INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 04/03/20 for the Period Ending 04/03/20

Telephone	(888) 776-6804
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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): April 3, 2020

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

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

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.

The InspireMD, Inc. (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 April 2020 (furnished herewith pursuant to Item 7.01).

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.

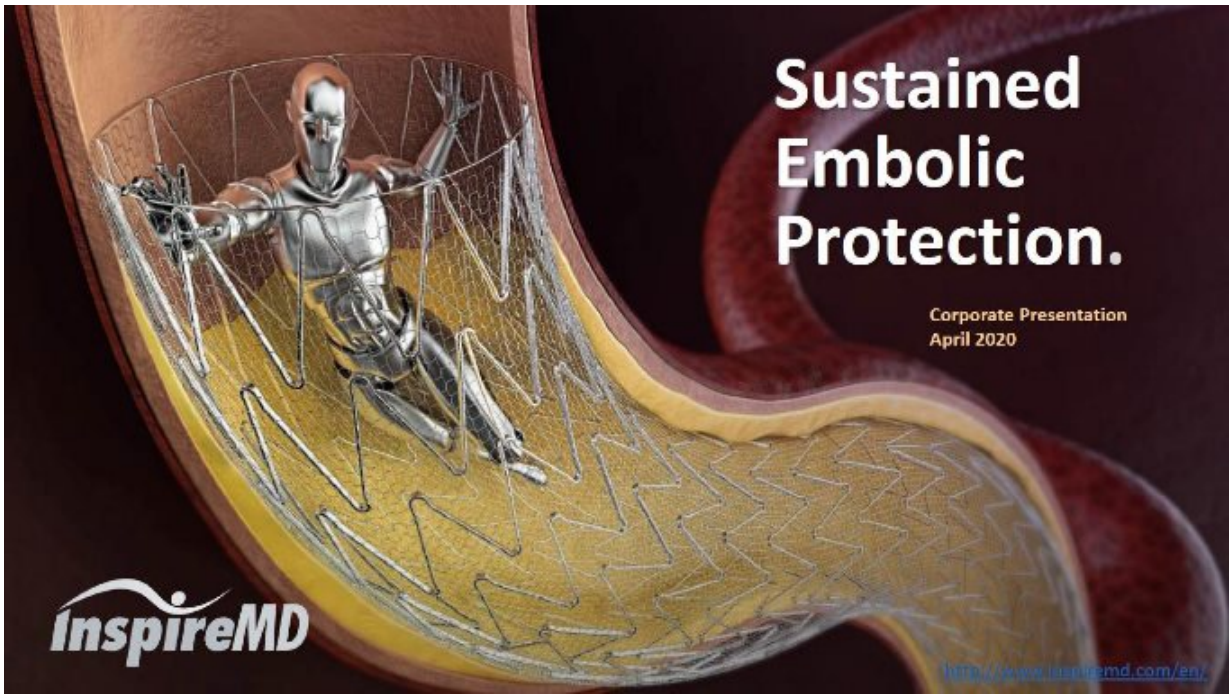
Date: April 3, 2020

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1


Sustained
Embolic
Protection.
Corporate Presentation
April 2020
InspireMD

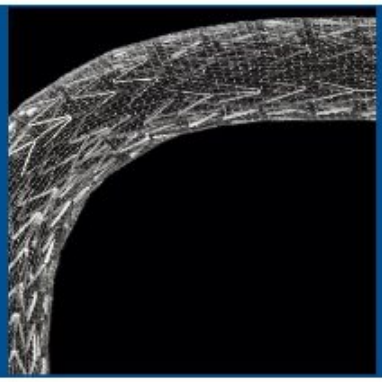
DISCLAIMER

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) the impact of the novel coronavirus (COVID-19) on our sales as hospitals delay or cancel elective surgeries, (iii) the geographic, social and economic impact of COVID-19 on our ability to conduct its business and raise capital in the future when needed, negative clinical trial results or lengthy product delays in key markets, 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 focused on stroke prevention in patients with carotid artery disease and treatment of other minimally invasive indications utilizing an integrated embolic protection stent platform.



MicroNet is a proprietary platform comprised of thin, 20-micron polyethylene terephthalate mesh that is designed to trap and maintain plaque stability against the arterial wall for protected flow to eliminate events such as heart attack, stroke and death.

- The company develops, manufacturers and commercializes a portfolio of embolic protection systems
- MicroNet™, a key differentiator of InspireMD's commercial products, is revolutionizing the field of vascular stenting
- Today, InspireMD is a global company traded in the NYSE under NSPR

About InspireMD

Ticker NYSE AMER: NSPR

# of employees: 47

Headquarters & manufacturing facility: Tel Aviv

Commercial & clinical employee locations: Germany, UK, Spain, Israel

Price (A/O 4/1/20): $0.62

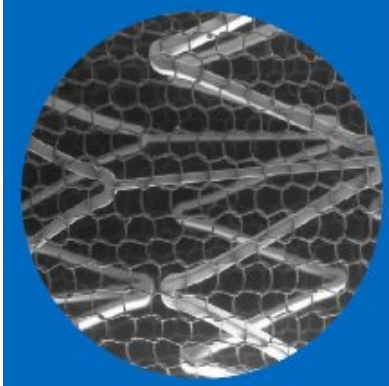
Shares outstanding (including full conversion of preferred shares): 5.0 million

Market cap (including full conversion of preferred shares): $3.0 million

Fiscal year end: December 31

Cash Balance as of Dec. 31 = $5.5 million

About InspireMD



Proprietary MicroNet™ Technology

Commercial Stage

Stroke Protection: CGuard™ EPS	The CGuard™ Carotid Stent with Embolic Prevention System (EPS) is designed to improve patient safety through sustained embolic protection[1,2] using our MicroNet technology.
Myocardium Protection: MGuard™ EPS	The MGuard™ EPS, integrated with MicroNet™, is designed to trap and seal thrombus and ruptured plaque, preventing embolization and optimize flow.

Developing Products

Carotid Treatment:	CGuard™ EPS US CGuard™ Next Generation
Peripheral Treatment:	PGuard™ EPS US
Neuro Treatment:	NGuard™

References: 1. Musialek P et al. PARADIGM-Extend Prospective Academic Trial: Accumulating long-term evidence for MicroNet-covered stent safety and stroke prevention efficacy. Presentation at ESC Congress 2019, Paris, France, 31 August 2019 to 4 September 2019. 2. Wissgott C et al. J Endovasc Ther 2017;24(1):130–137. 3. Musialek P, Hopkins LN, Siddiqui AH. Postepy Kardiol Interwencyjnej 2017;13(2):95–106. 4. Schofer J et al. JACC Cardiovasc Interv 2013;17(8):1229–1234. 5. CGuard™ Instructions for Use.

Company Highlights

CGuard™ EPS	**Enabling a paradigm shift** (CAS) in the treatment of carotid artery disease and stroke prevention **Breakthrough platform:** Highly differentiated, with strong support from leading clinicians **MicroNet™ technology** that is elegantly simple, propriety and easily leveraged to other medical devices
Benefits Demonstrated in Multiple Trials	**Clinical evidence / data driven:** 7 clinical trials completed with >1,500 patient procedures and 4 ongoing clinical trials **Differentiation** versus conventional carotid stents and surgery with both short- and long-term results **Outcomes based:** No device related major adverse events. No major strokes or deaths related to device. **Sustainable results**: Long term benefit reported in all-comer population
Commercial Growth	**Expanding existing footprint**: Deeper penetration within key markets (18,000 devices sold to date) **Results:** 2019 CGuard™ EPS sales increased 31% Q4/Q4 **Commercial model development:** Evaluating opportunities to go direct in key markets
1B Global Market Opportunity	**Expansion into OUS markets**: Near term: Brazil; strategic partners discussions in Japan and China **United States**: • IDE FDA submission for CGuard™ EPS July 2019 • Critical step in commencing human trial in the USA
Capital Structure	**Recapitalized** the company to clean up the capital structure and prepare for growth **Capital use** focused on commercial execution and pipeline
Pipeline and Strategic Opportunities	**Leverage** MicroNet™ into other pipeline opportunities in other neurovascular and peripheral techniques and treatments **Proactively** seek synergistic product opportunities **Add** BD resources to effectively assess inbound queries and implement a more focused and proactive BD strategy.

InspireMD 2.0

Re-setting Awareness, Establishing Value, and Advancing Body of Evidence to Change The Standard of Care

In late 2019, InspireMD:

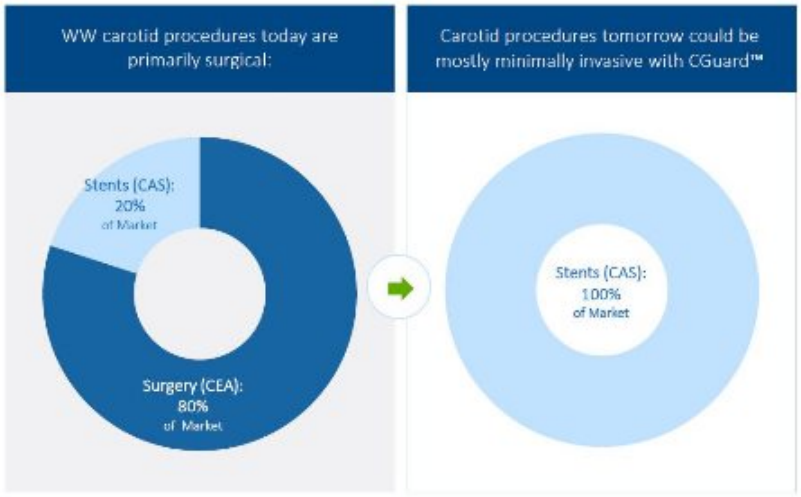
- Established new leadership
- Implemented focused commercial strategy in approved markets
- Committed to a patient-first approach while being accountable to delivering results, credibility, and quality

OUR 2020 PRIORITIES INCLUDE:

- **Building continued market share and utilization of CGuard™ in European markets**
- **Focusing on vascular surgeon's utilization of CGuard™ platform vs surgical approach (CEA)**
- **Opening and expanding markets in South America, including Brazil**
- **Completing IDE approval for CGuard™ for the U.S. market**
- **Prudent expense and cash management**
- **Advancing next generation CGuard™ platform / advanced delivery system**
- **Building a strategic plan with multiple pillars of indications**

A Billion Dollar Market Opportunity

Our MicroNet™-covered stents like CGuard™ could become the new gold standard



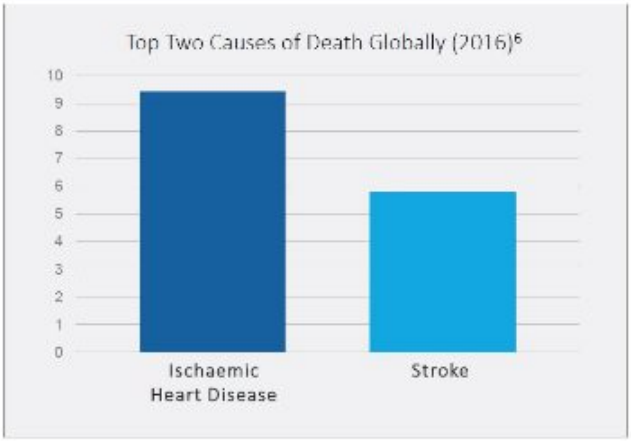
- 2.2M diagnosed with carotid artery disease (CAD)
- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) required interventions for CAD
- At present, ~80% are surgically treated CEA
- At a price of $1,650 per stent, the addressable market is estimated to be more than $1 billion

2017 Health Research International Market Report
CAS = Carotid Artery Stenting
CEA = Carotid Endarterectomy

Stroke is the Second Biggest Cause of Death Globally

An estimated 15 million people suffer from stroke annually[1]

- 6.2 million deaths[2]
- 5 million people left permanently disabled[3]
- $34 billion associated with stroke management in the US alone[3]
- ~85% of all strokes are ischemic strokes, which result from a lack of blood flow to the brain[4]
- Carotid artery disease (CAD) is a major risk factor for stroke
- ~20% of all ischemic strokes are estimated to be caused by CAD (2.2-2.4 million)[5]



[1] http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html
[2] https://professional.heart.org/idc/groups/ahamah-public/@wcm/@sop/@smd/documents/downloadable/ucm_505643.pdf
[3] Center For Disease Control and Prevention – Stroke Facts – 2017
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4562827/
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2861013/
[6] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

THE PROBLEM: Risks with Existing Approaches to CAD

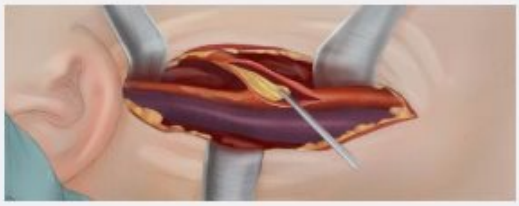
Surgery (CEA) and conventional Carotid Artery Stenting (CAS) both come with risks

Carotid Endarterectomy (CEA)

Surgical Approach

Risk of complications:

- Myocardial infarction risk[1] (heart attack)
- Cranial nerve injury risk[2] (vertigo, hearing loss, paralysis, etc)
- Esthetic concern



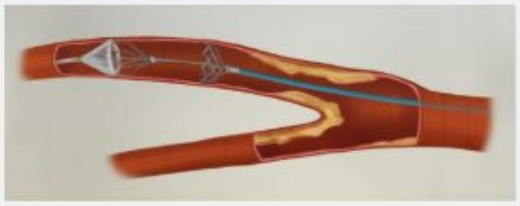
Carotid Artery Stenting (CAS)

Conventional Approach (Bare Stent)

Risk of complications:

- Procedural and post-procedural increase minor stroke risk[1]

Bare stent deployment



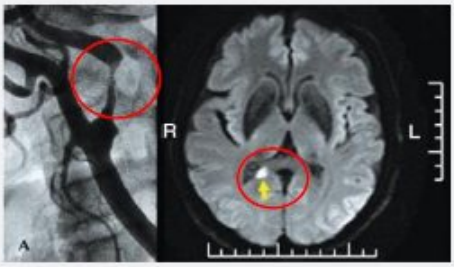
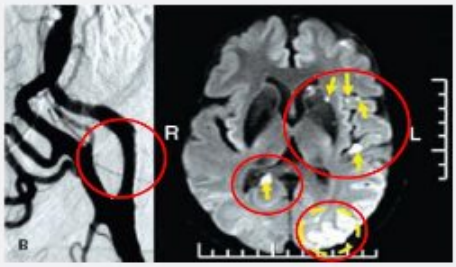
Based on the CREST clinical trial data[1], in which only conventional carotid stents were used vs.surgery

[1]CREST Trial. N Engl J Med 2010;363:11-23

[2]Circulation. 2012;125:2956-2964

THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post-procedural cerebral embolization

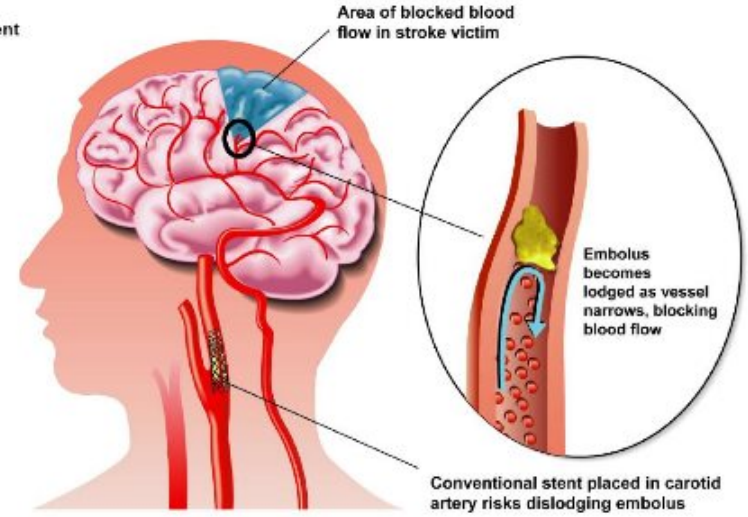
Pre-Procedure	Post-Procedure with Conventional Stent
	
90% occlusion of the carotid artery	Successful opening of the carotid artery
MRI of a pre-existing white matter infarction (obstruction)	MRI reveals new multiple micro-infarcts (obstructions) due to liberation of embolic particles

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

THE PROBLEM: Risk of Embolism Following Conventional CAS

Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents,* resulting in embolus formation and cerebral embolization

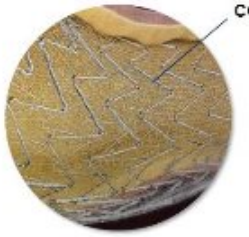
Conventional stents run the risk of plaques entering the blood stream and causing stroke



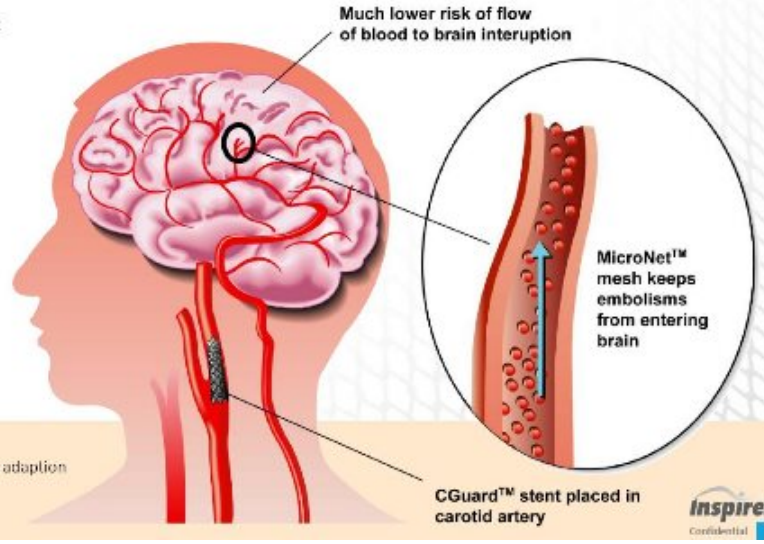
*depending on plaque morphology/symptomatic status and stent type; Mustafa, et al. EuroIntervention 2016;12:August 2016

CGuard™ EPS Is Our Solution for Carotid Artery Stenting (CAS)

Covered stent with the smallest pore size, permanently prevents the occurrence of plaque prolapse and thrombus facilitating natural endothelialization



CGuard™ uses MicroNet™, an open cell, nitinol, polyethylene terephthalate (PET)-covered mesh which permanently prevents the occurrence of plaque prolapse and thrombus



- SmartFit™ self tapering technology for excellent adaption
- Accurate placement (no foreshortening)

OUR SOLUTION: Proprietary MicroNet™ Technology

New mesh covered stent that offers superior plaque coverage when compared to conventional stent approaches

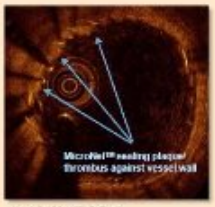
Conventional Stent:

Bare or dual layer approach, with plaque protrusion risk

Vs.

New Covered Stent:

Stents are covered in Micronet™



MicroNet™: an Embolic Prevention System (EPS) for Ultimate Thrombus Protection

- **Ultrathin flexible mesh** sleeve, designed to expand seamlessly during stent deployment
- Net **captures and locks** thrombus and plaque materials against the arterial wall
- Prevents thrombus or plaque fragments dispersing, **avoids debris** entering the bloodstream
- Acts as a mechanical barrier to prevent **plaque protrusion**

InspireMD

Carotid Solution: Our Well Studied Mesh-Covered Technology

More than 1,600 patients in Clinical Publications and Studies

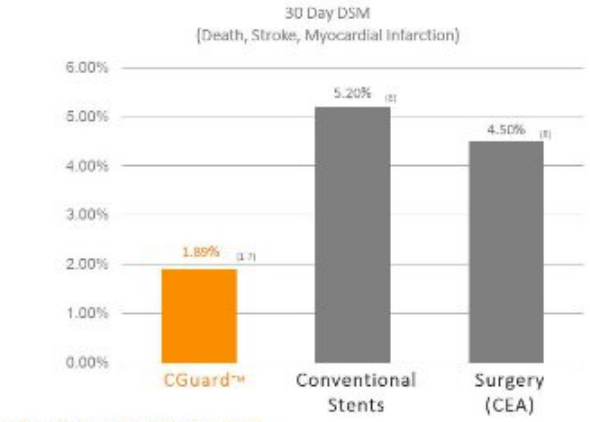
Timeline Growth: From Alternative Stent to New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (known & anticipated)
2015	CARENET 30D	Safety, feasibility & neuroprotection; Neuroprotection over other stents data	☑ CGuard evaluated as new approach to CAS
2016	PARDIGM 101 30D	All commers population; Excellent clinical results	
2017	CASANA	Large surgical center; Excellent clinical results	
2017	WISSGOTT	Clinical & mechanical assessment; Mechanical advantages vs competitive stents	☑ CGuard demonstrates best performance in field
2017	IRON GUARD 1	Real world multicentric 30d results; Excellent clinical results in multicentric	
2018	WISSGOTT 10MM	"One size fit all"; Safety & feasibility of a size fit all approach	
2019	IRON GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric	
2020	IRON-GUARD 2 *	Large real world multicentric	☐ CGuard demonstrates superiority to other stents
2020	SIBERIA *	Randomized Trial; CGuard neuroprotection vs conventional stents	
2021	POLISH VASCULAR REGISTRY *	Large real world multicentric	
2022	OCTOPVS *	OCT comparison CGuard vs CEA; to demonstrate CGuard superior procedural results than CEA	
2022	PARADIGM EXTEND *	Large long-term study for all commers; CGuard study of long-term results	☐ CGuard demonstrates superiority to surgery
2022	OPTIMA *	IVUS assessment after CGuard; intended to demonstratePlaque exclusion demonstrated	
2023	FLOW-GUARD *	Use of CGuard as flow diverter in very high-risk patients beyond carotids; Potential new CGuard indications	

Expected *

CGuard™ EPS Yields Superior Clinical Outcomes

When compared with Conventional Stents and Surgery (CEA), CGuard™ trends Superior



- CGuard™ 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
- NO MAJOR STROKE with CGuard (Minor stroke in 17/1507 Pts in 7 Studies (1.13%)

Our Commercial Strategy

Continued commercial focus on CGuard™ EPS clinical data	Continue to support investigator initiated clinical studies	Continue to develop KOLs, broaden centers of excellence to multiple clinical disciplines
Publish, present, and communicate data demonstrating CGuard™ as safe as CEA	Establish a presence at major vascular surgery meetings	Expand digital, social and other tools to more effectively communicate
Focus resources on larger markets with highest opportunities (Germany, Italy, Spain, Poland)	Build on the clinical database & broaden support (clinical registries, etc)	Evaluating further market growth via direct sales in key regional markets
Ongoing discussions with partners to bring CGuard™ to Japan and China	Obtain US IDE approval	

We Are Currently Active in Over 39 Markets (Dark Blue)

- Over 90% of sales are indirect through a range of distributors
- New markets under consideration / development include Japan, S Korea and China
- Discussions progressing with FDA regarding IDE; targeting initiation of US trial in 2021 (subject to FDA approval)

Our Lead Product, CGuard™ - Advancing Rapidly

31%

growth of CGuard™ portfolio in Q4 2019

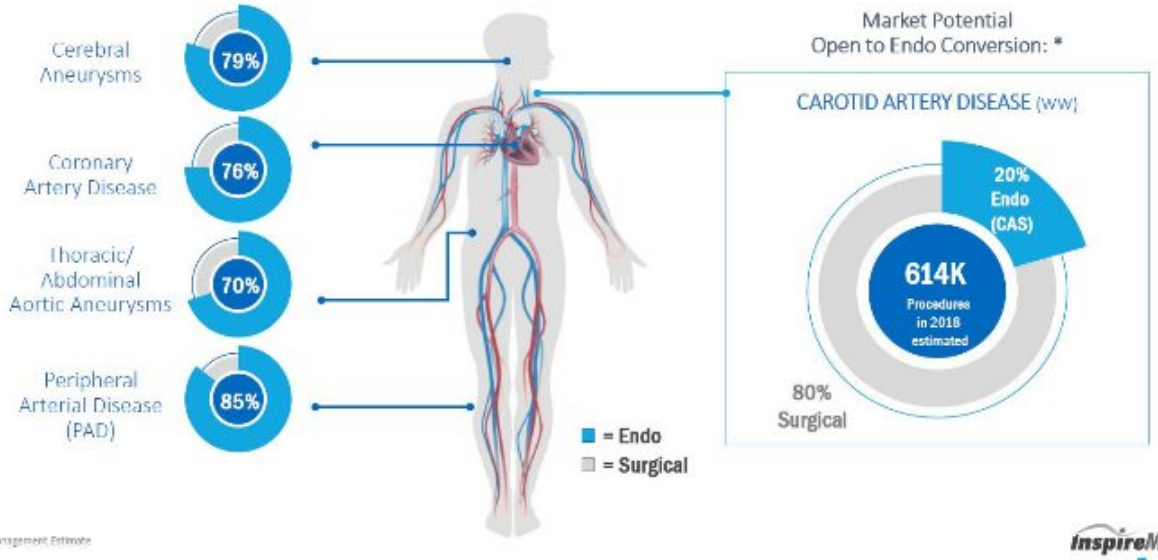
18,000

Total protected stents sold to date with excellent clinical results

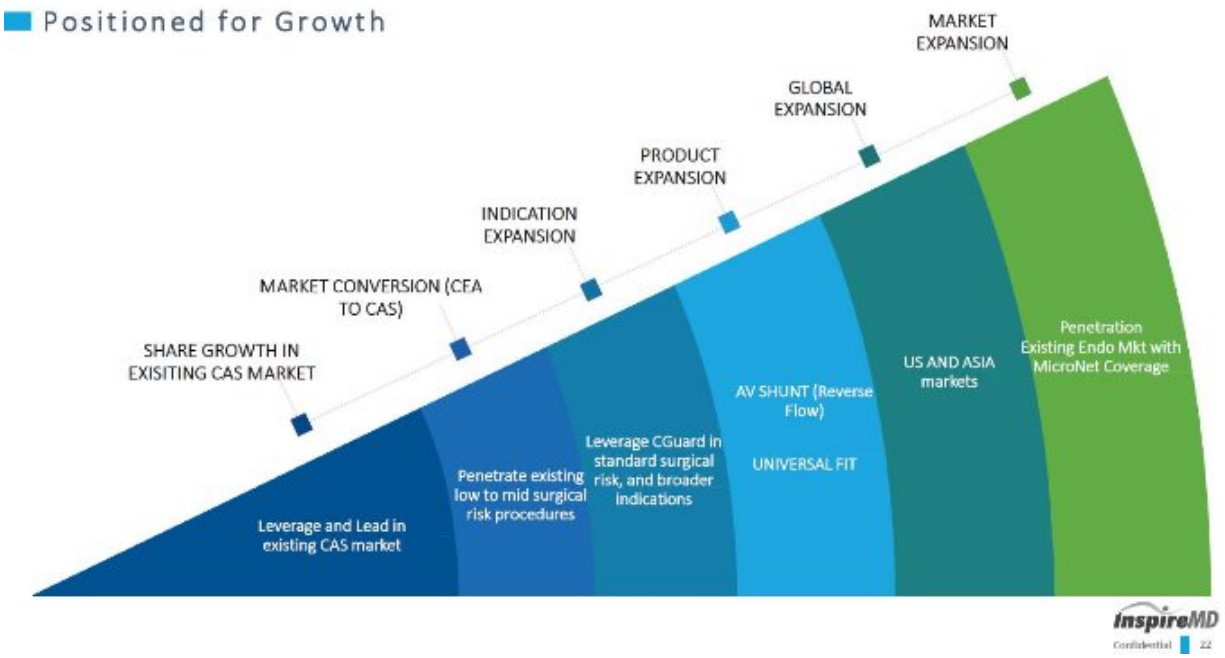
CGuard™ has potential to become the new standard-of-care for carotid indications

*Achieved clinical milestones; neuroprotective vs other carotid artery stenting (SERBIA)

Endovascular Procedures: Landscape and InspireMD Potential*



*Management Estimate


Positioned for Growth
MARKET EXPANSION
GLOBAL EXPANSION
PRODUCT EXPANSION
INDICATION EXPANSION
MARKET CONVERSION (CFA TO CAS)
SHARE GROWTH IN EXISITING CAS MARKET
Leverage and Lead in existing CAS market
Penetrate existing low to mid surgical risk procedures
Leverage CGuard in standard surgical risk, and broader indications
AV SHUNT (Reverse Flow)
UNIVERSAL FIT
US AND ASIA markets
Penetration Existing Endo Mkt with MicroNet Coverage
InspireMD
Confidential 22

Our Advancement Roadmap / Milestones

Key Value Drivers and Strategic Pathways

Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Allowed	Pending
USA	13	2	6
Rest of World	47	0	19

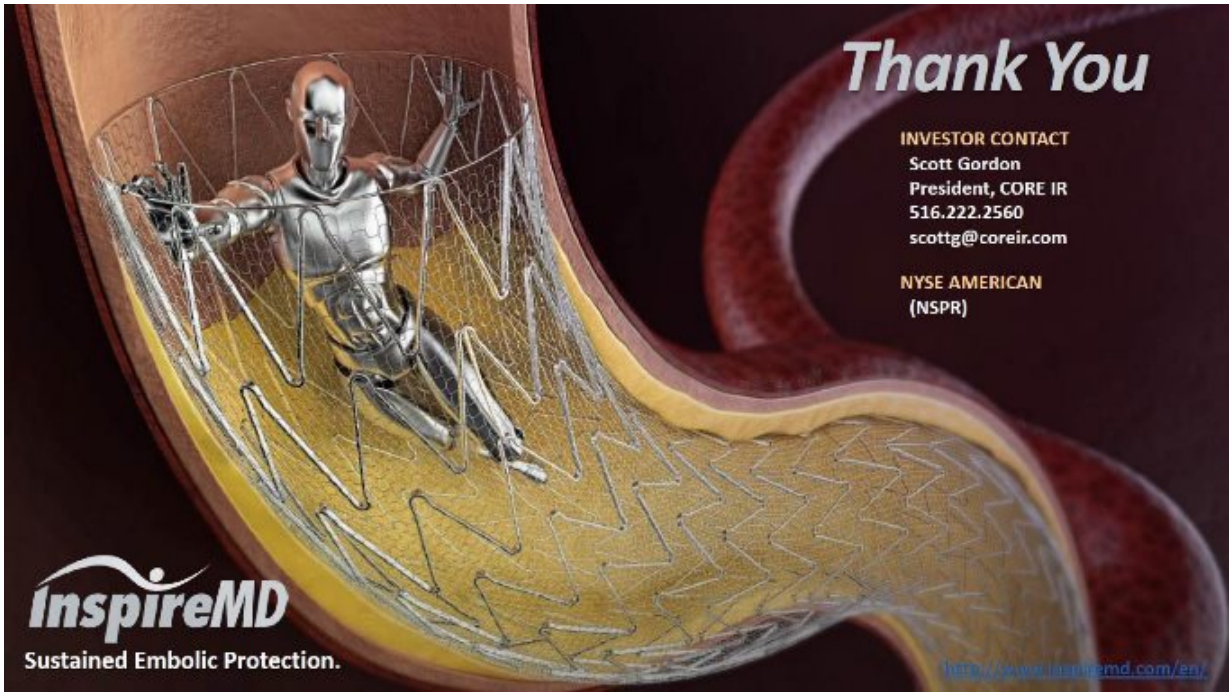
- InspireMD will continue to strengthen and broaden its patent protection globally to enable future pipeline products

Our Business and Market Development

Strategic Targets for Merger or Acquisition

Our Leadership

Marvin L. Slosman President and CEO	Mr. Slosman has over 30 years of experience in the medical device industry with focused leadership in commercialization and international market development in both public and privately held companies. He has had senior management roles in a variety of public and privately held companies.	
Craig Shore CFO	Mr. Shore has over 25 years of experience in financial management in the United States, Europe and Israel. He has served in various senior financial and general management roles at General Electric, Dunn and Bradstreet, Pfizer Pharmaceuticals and Bristol Myers Squibb.	
Paul Stuka Chairman	Mr. Stuka was named to the Board of Directors in August of 2011 and serves as Chairman of the Board of Directors. Mr. Stuka is a Managing Member of Osiris Partners and a 30-year investment industry veteran.	
Michael Berman Director	Mr. Berman is a successful entrepreneur within the medical device industry. He joined Scimed in 1986, leading its marketing activities until its merger with Boston Scientific in 1995. From 1995-2000, he served as President of Boston Scientific/Scimed.	
Campbell Rogers, M.D. Director	Dr. Rogers currently serves as the CMO of HeartFlow, Inc., a private cardiovascular diagnostics company based in California.	
Thomas Kester Director	Mr. Kester is CFO of Kester Search Group, Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies. He spent 28 years at KPMG LLP.	


Thank You
INVESTOR CONTACT
Scott Gordon
President, CORE IR
516.222.2560
scottg@coreir.com
NYSE AMERICAN
(NSPR)
InspireMD
Sustained Embolic Protection.