INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 01/09/19 for the Period Ending 01/09/19

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): January 9, 2019

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 2.02 Results of Operations and Financial Condition.

InspireMD, Inc. (the "Company") is currently finalizing its financial results for the year ended December 31, 2018. While complete financial information and operating data as of and for such period are not yet available, based on the information and data currently available, as of December 31, 2018, the Company had approximately $9.4 million of cash. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2018.

The estimated cash has neither been audited nor reviewed by the Company's independent registered public accounting firm, nor has the Company's independent registered public accounting firm expressed an opinion or any other form of assurance with respect thereto. The Company's financial statements and operating data as of and for the year ended December 31, 2018, will not be available until the Company's annual report on Form 10-K for the year ended December 31, 2018, is filed.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K that is furnished pursuant to this Item 2.02 shall not be deemed to be "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, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

The Company, from time to time, intends 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 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 January 2019 (furnished herewith pursuant to Item 7.01).

*This exhibit is furnished pursuant to Item 7.01 and shall not be deemed to be "filed."

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: January 9, 2019

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

INVESTOR PRESENTATION

NYSE AMER: NSPR I January 2019

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

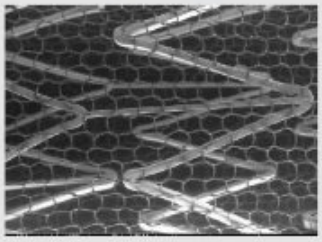
InspireMD is a commercial-stage medical device company developing and marketing innovative embolic prevention systems (EPS) that can prevent harmful consequences, with a primary focus on preventing stroke in patients with carotid artery disease (CAD)

COMPANY

NYSE AMER:	NSPR
Employees:	40
Headquarters:	Tel Aviv
Manufacturing Facility:	Tel Aviv

TECHNOLOGY

Proprietary MicroNet™ technology



PRODUCTS

Commercial:	CGuard™ EPS (Carotid)
	MGuard™ EPS (Coronary)
Pipeline:	CGuard EPS IDE Next Gen CGuard™
	PVGuard™ (Peripheral)
	NGuard™ (Neuro)

Company Highlights

Lead product, CGuard™ EPS	A potential *paradigm shift* in the treatment of carotid artery disease and stroke prevention Highly differentiated with strong KOL support
Benefits demonstrated in multiple trials	Seven completed and four ongoing clinical trials Demonstrates strong benefits versus conventional carotid stents and surgery
Commercial-stage with accelerating sales growth	New commercial strategy implemented Q3 YTD 2018 sales increased 44% YOY Sept. YTD 2018 CGuard™ EPS sales increased 72% YoY
$1bn+ global market opportunity	CE Mark approved; other OUS territories pending (Brazil, Australia) Expect to file US IDE in mid-2019
Capital Structure	Recapitalized the company resulting in a clean capital structure Successfully raised $18MM in 2018 Sufficient capital raised to execute on current commercial strategy, file US IDE and other pipeline products
Strong IP franchise	US: 13 patents issued/allowed, 7 pending RoW: 38 patents issued/allowed, 22 pending

Leadership

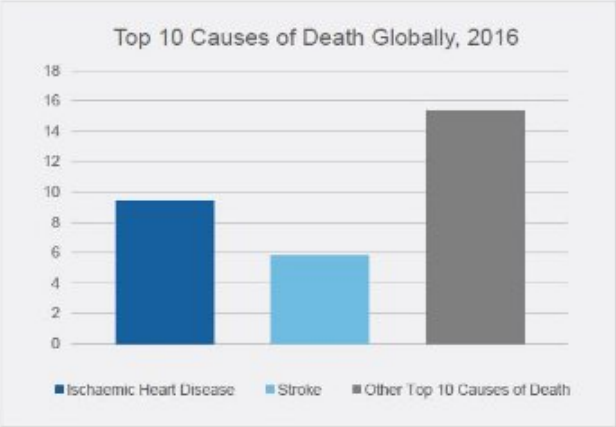
Significant track records of success

James Barry, Ph.D. President and CEO	Boston Scientific, Pfizer
Craig Shore CFO	Pfizer, Bristol-Myers Squibb, GE
Paul Stuka Chairman	Osiris, Fidelity Investments
Michael Berman Director	Boston Scientific, Velocimed, LUTONIX
Campbell Rogers, M.D. Director	HeartFlow, Cordis, Harvard Medical School
Thomas Kester Director	Kester Search Group, KPMG
Sol Barer, Ph.D. Special Advisor to the Board	Celgene, Teva

Stroke is the Second Biggest Cause of Death

An estimated 15 million people suffer from stroke annually[3]

- 5.7 million deaths[1]
- 5 million people left permanently disabled[3]
- $34 billion associated with stroke management in the US alone[2]



InspireMD

[1] http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death
[2] Center For Disease Control and Prevention – Stroke Facts – 2017
[3] http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html

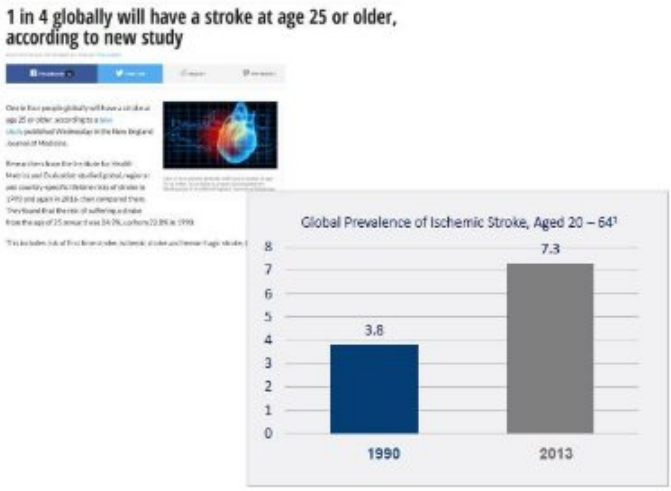
Stroke Prevalence Increasing Among Young People

Between 1990 and 2013, there was a significant increase in the global prevalence of ischemic stroke among young people aged 20-64

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)



Unmet Need: A Safer Technology for Stroke Prevention in CAD

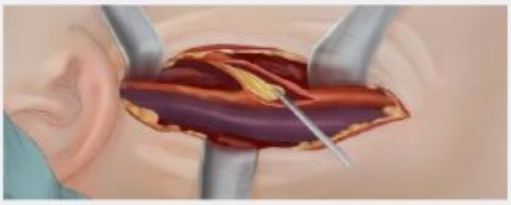
Surgery vs. Carotid Artery Stenting

Carotid Endarterectomy (CEA)

"Gold standard"[1], but…

Invasive; risk of surgical complications

- Myocardial Infarction[1]
- Risk of cranial nerve injury[2]
- Esthetic concern

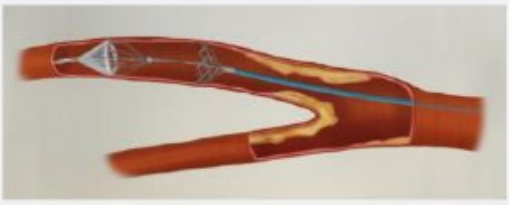


Filter Protected Stenting (CAS)

Patient friendly, long-term durability[1],

Non-Invasive; risk of complications

- Procedural minor stroke risk (with conventional stents)[1]
- Post-procedural minor stroke risk (with conventional stents)[1]

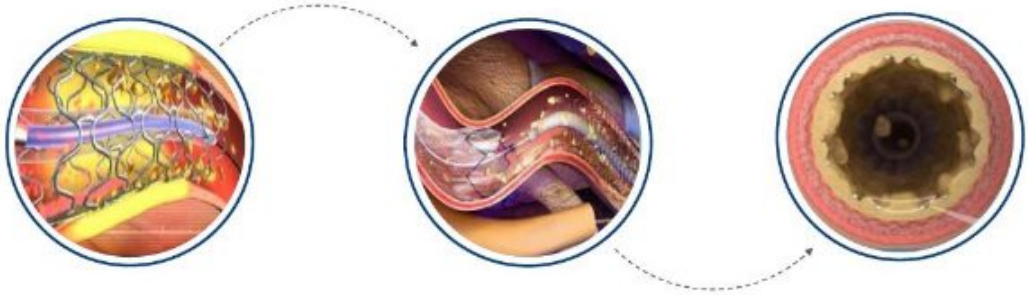


Based on the **CREST** clinical trial data, in which only **conventional carotid stents** were used vs **sugery**

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

Embolization Following Carotid Artery Stenting

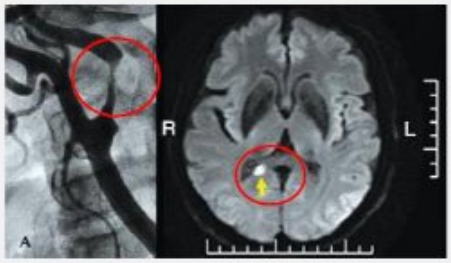
Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents, depending on plaque morphology/symptomatic status and stent type. The consequence is cerebral embolization, either directly or via additional thrombus formation.



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

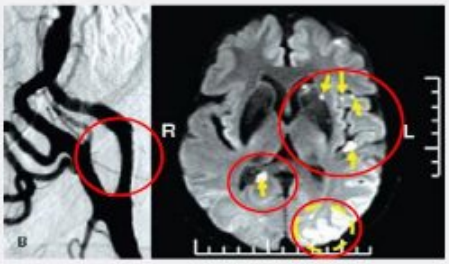
Consequences Range from Neurological Deficit to Stroke

Pre-Procedure



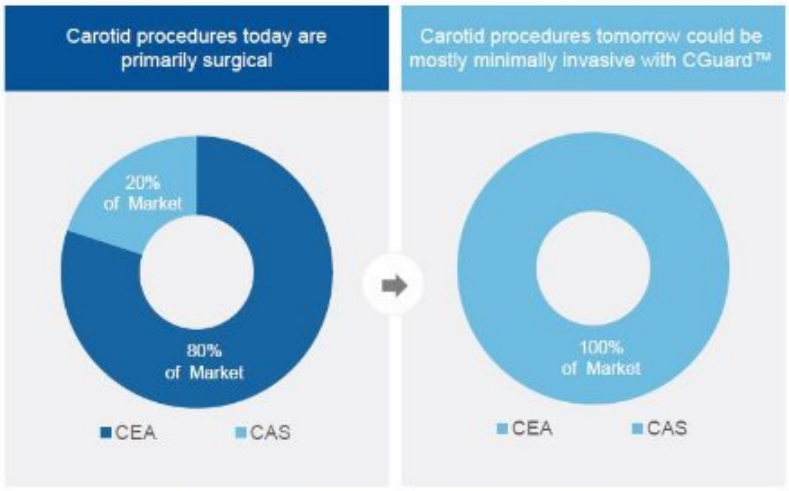
Pre-intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction).

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.

A Billion Dollar Market Opportunity

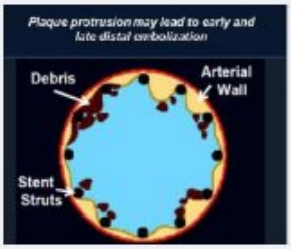


- 2.2M diagnosed with carotid artery disease
- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD
- At present, ~80% are surgically treated with carotid endarderectomy (CEA)
- At a price of $1,650 per stent, the addressable market is more than $1 billion

MicroNet™ covered stents could become the Gold Standard

The InspireMD Solution: CGuard™ EPS

Conventional Carotid Stent



Carotid plaque can protrude through the stent struts

CGuard™ EPS

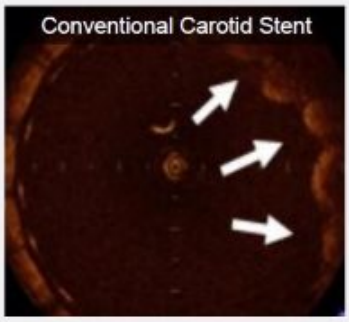
- The MicroNet™ **permanently covers** plaque and stops "debris" from passing through the mesh.
- Ultrathin PET mesh made of a single 20 micron fibre from a biocompatible polymer - widely used in other medical implants
- MicroNet™ acts as a "safety net" with greater vessel area coverage to prevent plaque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

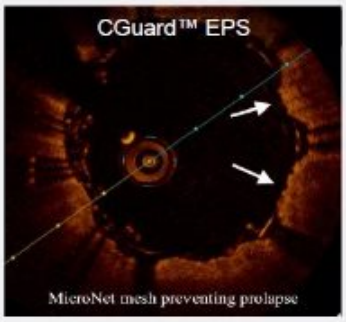
CGuard™ EPS has been shown to prevent embolic debris passing into the carotid artery

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

The InspireMD Solution: CGuard™ EPS

Conventional Carotid Stents [1]	CGuard™ EPS[2]
No plaque coverage - leading to plaque protrusions or prolapse passing into the vessel lumen	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 2-8
2. Umemoto, et al. EuroIntervention 192 2017

Positive CGuard™ EPS 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, 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 (1 minor stroke resolved by discharge)
No device-related adverse events and no procedure-related events at 12, 24, or 36 months months* **
Sustained stroke prevention out to 36 months* **

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

- P. Musialek, MD

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* 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, Veith Conference, 2018

Independent Clinical Validation

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™ EPS 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

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

- C. Wissgott, MD

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

Independent Clinical Validation (continued)

The Iron-Guard Registry

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

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
- At 12 months, there were no new major neurological adverse events, thrombosis or external carotid occlusion recorded**

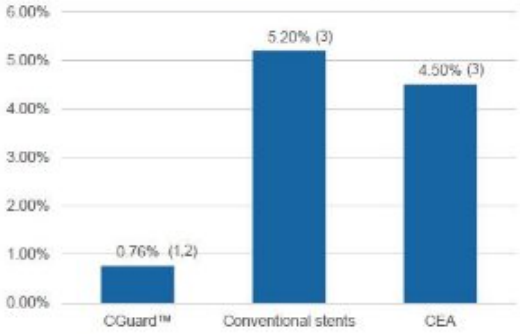
"The IRON-Guard Registry shows promising results in this interim analysis with a low incidence of complications and the lowest reported rate of new MRDWI lesions
F. Spezaile, MD and P. Sirignano, MD


SPECIAL ARTICLES

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

CGuard™ EPS vs Conventional Stents and Surgery

- CGuard™ EPS has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
  - 7 completed clinical trials and 4 ongoing trials
- Long term sustained and consistent benefit (MACCE 0.9% @ 12 months)[4]



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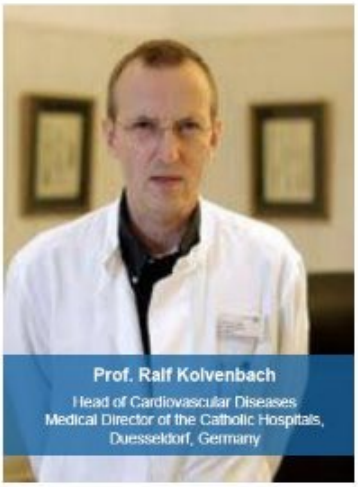
*NOTE: IRON-GUARD, Wiggett and Cassana trials are not included in this calculation of the CGuard data as these trials were not independently monitored
1. JACC Cardiovasc Interv 2015 Aug 17; 8:1228-1234. 2. EuroIntervention 2016 Aug 05; 668-70. 3. N Engl J of Med 2010 July 1; 11-23. 4. Muslalek et. al. TCT 2018 Featured Research Presentation

A Leading Vascular Surgeon's View



"The CGuard™, in comparison to other [carotid] stents, even in comparison to other mesh covered stents, is a very easy to use device. Very simple, you take it off the shelf and you use it and that's it."

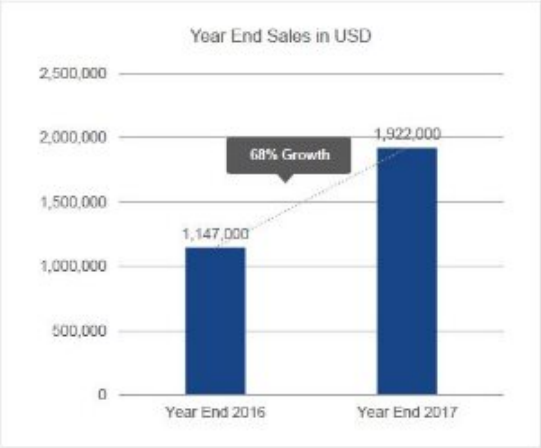
"Patient risks associated with stenting using CGuard™ are far lower than those associated with CEA or with other types of carotid stents.

"CGuard™ will become a major factor in preventing strokes caused by carotid artery disease."

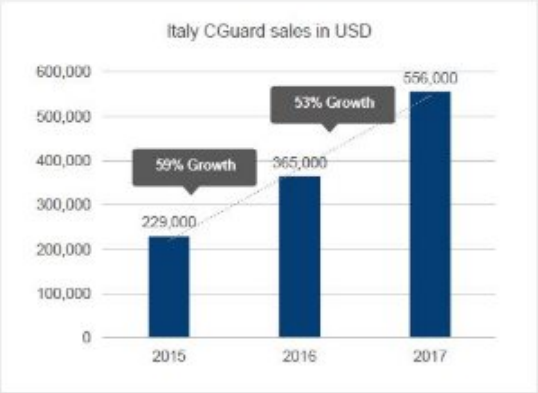
"With CGuard™ we can get excellent results, probably better than open surgery, the Gold Standard"

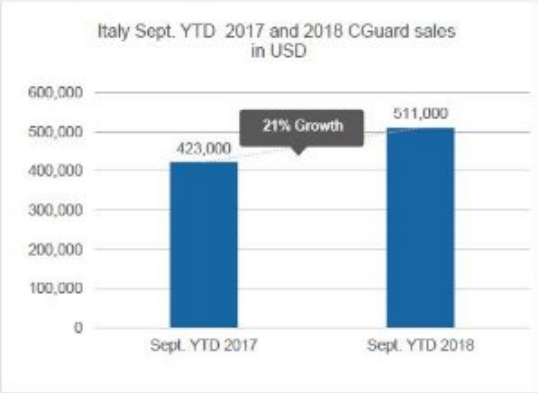
CGuard™ EPS - Accelerating Sales Growth

Growth continues to accelerate for 2018/2017



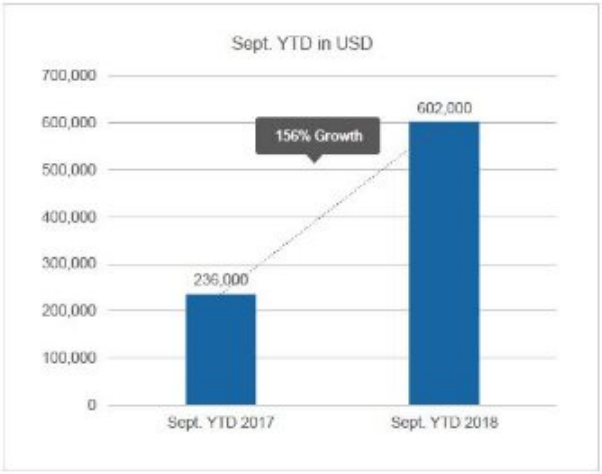
Accelerating CGuard™ Sales Growth: Italy





- CGuard™ sales in Italy have been strong over the last three years with continuing momentum
- September YTD comparisons between 2017 and 2018 show a 21% increase

Accelerating CGuard™ Sales Growth: Germany



Accelerating CGuard™ Sales Growth: Poland

Addressable Stroke Prevention Device Market

2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD. At present, ~80% are surgically treated with carotid endarterectomy (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 estimated to be more than $1 billion

Commercial Strategy

Transition current users of conventional carotid stents to CGuard™ EPS

Communication of CGuard™ EPS clinical data

Continue to support investigator initiated clinical registries

Engage advisory board, further develop network of KOLs, establish centers of excellence

Transition Vascular Surgeons to CGuard™

Advisory boards, surgeon specific clinical registries, centers of excellence

Publish, present, and communicate 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

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 NICE (National Institute for Clinical Excellence) in the UK who set clinical guidelines

Continue geographical expansion where strategically relevant

Continued focus on markets where a CE mark is already in place

Continue to evaluate Asia Pacific

Submit US IDE

CGuard™ EPS Product Development

US FDA	• Pre-IDE FDA submission for CGuard™ EPS 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
Innovative Pipeline Developments	
Evaluating synergistic opportunities	• Proactively evaluating synergistic opportunities to further broaden the product portfolio and take advantage of the global distribution network that has been developed

Recent/Upcoming Anticipated Milestones

Continued clinical trial/registry results

H12018	H22018	H12019	MID2019	H22019
Establish Centers of Excellence	CGuard approval and launch in Mexico	Approval in Australia	CGuard U.S. IDE submission	CGuard approval in Brazil

Continued market execution and revenue growth

Intellectual Property Portfolio

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	12	1	7
Rest of World	36	2	22

Proprietary platform technology supported by a robust intellectual property portfolio

Continue to strengthen and broaden patent protection globally to enable future pipeline products

Summary Financials

NYSE AMER	NSPR
Stock Price (1/4/19):	$0.17
Average three month daily trading volume:	1.9 M
Shares outstanding (12/31/18):	38.4 M
Shares Outstanding Including full conversion of preferred shares and prefunded warrants (12/31/18):	44.7 M
Market Capitalization including full conversion of preferred shares and prefunded warrants (1/4/19):	$7.6 M
Cash (12/31/18)	$9.4mn*

*Based on the information and data currently available. We are currently finalizing our financial results for the year ended December 31, 2018, and complete financial information and operating data as of and for such period is not yet available. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2018. The estimated cash has neither been audited nor reviewed by our independent registered public accounting firm, nor has our independent registered public accounting firm expressed an opinion or any other form of assurance with respect thereto.

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 3 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™ EPS are featured at major and regional clinical conferences
- Product pipeline to support continued growth in all geographies, including the United States

InspireMD

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Craig Shore, CFO
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