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INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 09/06/18 for the Period Ending 09/06/18

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

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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): September 6, 2018

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") is furnishing the presentation materials as Exhibit 99.1 to this report pursuant to Regulation FD promulgated by the Securities and Exchange Commission. These materials will be used by the Company's management on September 6, 2018 at the H.C. Wainwright 20th Annual Global Investment Conference (previously known as the Rodman and Renshaw conference).

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 2018.

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 6, 2018

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

Investor Presentation

NYSE MKT: NSPR

September 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) 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

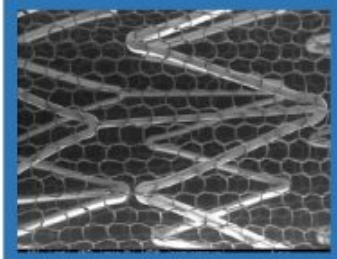
InspireMD is a commercial-stage medical device company developing and marketing innovative embolic prevention systems (EPS), with a primary focus on preventing stroke in patients with carotid artery disease (CAD)

COMPANY

NYSE AMER:	NSPR
Employees:	38
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)

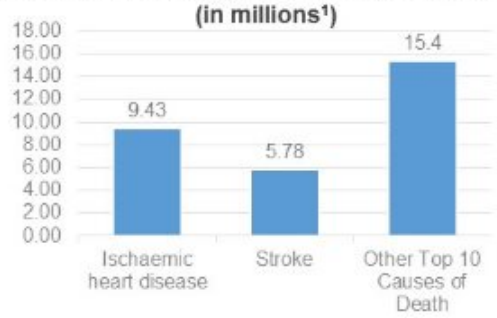
Company Highlights

- Four consecutive quarters of year over year growth in excess of 50%
- First half 2018 vs. first half of 2017 growth of greater than 65%
- Four consecutive quarters of year over year growth for CGuard in excess of 90%
- Growth of CGuard in excess of 110% first half 2018 vs. first half 2017
- Recapitalized the company resulting in a clean capital structure
- Successfully raised $18MM in 2018
- Sufficient capital raised to execute on commercial strategy, file US IDE and execute on other pipeline products

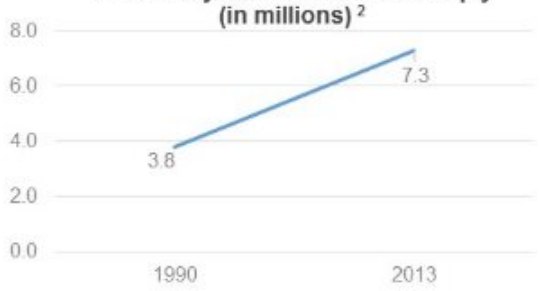
Stroke: the second biggest cause of death globally

- 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 ischemic 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)

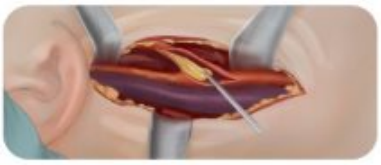
[1] http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death
[2] Prevalence of stroke in people aged 20-64 (Neuroepidemiology 2015;45:190-20) in millions
[3] Center For Disease Control and Prevention – Stroke Facts – 2017
[4] http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html

Stroke prevention in carotid artery disease: Surgery vs. Stenting

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

Carotid Endarterectomy (CEA)

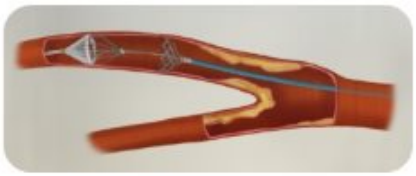
- Low stroke risk[1], but…
- Invasive; risk of surgical complications
  - Myocardial Infarction[1]
  - Risk of cranial nerve injury[2]
  - Esthetic concern



CREST: 2.1% unresolved facial nerve at 6 months [2] (90% 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]

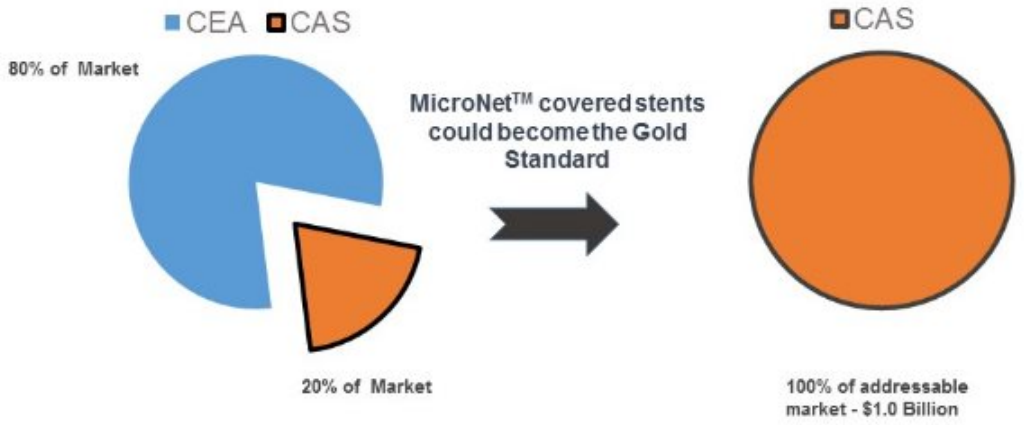


[1] CREST Trial: N Engl J Med 2010;363:11-23
[2] Circulation. 2012;125:2256-2264

The potential paradigm shift with CGuard™

Carotid procedures today are primarily surgical

Carotid procedures tomorrow could be mostly minimally invasive with CGuard™

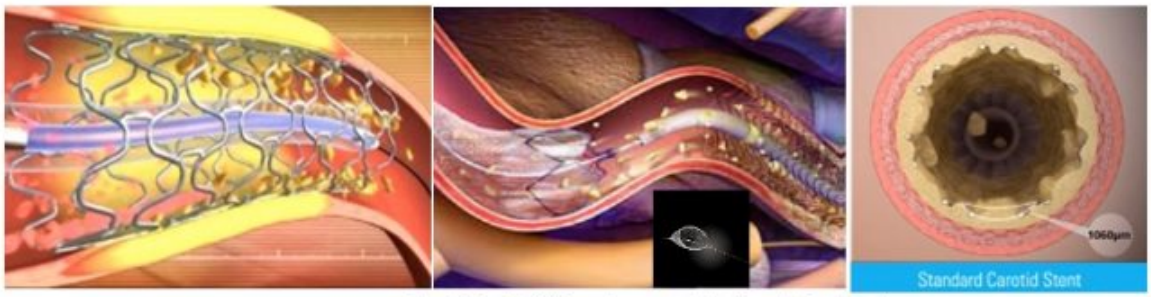


- 2.2M diagnosed with carotid artery disease
- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD
- At present, ~80% are surgically treated with carotid endarderectomy (CEA)
- At a price of $1,650 per stent, the addressable market is more than $1 billion

2017 Health Research International Market Report

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.*

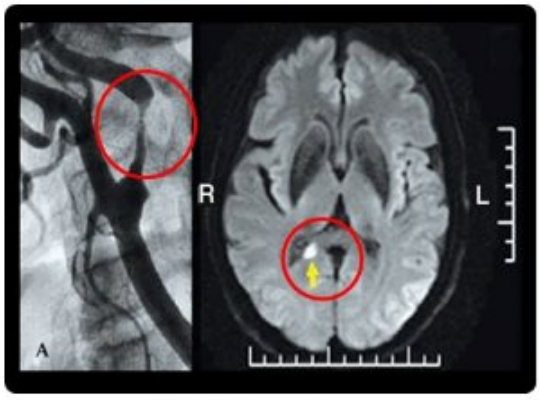


https://biotextiles2015.wordpress.com/embolic-protection-device/

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

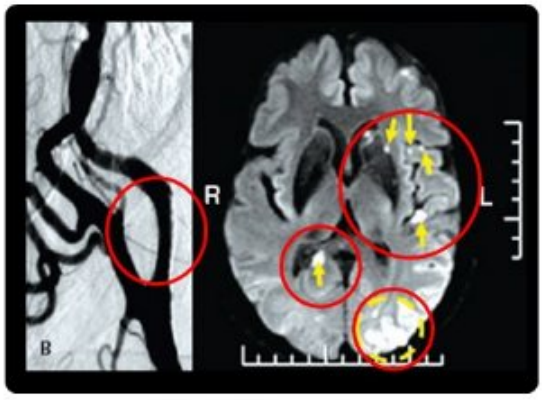
* Musialek, et al. Eurointerventions 2016;12 August 2016.
** Boslers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

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.

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

Conventional Carotid Stent

Carotid plaque can protrude through the mesh

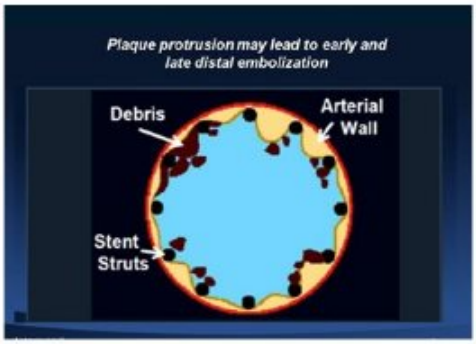
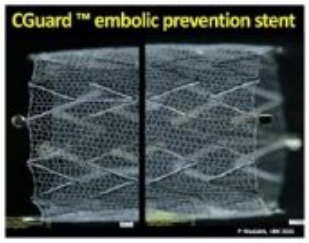


Image presented at TCT 2014
https://www.tctmd.com/conference/tct-2014
https://www.nyp.org/locations/newyork-presbyterian-columbia-university-medical-center

CGuard™ EPS

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

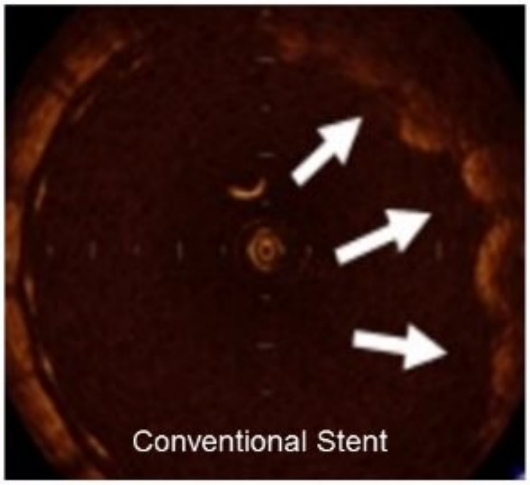


- Ultrathin PET mesh made of a single 20 micron fibre from a biocompatible polymer - widely used in other medical implants
- MicroNet™ acts as a "safety net" with greater vessel area coverage to prevent plaque protrusion through the stent into the blood vessel

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

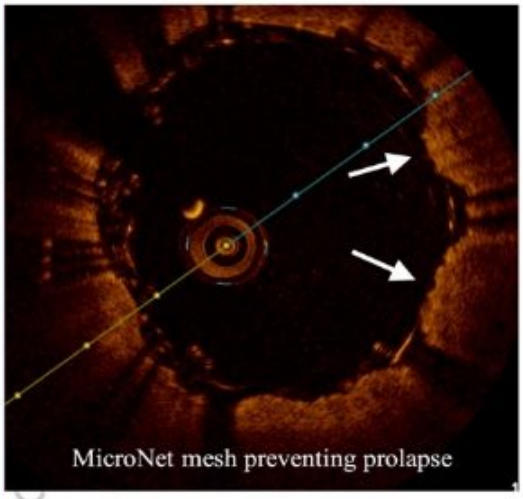
Conventional Carotid Stents [1]

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

Positive CGuard™ Clinical Experience

InspireMD

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, 2016, and 2018)

- 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**
  - **No device-related adverse events and no procedure-related events at 24 months*****
  - **Sustained stroke prevention at 24 months**

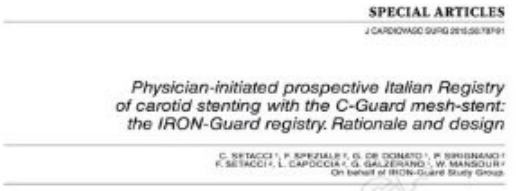
"CGuard can safely be used on more than 90% of all-comer patients that have carotid artery stenosis."
P. Musialek, MD

* 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
*** Musialek, ICCA 2018

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

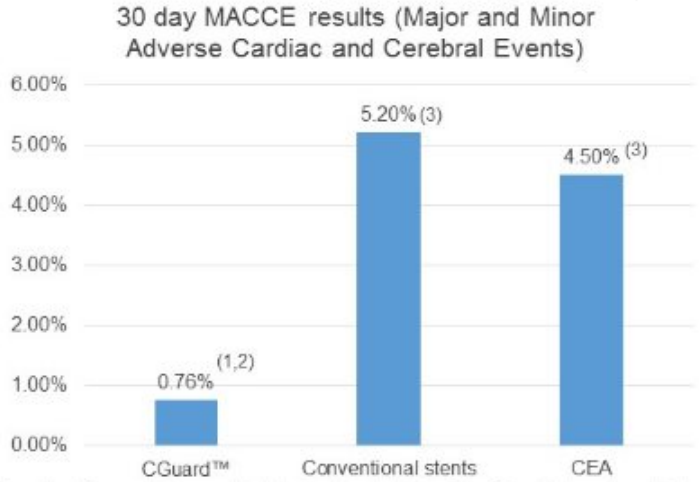
- **100% success** in implanting the CGuard EPS
- **No major adverse cerebrovascular cardiac events** at 30 days
- DW-MRI performed in 61 of 200 patients found **only 19% new lesions** between 24-72 hours
  - CARENET reported 37% new lesions in 30 patients
  - PROFI reported 66% new lesions in 62 patients

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



*NOTE: *IRON-GUARD, Wiggott 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.*

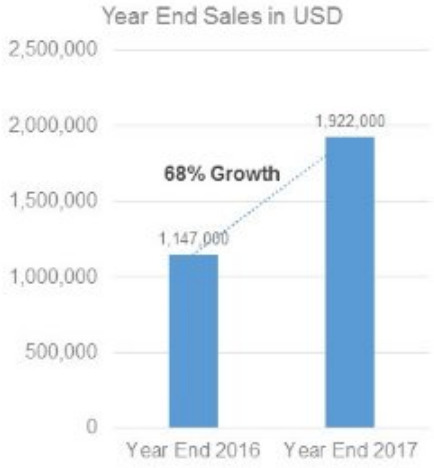
Patient risks associated with stenting using CGuard™ are far lower than those associated with CEA or with other types of carotid stents. ***CGuard™ will become a major factor in preventing strokes caused by carotid artery disease.***

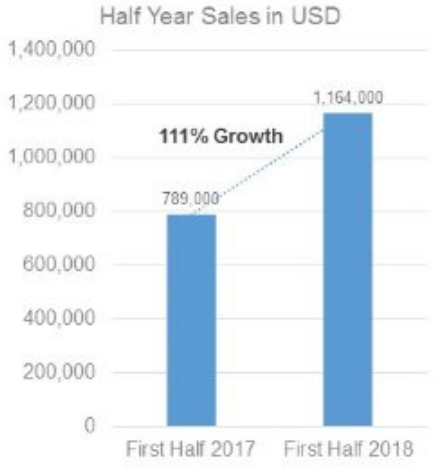
With CGuard™ … we can get excellent results…probably better than open surgery … the Gold Standard"

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

CGuard™ EPS - accelerating sales growth

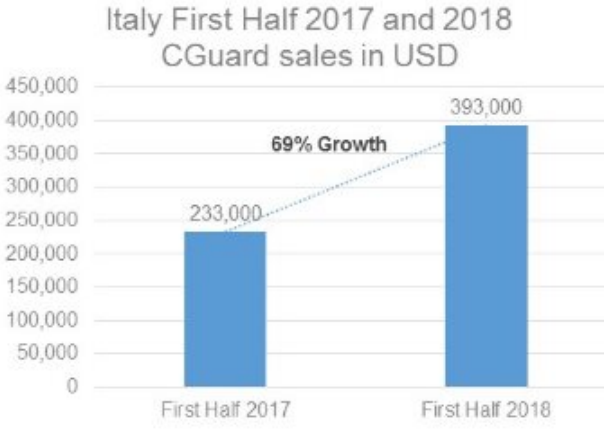
- Growth continues to accelerate for 2018/2017





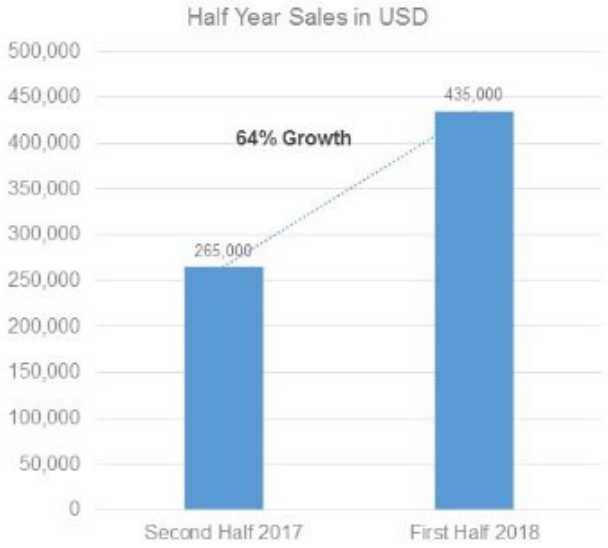
Accelerating CGuard™ EPS sales growth: Italy

- CGuard™ sales in Italy have been strong over the last three years with continuing momentum
- Q2 comparisons between 2017 and 2018 show a 69% increase



CGuard™ EPS - Germany

- New Distributor in Q2 2017
- Growth Trend is accelerating

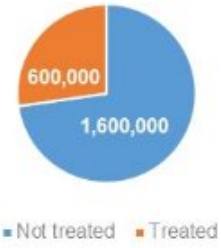


CGuard™ : market potential in stroke prevention

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

Proportion of diagnosed HGCS patients who received treatment in 2016



2017 Health Research International Market Report

Implementing our commercial strategy: Overview

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

1

Transition current users of conventional carotid stents to CGuard™

- Persuade current users of conventional carotid stents to switch to CGuard™
- Continue to support investigator initiated clinical registries
- Engage advisory board, further develop network of KOLs, establish centers of excellence

2

Transition Vascular Surgeons to CGuard™

- Advisory boards, surgeon specific clinical registries, centers of excellence
- Establish a presence at major vascular surgery meetings
- Publish, present, and communicate all data demonstrating that CGuard™ is as safe as CEA
- Partner with appropriate societies focused on Stroke

3

Expand footprint in existing geographical areas

- Focus on larger growing markets – Germany, Italy, Poland
- Support regional clinical and clinical specialty registries
- Initiate discussions with the institutions and organizations that 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

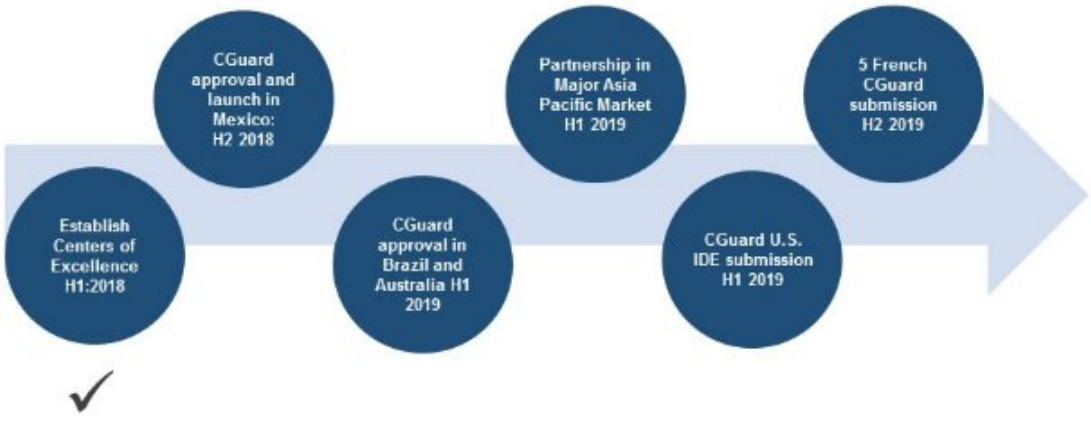
CGuard™ Product Development

- US FDA
  - Pre-IDE FDA submission for CGuard™ February 2017
  - Formal FDA meeting held April 2017
  - 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 usage
  - Advantageous in the Asia Pacific markets
  - Transradial delivery (delivery from the wrist vs. femoral artery) gaining favor among interventionalists
- Evaluate synergistic opportunities to broaden the product portfolio and take advantage of the global distribution network

Recent/Upcoming Anticipated Milestones

Continued clinical trial/registry results



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	8	3	9
Rest of World	35	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, EZEM
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 preventing stroke that is estimated to cost the US healthcare system more than $34BB annually
- 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
- Positive and consistent clinical data continues to validate the safety profile of CGuard™ EPS with data indicating stroke prevention out to 2 years
- Increasingly more presentations and live clinical cases with CGuard™ are featured at major and regional medical conferences
- Vascular surgeons treat the majority of patients with carotid artery disease: Begin a focus on converting vascular surgeons to using CGuard™ EPS
- Commercial strategy beginning to take hold as indicated by sales growth over the last year
- Product pipeline to support continued growth in all geographies, including the United States

NYSE AMER: NSPR

Stock Price (8/31/2018):	$0.19
Average 3 Month Volume (8/31/2018):	770 K
Shares Outstanding (8/31/2018):	23.8 M
Shares Outstanding Including full conversion of preferred shares and prefunded warrants (8/31/2018):	44.7 M
Market Capitalization including full conversion of preferred shares and prefunded warrants (8/31/2018):	$8.5 M
Headquarters:	Tel Aviv, Israel
# of Employees (8/31/2018)	38

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