

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 10/09/18 for the Period Ending 10/09/18

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

**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): October 9, 2018

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35731

(Commission
File Number)

26-2123838

(IRS Employer
Identification No.)

4 Menorat Hamaor St.
Tel Aviv, Israel

(Address of principal executive offices)

6744832

(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 October 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: October 9, 2018

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



INVESTOR PRESENTATION
NYSE MKT: NSPR | OCTOBER 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) that can prevent harmful consequences, with a primary focus on preventing stroke in patients with carotid artery disease (CAD)

COMPANY	TECHNOLOGY	PRODUCTS
<p>NYSE AMER: NSPR</p> <p>Employees: 39</p> <p>Headquarters: Tel Aviv</p> <p>Manufacturing Facility: Tel Aviv</p>	<p>Proprietary MicroNet™ technology</p> 	<p>Commercial: CGuard™ EPS (Carotid)</p> <p>MGuard™ EPS (Coronary)</p> <p>67.4%</p> <p>Pipeline: Next Gen CGuard™</p> <p>PVGuard™</p> 



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 1H 2018 sales increased 65% YoY 1H 2018 CGuard™ EPS sales increased 110% YoY
\$1bn+ global market opportunity	CE Mark approved, other OUS territories pending (Brazil, Australia) Expect to file US IIR in mid-2019
Capital Structure	Recapitalized the company resulting in a clean capital structure Successfully raise \$16MM in 2018 Sufficient capital raised to execute on commercial strategy, file US IDE and other pipeline products
Strong IP franchise	US: 11 patents issued/allowed, 8 pending RoW: 37 patents issued/allowed, 19 pending

Leadership

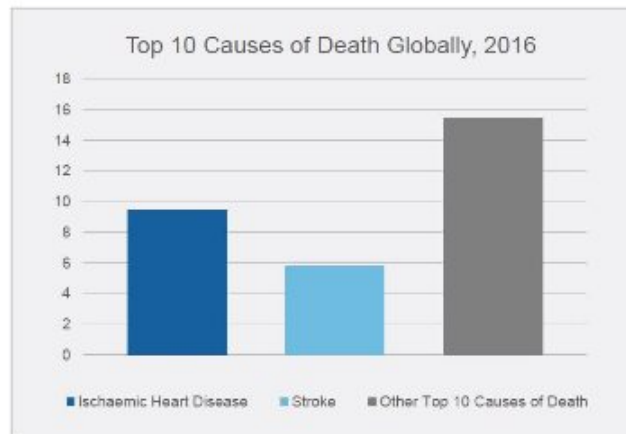
Significant track records of success

James Barry, Ph.D. President and CEO	 
Craig Shore CFO	  
Paul Stuka Chairman	 
Michael Berman Director	  
Campbell Rogers, M.D. Director	  
Thomas Kester Director	 
Sol Barer, Ph.D. Special Advisor to the Board	 

Stroke is the Second Biggest Cause of Death

An estimated 15 million people suffer from stroke annually³

- 5.7 million deaths¹
- 5 million people left permanently disabled³
- \$34 billion associated with stroke management in the US alone²



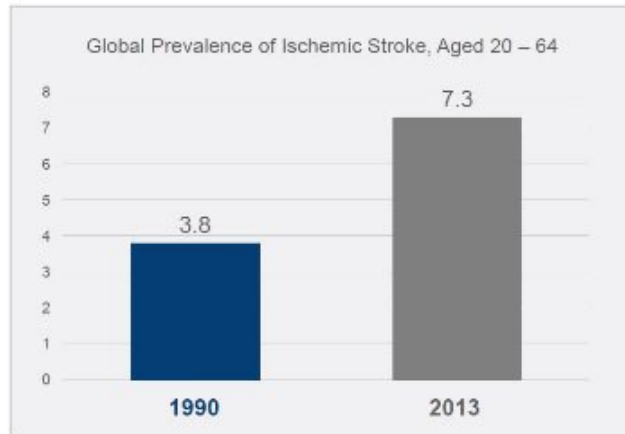
Stroke Prevalence Increasing Among Young People

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)



† Prevalence of stroke in people aged 20-64 (Neuroepidemiology 2015;45:190-20)

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Unmet Need: A Safer Technology for Stroke Prevention in CAD

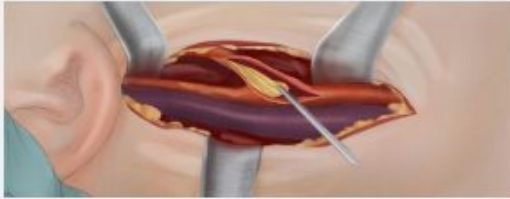
Surgery vs. Carotid Artery Stenting

Carotid Endarterectomy (CEA)

Low stroke risk¹, but...

Invasive; risk of surgical complications

- Myocardial Infarction¹
- Risk of cranial nerve injury²
- Esthetic concern

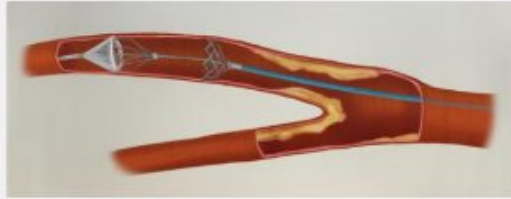


Filter Protected Stenting (CAS)

Patient friendly, long-term durability¹,

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

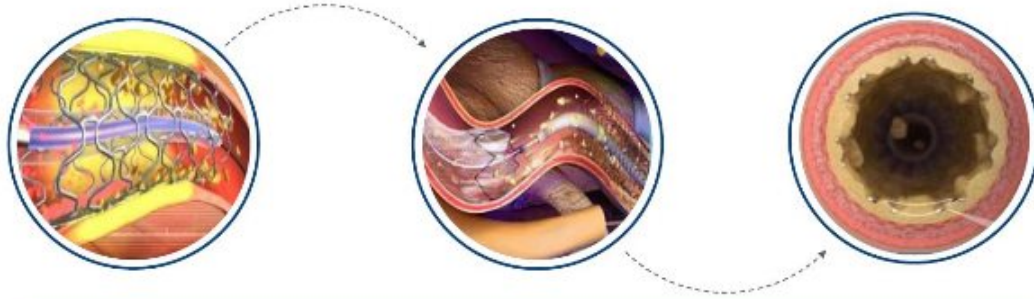


¹CHLST Trial. N Engl J Med 2010;363:11-23. ²Circulation. 2012;125:2267-2274. CREST. 2.1% unresolved facial nerve; at 6 months 2 (0.0% motor)

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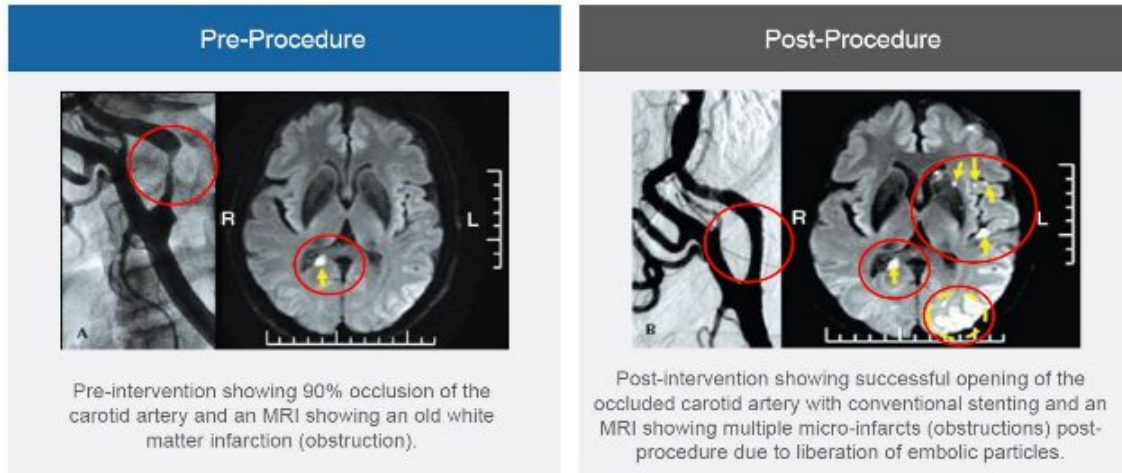
Embolization Following Carotid Artery Stenting

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.

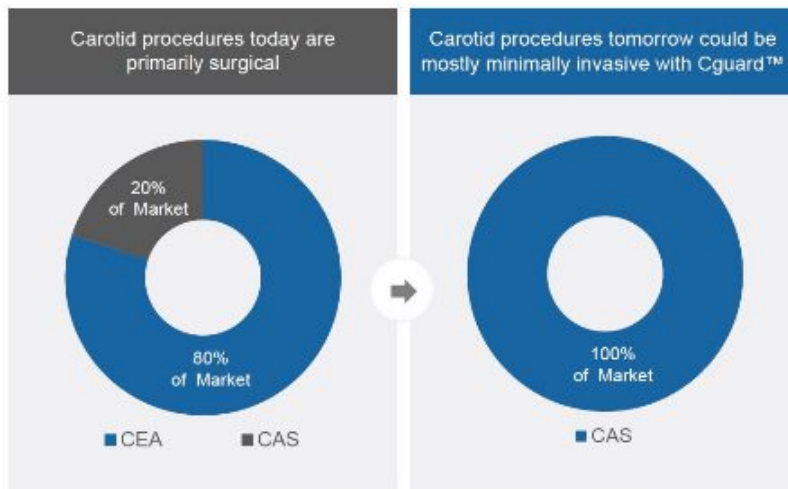


2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

Consequences Range from Neurological Deficit to Stroke



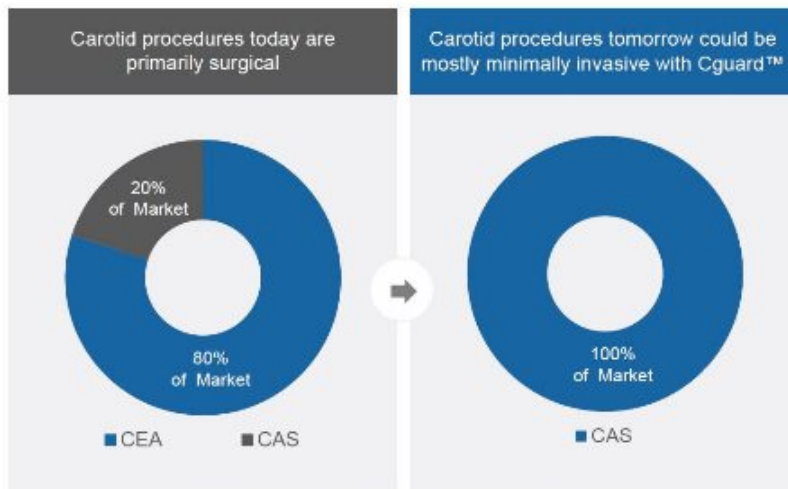
A Billion Dollar Market Opportunity



- 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 endarterectomy (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

A Billion Dollar Market Opportunity



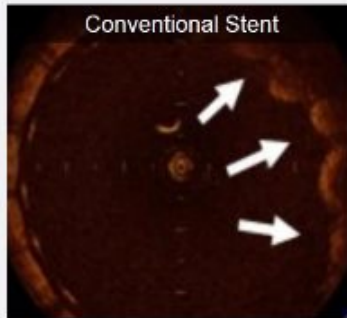
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MicroNet™ covered stents could become the Gold Standard

The InspireMD Solution: CGuard™ EPS

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: 43-46
² Umemoto, et al. Coronary Intervention 192 2017

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Positive CGuard™ Clinical Experience

CARENET Clinical Trial (2014)	PARADIGM 101 Clinical Trial (2015, 2016, and 2018)
30 Patient Safety and Efficacy clinical trial	101 patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)
Zero major adverse cardiac or cerebral events (MACCE) at 30 days (Comparative data 5.72% ^{**})	99.1% device success
50% fewer new ischemic lesions with lesion volume being 10x times smaller compared to historical non-mesh carotid artery stenting data	0% MACCE (Death/stroke/MI) @ 48 hrs
All new ischemic lesions fully resolved at 30 days except one	Less than 1% MACCE @ 30 days (1 minor stroke)
3.6% MACCE rate at 6 months (Comparative data 8.09% ^{**})	No device-related adverse events and no procedure-related events at 24 months ^{***}
Zero strokes or stroke related deaths at 12 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



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™ 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



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
 - PROF1 reported 68% new lesions in 62 patients



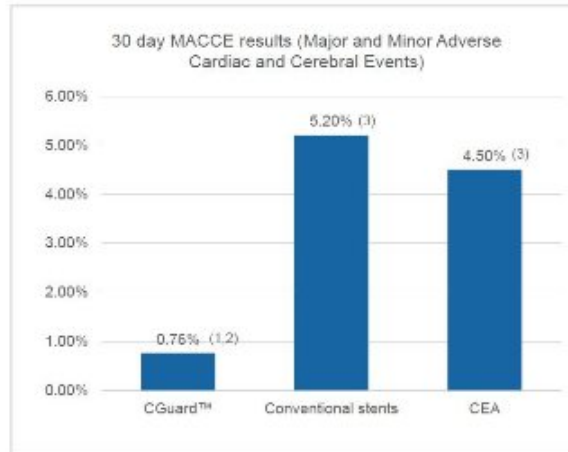
SPECIAL ARTICLES

Physician-initiated prospective analysis: Registry of sinus node ablation with the C-Guard mesh stent: the IRON-Guard registry: Rationale and design

F. Speziale, MD and P. Singano, MD
Department of Cardiology, University of Campania "Luigi Vanvitelli", Naples, Italy

CGuard™ vs Conventional Stents and Surgery

- CGuard™ has a superior profile versus historical data on both 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



*NOTE: IRON-GUARD®, Wisgott and Casasco 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; 12(8):70. 3. N Engl J of Med 2010 July 1; 11:23. 4. Moselek et al. TCT 2016 Featured Research Presentation

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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.”

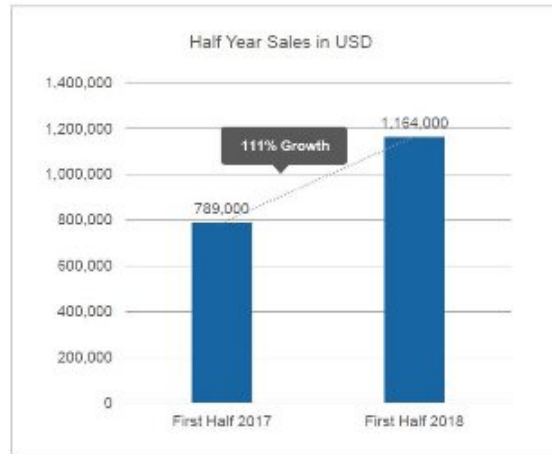
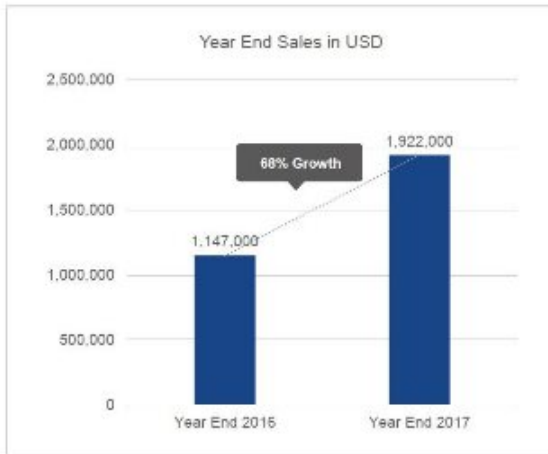
“Patient risks associated with stenting using CGuard™ are far lower than those associated with CEA or with other types of carotid stents.

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

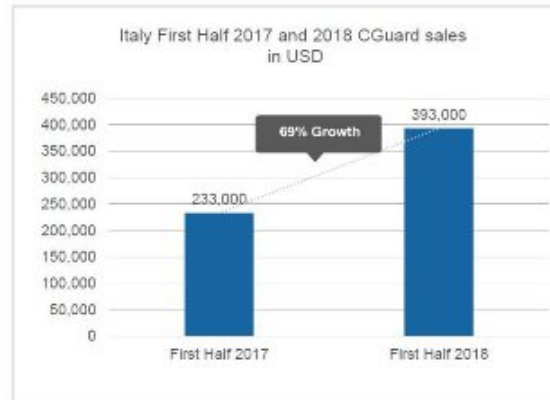
“With CGuard™ we can get excellent results, probably better than open surgery, the Gold Standard”

CGuard™ - Accelerating Sales Growth

Growth continues to accelerate for 2018/2017

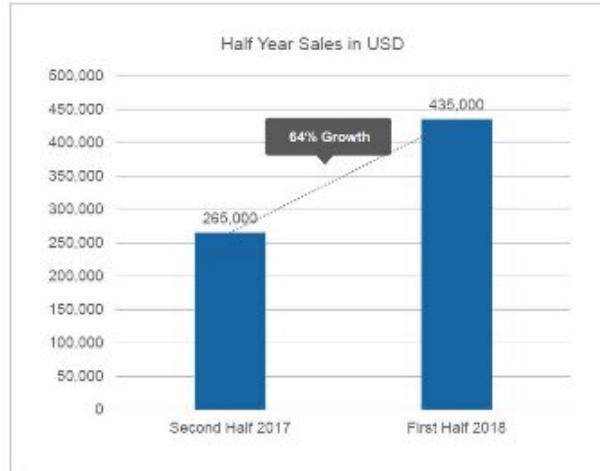


Accelerating CGuard™ Sales Growth: Italy

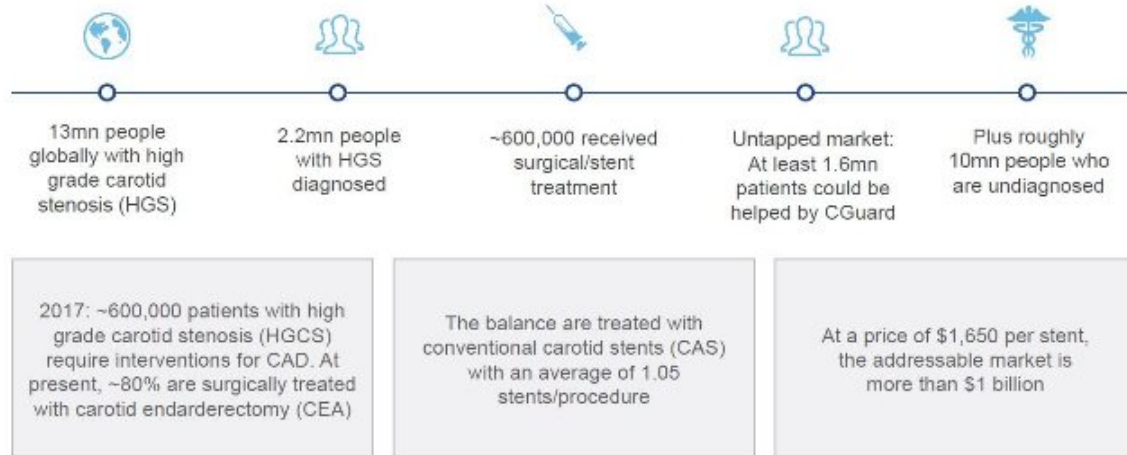


- CGuard™ sales in Italy have been strong over the last three years with continuing momentum
- Q2 comparisons between 2017 and 2018 show a 69% increase

Accelerating CGuard™ Sales Growth: Germany



Addressable Stroke Prevention Device Market



Commercial Strategy

Transition current users of conventional carotid stents to CGuard™

- Communication of CGuard™ 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
- 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

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	H22019	MID2019	H22019
Establish Centers of Excellence	CGuard approval and launch in Mexico	Partnership in Major Asia Pacific Market	CGuard approval in Brazil and Australia	CGuard U.S. IDE submission	5 French CGuard™ submission

Continued market execution and revenue growth



Intellectual Property Portfolio

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	8	3	9
Rest of World	35	2	19



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 (10/5/18):	\$0.27
Average three month daily trading volume:	3.4 M
Shares outstanding (10/5/18):	37.0 M
Shares Outstanding Including full conversion of preferred shares and prefunded warrants (10/5/2018):	44.7 M
Market Capitalization including full conversion of preferred shares and prefunded warrants (10/5/2018):	\$12.1 M
Cash (9/30/18)	\$11.2mn

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™ EPS are featured at major and regional clinical conferences



Product pipeline to support continued growth in all geographies, including the United States



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