disease (CAD)**

## COMPANY

| | |
|---|---|
| **NYSE AMER:** | NSPR |
| **Employees:** | 36 |
| **Headquarters:** | Tel Aviv |
| **Manufacturing Facility:** | Tel Aviv |

## TECHNOLOGY

Proprietary MicroNet™ technology



## PRODUCTS

**Commercial:**

CGuard™ EPS (Carotid)

MGuard™ EPS (Coronary)

**Pipeline:**

Next Gen CGuard™

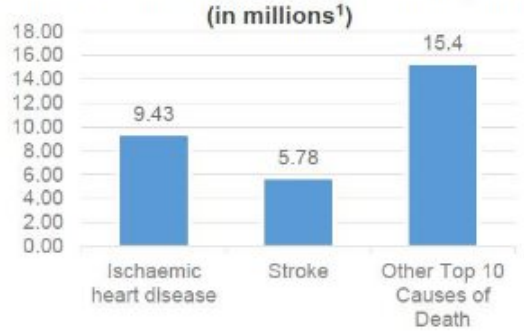
NGuard™ (Neuro)

PVGuard™ (Peripheral)

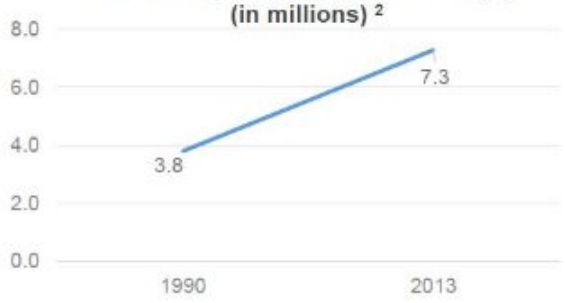
# Stroke: the second biggest cause of death globally

- There are 15 million new strokes a year [4]
- In 2016, 5.7 million deaths, were caused by stroke[1]
- 5 million people/year are left permanently disabled[4]
- $34BB in healthcare costs in the U.S. is associated with stroke management[3]
- 7.3 million young people are affected by stroke[2]

**Stroke: second biggest cause of death globally (in millions[1])**




**The number of younger people affected by stroke has risen sharply (in millions) [2]**




- Approximately 85% of all strokes are ischaemic strokes, which result from a lack of blood flow to the brain
- Carotid artery disease (CAD) is a major risk factor for stroke
- Approximately 20% of all ischemic strokes are estimated to be caused by CAD (2.2-2.4 million)

[1] http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death
[2] Prevalence of stroke in people aged 20-64 (Neuroepidemiology 2015;45:190-20 ) in millions
[3] Center For Disease Control and Prevention – Stroke Facts – 2017
[4] http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html

# Addressable device market in stroke prevention


- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD. At present, ~80% are surgically treated with carotid endarderectomy (CEA)
- The balance are treated with conventional carotid stents (CAS) with an average of 1.05 stents/procedure
- At a price of $1,650 per stent, the addressable market is more than $1 billion

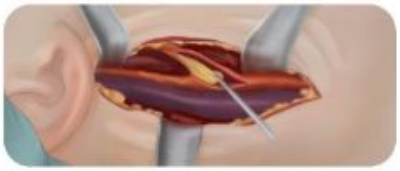
2017 Health Research International Market Report

# Stroke prevention in CAD: Surgery vs. Carotid Artery Stenting

**Based on CREST trial data, in which only conventional carotid stents were used**

## Carotid Endarterectomy (CEA)

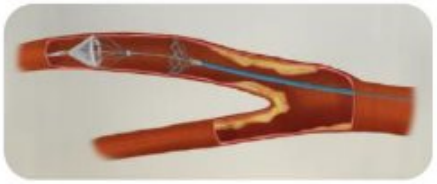
- Low stroke risk[1], but…
- Invasive; risk of surgical complications
  - Myocardial Infarction[1]
  - Risk of cranial nerve injury[2]
  - Esthetic concern



CREST: 2.1% unresolved facial nerve at 6 months[2] (80% motor)

## Filter Protected Stenting (CAS)

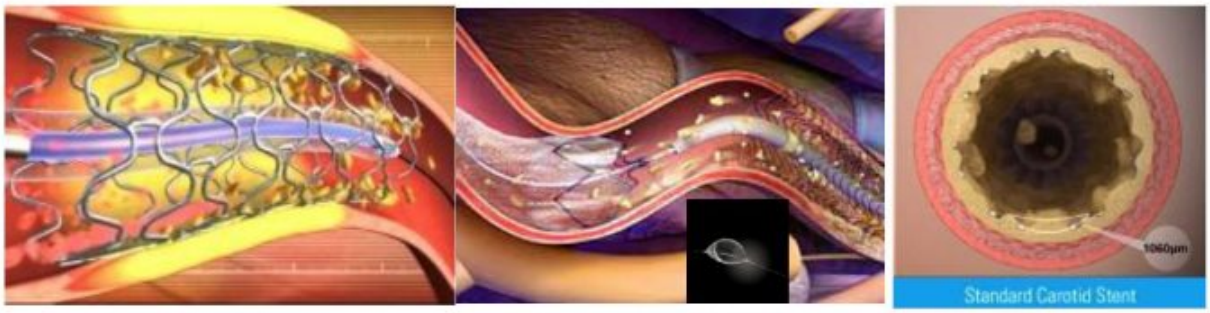
- Patient friendly, long-term durability[1],
- Non-Invasive; risk complications
  - Procedural minor stroke risk (with conventional stents)[1]
  - Post-procedural minor stroke risk(with conventional stents)[1]



[1]CREST Trial: N Engl J Med 2010;363:11-23
[2] Circulation. 2012;125:2256-2264

# 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.*

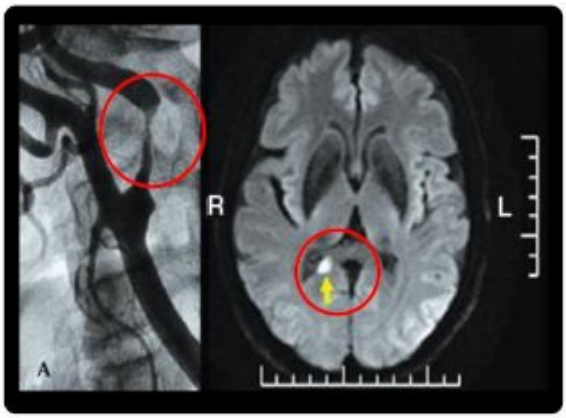



https://biotextiles2015.wordpress.com/embolic-protection-device/

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

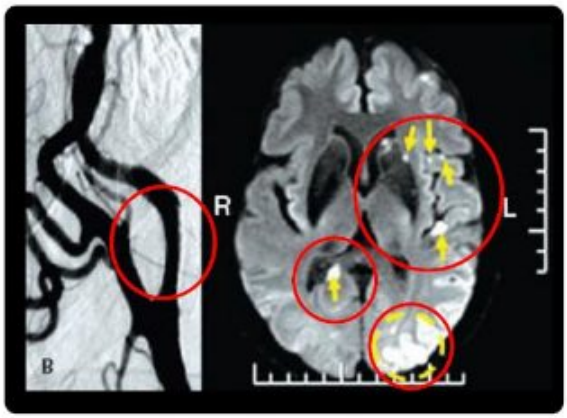
* Musialek, et.al. Eurointerventions 2016;12 August 2016.
** Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

# 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.

# CGuard™ EPS has been shown to prevent embolic debris passing into the carotid artery

## Conventional Carotid Stent

Carotid plaque can protrude through the mesh

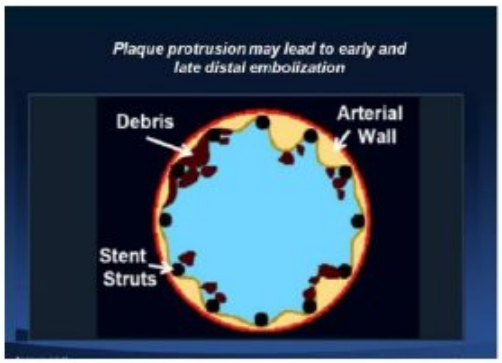
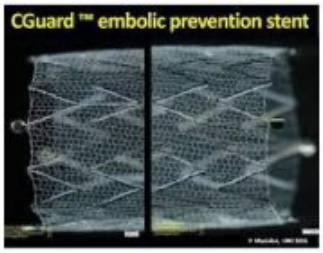



Image presented at TCT 2014
https://www.tctmd.com/conference/tct-2014
https://www.nyp.org/locations/newyork-presbyterian-columbia-university-medical-center

## CGuard™ EPS

- The MicroNet™ **permanently covers** plaque and stops "debris" from passing through the mesh.



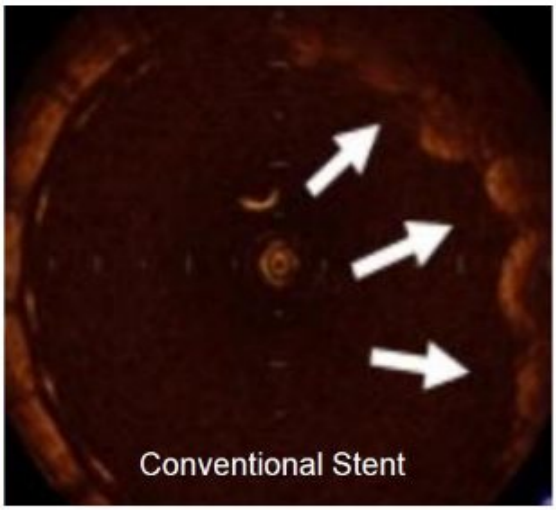

- Ultrathin PET mesh made of a single 20 micron fibre from a biocompatible polymer - widely used in other medical implants
- MicroNet™ acts as a "safety net" with greater vessel area coverage to prevent plaque protrusion through the stent into the blood vessel

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

# CGuard™ EPS has been shown to prevent debris passing into the carotid artery

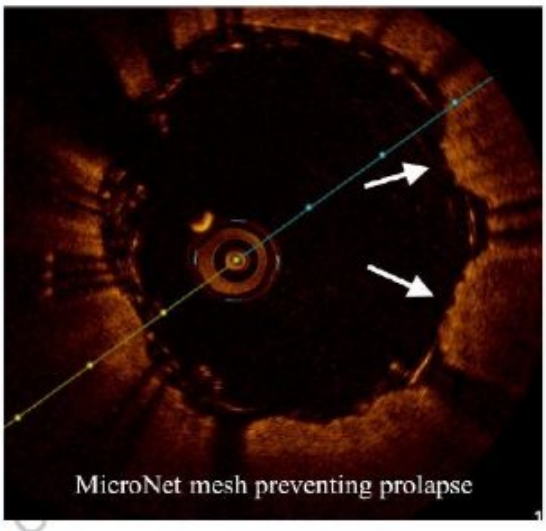
## Conventional Carotid Stents [1]

No plaque coverage - leading to plaque protrusions or prolapse passing into the vessel lumen




## CGuard™ EPS [2]

The MicroNet™ **permanently covers** plaque and prevents "debris" from passing through the mesh.



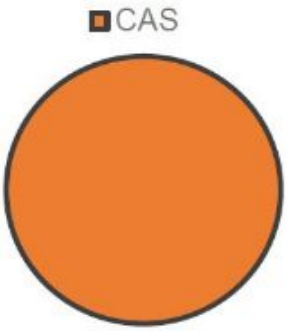

[1]Yoshimura, et al. J A C C : Cardiovascular Imaging 4; 4, 2011 : 43 2-6
2 Umemoto. et.al. Eurointervention 192 2017

# The potential paradigm shift with CGuard™

**Carotid procedures today are primarily surgical**


**MicroNet™ covered stents could become the Gold Standard**

**Carotid procedures tomorrow could be mostly minimally invasive with CGuard™**



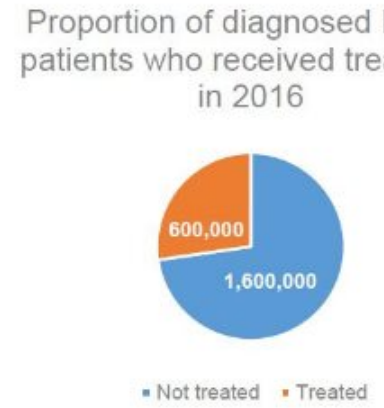

**100% of addressable market - $1.0 Billion**

2017 Health Research International Market Report

# CGuard™ : market potential in stroke prevention

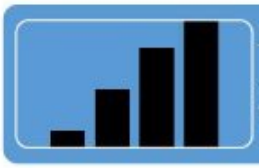
**In 2016…**

- ~13 million people are estimated globally to have high grade carotid stenosis
- ~2.2 million people were diagnosed with a high grade carotid stenosis (HGS)
- ~600,000 (30%) received surgical/stent stroke treatment in the same year
- There is an untapped market of at least 1.6 million patients who could be helped by CGuard™
- plus the undiagnosed patients estimated at more than 10 million




2017 Health Research International Market Report

## A body of evidence is accumulating that show CGuard™ has nearly-eliminated peri-procedural and 30-day complications [1]



Ten-year follow-up from the CREST trial in patients with symptomatic and asymptomatic carotid stenosis shows that CAS and CEA produce the same clinical benefit

Conventional carotid stents are associated with a higher risk of (mostly minor) strokes up to 30 days after the procedure.[2] This could be caused by atherosclerotic plaques protruding through the struts of the stent

The rate of any procedural stroke, death MI or postprocedural ipsilateral stroke at 30 days following CEA was 4.5% in the CREST trial [2]

Data from more than 1237[3] patients treated with CGuard™ EPS in clinical trials/registries show an overall 30-day complication rate below 1%


1. Postepy Kardiol Interwencyjnej. 2017; 13(2): 95–106
2. CREST https://www.nejm.org/doi/full/10.1056/NEJMoa0912321
3. Internal data

# 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 Bektas Andresen, MD[1]

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

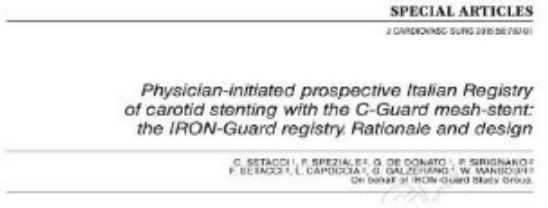
C. Wissgott, MD

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

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

## Clinical Results

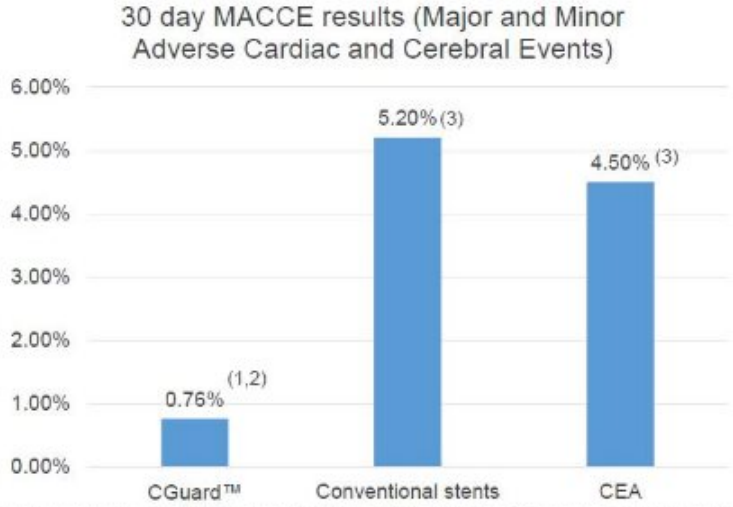
- **100% success** in implanting the CGuard EPS
- **No major adverse cerebrovascular cardiac events** at 30 days
- DW-MRI performed in 61 of 200 patients found **only 19% new lesions** between 24-72 hours
  - CARENET reported 37% new lesions in 30 patients
  - PROFI reported 66% new lesions in 62 patients


*"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

# CGuard™ EPS vs conventional stents and surgery

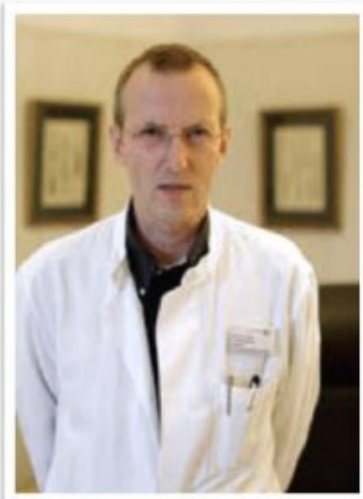
- CGuard™ shows strong benefits compared to both conventional carotid stents and surgery
- CGuard™ is a widely researched next generation carotid device stent (7 completed clinical trials and 4 ongoing trials)
- Long term sustained and consistent benefit (MACCE 0.9% @ 12 months)[4]




*NOTE: *IRON-GUARD, Wisggott and Casana trials are not included in this calculation of the CGuard data as these trials were not independently monitored*

[1] JACC Cardiovasc Interv 2015 Aug 17. 8:1229-1234
[2] EuroIntervention 2016 Aug 05. 658-70
[3] N Engl J of Med 2010 July 1. 11-23
4 Musialek et. al. TCT 2016 Featured Research Presentation

# A leading vascular surgeon's view



**Prof. Ralf Kolvenbach**,
Head of Cardiovascular Diseases
Medical Director of the Catholic Hospitals,
Duesseldorf, Germany

"*As a vascular surgeon I am very experienced with CEA.* ***From my perspective the near future will show a shift towards carotid stenting because of mesh covered stents.***

***The CGuard™, in comparison to other [carotid] stents, even in comparison to other mesh covered stents, is a very easy to use device.****. When I use other mesh covered stent grafts I need very complicated measurements ….. With CGuard™ …very simple, you take it off the shelf and you use it and that's it.*

*Patient risks associated with stenting using CGuard™ are far lower than those associated with CEA or with other types of carotid stents.* ***CGuard™ will become a major factor in preventing strokes caused by carotid artery disease.***

***With CGuard™ … we can get excellent results…probably better than open surgery … the Gold Standard*** "

https://www.youtube.com/watch?v=A-FNpvP8PVQ

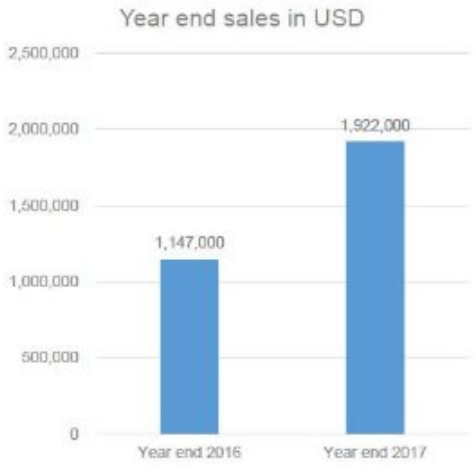
# Sales Performance

## Following the change in sales and distribution strategy in early 2017…

- **132%** increase in **CGuard™ EPS** sales for Q1 2018 compared to Q1 2017
- **77%** increase in company revenues for Q1 2018 compared to Q1 2017
- **5 consecutive quarters** of double digit growth
- Increase in global presence

# CGuard™ EPS - accelerating sales growth

- Growth trends have been consistent for 2017/2018
- Quarter to quarter Q1 sales have more than doubled

# Accelerating CGuard™ EPS sales growth: Germany

- German sales are on a positive trajectory following the change in distributors last year with full implementation occurring mid-way through Q3 2017
- CGuard™ Q1 sales in Germany for 2018 alone are 64% of sales in Germany for the whole of 2017


# Accelerating CGuard™ EPS sales growth: Italy

- CGuard™ sales in Italy have been strong over the last three years with continuing momentum
- Q1 comparisons between 2017 and 2018 show an 85% increase


# Implementing our strategy: Overview

***InspireMD is seeking to become the leading stroke prevention company, focused on reducing the global burden of stroke***

**1**

- **Transition Vascular Surgeons to CGuard™**
  - Advisory boards, surgeon specific clinical registries, centres of excellence
  - Publish, present, and communicate all data demonstrating that CGuard™ is as safe as CEA
  - Establish a presence at major vascular surgery meetings
  - Expand digital, social and other tools to more effectively communicate
  - Partner with appropriate societies focused on Stroke

**2**

- **Transition current users of conventional carotid stents to CGuard™**
  - Persuade current users of conventional carotid stents to switch to CGuard™ through communication of clinical data
  - Continue to support investigator initiated clinical registries
  - Continue to engage advisory board and continue to develop network of KOLs

**3**

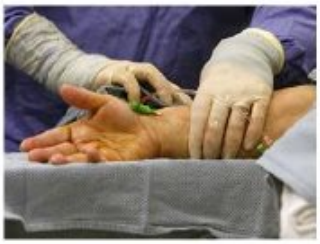
- **Expand footprint in existing geographical areas**
  - Focus on larger growing markets – Germany, Italy, Poland
  - Support regional clinical and clinical specialty registries to build on the clinical database and broaden support
  - Initiate discussions with the National Institute for Health and Clinical Excellence in the UK who set clinical guidelines

**4**

- **Continue geographical expansion where strategically relevant**
  - Continued focus on markets where a CE mark is already in place
  - Increase efforts in China and Japan
  - Submit US IDE

# CGuard™ Product Development*

- US FDA
  - Pre-IDE FDA submission for CGuard™ February 2017
  - Formal FDA meeting held April 2017
  - 6-9 months of pre-clinical work required to file IDE application to begin a US clinical trial
- Next generation CGuard™ - 5 French CGuard™



  - Minimally invasive devices trending smaller for broader and easier usage
  - Interventional neuroradiologists are major players in stroke treatment and tend to prefer lower profile devices
  - Advantageous in the Asia Pacific markets
  - Transradial delivery (delivery from the wrist vs. femoral artery) gaining favor among interventionalists
- Proactively evaluating synergistic opportunities to further broaden the product portfolio and take advantage of the global distribution network that has been developed

*Subject to sufficient funding

# 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 | 8 | 0 | 8 |
| Rest of World | 33 | 1 | 15 |

# 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 |

# Summary

- Focused on the deadly and catastrophic problem of stroke that is estimated to cost the healthcare system more than $34BB annually in the US alone
- The current addressable market for CGuard™ EPS is estimated to be $1BB with the potential to further expand into the 1.6MM patient population which is diagnosed but not treated
- Currently, vascular surgeons treat the majority of patients with carotid artery disease: Focus will be on converting the vascular surgeons to use CGuard™ EPS
- Strong and consistent clinical data continues to validate the safety profile of CGuard™ EPS even in a large "all comer" patient population with data indicating sustained benefit out to 2 years
- New commercial strategy beginning to take hold as indicated by sales growth over the last year
- Increasingly more presentations and live clinical cases with CGuard™ are featured at major and regional clinical conferences
- Beginning to focus more efforts on the major markets in Asia, including China and Japan
- Product pipeline to support continued growth in all geographies, including the United States

# NYSE AMER: NSPR

| Stock Price (6/22/2018): | $0.89 |
|---|---|
| Average 3 Month Volume (6/22/2018): | 809 K |
| Shares Outstanding (6/22/2018): | 6.5 M |
| Shares Outstanding Including full conversion of preferred (6/22/2018): | 8.6 M |
| Market Capitalization including full conversion of preferred shares (6/22/2018): | $7.6 M |
| Total Cash (3/31/2018) Adjusted for April 2, 2018 Net Raise: | $8.7 M |
| Headquarters: | Tel Aviv, Israel |
| # of Employees (6/22/18) | 36 |


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

Craig Shore, CFO
888.776.6804
craigs@inspiremd.com