INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/12/19 for the Period Ending 11/12/19

Telephone	(888) 776-6804
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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): November 12, 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** (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 2.02 Results of Operations and Financial Condition.

On November 12, 2019, InspireMD, Inc. (the "Company") issued a press release announcing its financial and operating results for the third fiscal quarter ended September 30, 2019. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, 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 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

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 99.2, 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	Press Release dated November 12, 2019 (furnished herewith pursuant to Item 2.02).
99.2	Slide Presentation of InspireMD, Inc. dated November 2019 (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: November 12, 2019

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

InspireMD Announces Third Quarter 2019 Financial Results

Strong revenue driven by record orders of CGuard™ EPS

Management to host investor conference call today, November 12, at 8:30am ET

Tel Aviv, Israel— November 12, 2019 – InspireMD, Inc. (NYSE American: NSPR), developer of the CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by the treatment of carotid artery disease, today announced financial and operating results for the third quarter ended September 30, 2019.

Third Quarter 2019 and recent highlights:

- Generated revenue of $939,000, up 22.1% over the third quarter 2018, driven largely by record orders of CGuard™ EPS
- CGuard™ EPS revenue of $852,000, up 41.1% over the third quarter 2018
- Announced the receipt of two new U.S. patents (No. 10,406,006 and No. 10,406,008) covering the company's proprietary single fiber mesh technology, known as MicroNet™
- Raised gross proceeds of $5 million through an underwritten public offering
- Continued to engage the FDA in productive discussions and is working methodically to provide the additional information and testing requested by the FDA for the company's IDE application

"We were pleased with our third quarter financial and operating results, typically a seasonally soft quarter, which were highlighted by record orders of CGuard™," said James Barry, PhD, Chief Executive Officer of InspireMD. "We believe our educational and outreach programs such as our Centers of Excellence and presentations at highly regarded medical meetings such as Joint Congress of the World Heart Federation and the European Society of Cardiology are gaining traction among interventional cardiologists and, more importantly, vascular surgeons who perform a majority of carotid procedures. This quarter's results also show the maturity of our distribution network in our key territories. Looking forward, we continue to work with the FDA to address outstanding questions regarding our IDE application, and we remain committed to initiating U.S. clinical trials to bring this game-changing technology to the USA. I believe the third quarter was an inflection for our company, and we are working tirelessly to sustain this momentum."

Financial Results

For the three months ended September 30, 2019, revenue increased by $170,000, or 22.1%, to $939,000, from $769,000 during the three months ended September 30, 2018. This increase was predominantly driven by a 41.1% increase in sales volume of CGuard EPS from $604,000 during the three months ended September 30, 2018, to $852,000 during the three months ended September 30, 2019, mainly due to our continued focus on expanding existing markets such as Italy and Russia. This increase in sales of CGuard EPS was partially offset by a 47.3% decrease in sales of MGuard Prime EPS from $165,000 during the three months ended September 30, 2018, to $87,000 during the three months ended September 30, 2019, largely driven by the move to drug-eluting stents rather than bare metal stents, such as MGuard Prime EPS, in ST-Elevation Myocardial Infarction ("STEMI") patients.

The company's gross profit for the quarter ended September 30, 2019 was $128,000, compared to a gross profit of $198,000 for the same period in 2018. Gross margin decreased to 13.6% in the third quarter of 2019 from 25.7% for the same period in 2018. This decrease in gross profit resulted from a $65,000 increase in write-offs predominantly driven by a non-recurring component supply issue and a $11,000 decrease associated with the higher sales volume of CGuard EPS (as mentioned above), sold at a lower average selling price for the three months ended September 30, 2019, compared to the average selling price of CGuard EPS for the three months ended September 30, 2018. These decreases in gross profit were partially offset by a decrease of $6,000 in miscellaneous expenses.

Total operating expenses for the quarter ended September 30, 2019 were $2,125,000, a decrease of 2.4% compared to $2,177,000 for the same period in 2018. This decrease was primarily due to a non-recurring marketing consulting expense associated with CGuard™ EPS in 2018.

Financial expenses for the quarter ended September 30, 2019 were $73,000 compared to financial expenses of $32,000 for the same period in 2018. This increase in financial expenses of $41,000 was predominately due to changes in exchange rates. Net loss for the third quarter of 2019 totaled $2,070,000 or $1.26 per basic and diluted share, compared to a net loss of $2,011,000, or $2.47 per basic and diluted share, for the same period in 2018.

For the nine months ended September 30, 2019, revenue decreased by $71,000, or 2.6%, to $2,708,000, from $2,779,000 during the nine months ended September 30, 2018. This decrease was predominantly driven by a 28.8% decrease in sales volume of MGuard Prime EPS from $511,000 during the nine months ended September 30, 2018, to $364,000 during the nine months ended September 30, 2019, largely driven by the move to drug-eluting stents rather than bare metal stents, such as MGuard Prime EPS, in STEMI patients. This decrease was offset by a 3.4% increase in sales volume of CGuard EPS from $2,268,000 during the nine months ended September 30, 2018, to $2,344,000 during the nine months ended September 30, 2019. This increase was primarily due to our continued focus on expanding existing markets such as Poland, Switzerland, India, Italy and Spain and expansion into new geographies such as Australia and South Africa. The overall increase was offset across the board due to shipment delays in the three months ended March 31, 2019 associated with us changing sterilization companies and sales decreases in certain of our markets. The transition to our new sterilization is now complete and we do not currently anticipate any future disruptions in fulfilling new orders and sales decreases in certain of our markets.

The Company's gross profit for the nine months ended September 30, 2019 was $497,000 compared to a gross profit of $768,000 for the same period in 2018. Gross margin decreased to 18.4% in the nine months ended September 30, 2019 from 27.6% in the same period in 2018. This decrease in gross profit resulted from a $106,000 increase in write-offs predominantly driven by a non-recurring component supply issue, a $92,000 decrease in revenues (as mentioned above), less the related material and labor costs, $69,000 of expenses related to upgrades made to our production facilities and $46,000 of expenses pertaining to annual and new employee training of the production workers, offset by a decrease of $42,000 in miscellaneous expenses.

Total operating expenses for the nine months ended September 30, 2019 were $7,807,000, an increase of 26.5% compared to $6,173,000 for the same period in 2018. This increase was primarily due to an increase in clinical expenses associated with CGuard™ EPS, mainly related to IDE efforts in 2019 and due to a settlement payment made to a former service provider pursuant to a settlement agreement.

Financial expenses for the nine months ended September 30, 2019, were $173,000 an increase of $551,000, or 145.8%, versus a gain of $378,000 for the nine months ended September 30, 2018. The increase in financial expenses primarily resulted from the $438,000 of financial income related to the revaluation of the embedded derivative of the Series C Preferred Stock recorded during the nine months ended September 30, 2018, which did not occur during the nine months ended in September 30, 2019, and an increase of $117,000 in financial expenses related to changes in exchange rates. These increases in financial expenses were partially offset by a decrease of $4,000 in miscellaneous expenses during the nine months ended September 30, 2019. Net loss for the nine months ended September 30, 2019 totaled $7,483,000, or $5.79 per basic and diluted share, compared to a net loss of $5,027,000, or $16.24 per basic and diluted share, for the same period in 2018.

As of September 30, 2019, cash and cash equivalents were $7,154,000, compared to $9,384,000 at December 31, 2018.

Conference Call and Webcast Details

The conference call will be available via telephone by dialing toll free 877-451-6152 for U.S. callers, or +1 201-389-0879 for international callers, and referencing conference ID 13683949. To access the webcast, please go to the following link: http://public.viavid.com/index.php?id=135364. The webcast will be archived on the Company's website.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for Carotid Stenting by providing outstanding acute results and durable stroke free long-term outcomes.

InspireMD's common stock is quoted on the NYSE American under the ticker symbol NSPR and certain warrants are quoted on the NYSE American under the ticker symbol NSPR.WS and NSPR.WSB.

Forward-looking Statements

This press release 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 payers 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.

Investor Contacts:

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CONSOLIDATED STATEMENTS OF OPERATIONS [1]

(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues	$ 939	$ 769	$ 2,708	$ 2,779
Cost of revenues	811	571	2,211	2,011
Gross Profit	128	198	497	768
Operating Expenses:				
Research and development	442	416	2,432	898
Selling and marketing	537	605	1,791	1,677
General and administrative	1,146	1,156	3,584	3,598
Total operating expenses	2,125	2,177	7,807	6,173
Loss from operations	(1,997)	(1,979)	(7,310)	(5,405)
Financial income (expenses)	(73)	(32)	(173)	378
Loss before tax expenses	(2,070)	(2,011)	(7,483)	(5,027)
Tax expenses (Income)	-	-	-	-
Net Loss	$ (2,070)	$ (2,011)	$ (7,483)	$ (5,027)
Net loss per share – basic and diluted	$ (1.26)	$ (2.47)	$ (5.79)	$ (16.24)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	1,648,302	815,283	1,293,321	334,581

CONSOLIDATED BALANCE SHEETS [1]
(U.S. dollars in thousands)

	September 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,154	$ 9,384
Accounts receivable:		
Trade, net	796	716
Other	186	104
Prepaid expenses	155	81
Inventory	1,283	1,134
Total current assets	9,574	11,419
Non-current assets:		
Property, plant and equipment, net	538	421
Right of use	975	-
Funds in respect of employee rights upon retirement	535	448
Total non-current assets	2,048	869
Total assets	$ 11,622	$ 12,288

	September 30, 2019	December 31, 2018
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 687	$ 929
Other	1,617	1,966
Contract liability	19	25
Total current liabilities	2,323	2,920
Long-term liabilities:		
Leasing liability	699	-
Liability for employees rights upon retirement	704	605
Total long-term liabilities	1,403	605
Total liabilities	3,726	3,525
Redeemable preferred shares		
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2019 and December 31, 2018; 3,456,915 and 768,615 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	-	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at September 30, 2019 and December 31, 2018; 17,303 shares issued and outstanding at September 30, 2019 and December 31, 2018.	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2019 and December 31, 2018; 36,869 and 61,423 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	-	-
Additional paid-in capital	162,971	156,355
Accumulated deficit	(155,075)	(147,592)
Total equity	7,896	8,763
Total liabilities, redeemable preferred shares and equity	$ 11,622	$ 12,288

(1) All 2019 financial information is derived from the Company's 2019 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; all 2018 financial information is derived from the Company's 2018 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All September 30, 2019 financial information is derived from the Company's 2019 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2018 financial information is derived from the Company's 2018 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2018 filed with the Securities and Exchange Commission.


InspireMD
InspireMD
James Barry, Ph.D. President and CEO | November 2019

Disclaimers

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

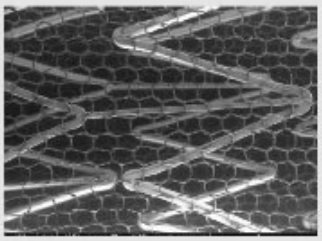
InspireMD is a commercial-stage medical device company focused on stroke prevention for patients with carotid artery disease and other vascular diseases utilizing an integrated embolic protection technology

COMPANY

NYSE AMER:	NSPR
Employees:	46
Headquarters:	Tel Aviv
Manufacturing Facility:	Tel Aviv
Commercial and Clinical Employees:	Germany UK Spain Israel

TECHNOLOGY

Proprietary MicroNet™ technology



PRODUCTS

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

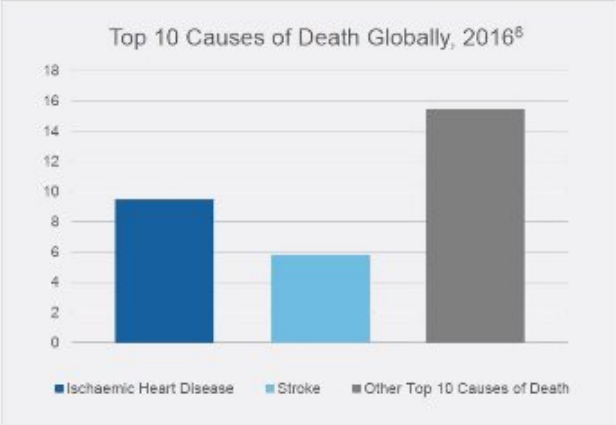
Company Highlights

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, precisely and easily leveraged to other medical devices
Benefits demonstrated in multiple trials	**Clinical Evidence / Data Driven**: 7 completed and 4 ongoing clinical trials **Differentiation** versus conventional carotid stents and surgery **Outcomes based**: No device related major adverse events. No major strokes **Sustainable results**: 1 only term benefit reported in all-comer population
Commercial Growth	**Expanding Existing Footprint**: Deeper penetration within key markets **Results**: 2018 CGuard™ EPS sales increased 55% YoY **Commercial Model Development**: Evaluating opportunities to go direct in key markets
1B Global Market Opportunity	**Expansion into OUS Markets**: Near Term: Recent Strategic Partners Discussions in Japan and China **United States**: IDE FDA submission for CGuard™ EPS July 2019 Additional request from FDA for information in support of application August 2019 Working closely with FDA to resolve additional requests for information 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, IDE and pipeline
Pipeline and Strategic Opportunities	Leverage MicroNet™ into other pipeline opportunities in neurovascular and peripheral vascular diseases **Proactively** seek synergistic product opportunities **Add** RD resources to effectively assess inbound queries and implement a more focused and proactive RD strategy

Stroke is the Second Biggest Cause of Death

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

- 6.2 million deaths[1]
- 5 million people left permanently disabled[3]
- $34 billion associated with stroke management in the US alone[2]
- ~ 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
- Approximately 20% of all ischemic strokes are estimated to be caused by CAD (2.2-2.4 million)[5]



InspireMD

[1] https://www.worldstrokecampaign.org/learn/stats-and-figures.html
[2] Center For Disease Control and Prevention – Stroke Facts – 2017
[3] http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html
[4] **State of the Nation** Stroke statistics - January 2018
[5] https://www.ncbi.nlm.nih.gov/pubmed/?term=10.1056%2Fnejm200008033422302
[6] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

Unmet Need: A Safer Technology for Stroke Prevention in CAD

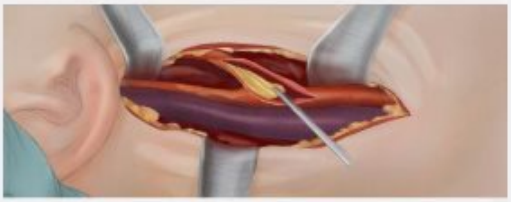
Surgery vs. Carotid Artery Stenting

Carotid Endarterectomy (CEA)

"Gold standard"[1], but…

Invasive; risk of surgical complications

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

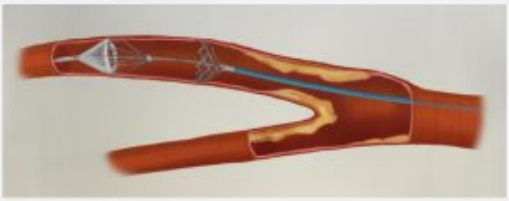


Filter Protected Stenting (CAS)

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.**surgery**

[1]CREST Trial: N Engl J Med 2010;363:11-23
[2] Circulation. 2012;125:2756-2764

Current Treatments for Carotid Artery Disease

Surgery (Carotid Endardarectomy) (CEA) vs. Conventional Carotid Stents (CAS)

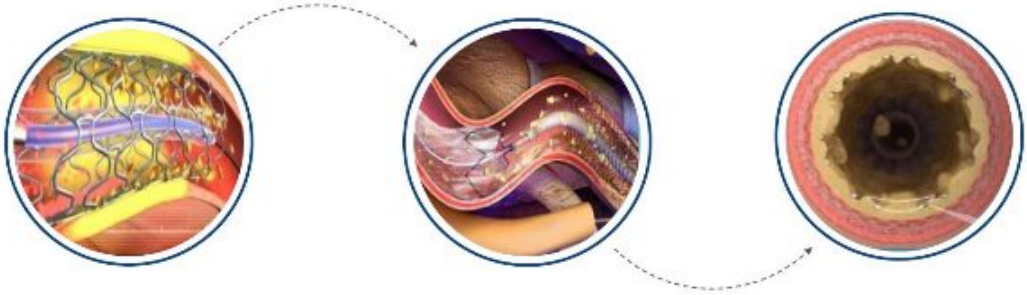
CREST

N Engl J Med 2010;363:11-23.

	CAS (N = 1262)	CEA (N = 1240)	Periprocedural Period: Absolute Treatment Effect of CAS vs. CEA (95% CI)	Hazard Ratio for CAS vs. CEA (95% CI)	P Value
	no. of patients (% ±SE)		*percentage points*		
Death	9 (0.7±0.2)	4 (0.3±0.2)	0.4 (−0.2 to 1.0)	2.25 (0.69 to 7.30)†	0.18†
Stroke					
Any	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major ipsilateral	11 (0.9±0.3)	4 (0.3±0.2)	0.5 (−0.1 to 1.2)	2.67 (0.85 to 8.40)	0.09
Major nonipsilateral‡	0	4 (0.3±0.2)	NA	NA	NA
Minor ipsilateral	37 (2.9±0.5)	17 (1.4±0.3)	1.6 (0.4 to 2.7)	2.16 (1.22 to 3.83)	0.009
Minor nonipsilateral	4 (0.3±0.2)	4 (0.3±0.2)	0.0 (−0.4 to 0.4)	1.02 (0.25 to 4.07)	0.98†
Myocardial infarction	14 (1.1±0.3)	28 (2.3±0.4)	−1.1 (−2.2 to −0.1)	0.50 (0.26 to 0.94)	0.03
Any periprocedural stroke or postprocedural ipsilateral stroke	52 (4.1±0.6)	29 (2.3±0.4)	1.8 (0.4 to 3.2)	1.79 (1.14 to 2.82)	0.01
Major stroke	11 (0.9±0.3)	8 (0.6±0.2)	0.2 (−0.5 to 0.9)	1.35 (0.54 to 3.36)	0.52
Minor stroke	41 (3.2±0.5)	21 (1.7±0.4)	1.6 (0.3 to 2.8)	1.95 (1.15 to 3.30)	0.01
Any periprocedural stroke or death or postprocedural ipsilateral stroke	55 (4.4±0.6)	29 (2.3±0.4)	2.0 (0.6 to 3.4)	1.90 (1.21 to 2.98)	0.005
Primary end point (any periprocedural stroke, myocardial infarction, or death or postprocedural ipsilateral stroke)	66 (5.2±0.6)	56 (4.5±0.6)	0.7 (−1.0 to 2.4)	1.18 (0.82 to 1.68)	0.38

Embolization Following Carotid Artery Stenting

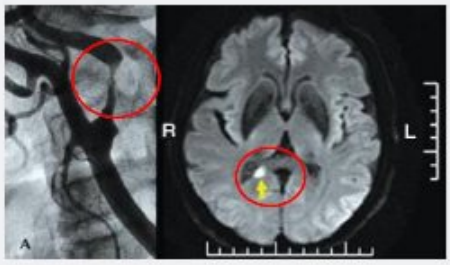
Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents, depending on plaque morphology/symptomatic status and stent type. The consequence is cerebral embolization, either directly or via additional thrombus formation.



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

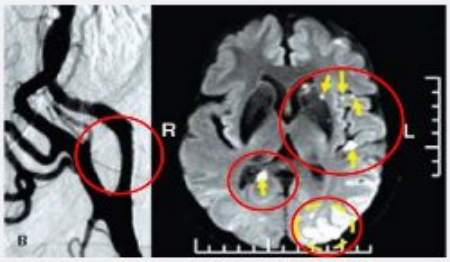
Consequences Range from Neurological Deficit to Stroke

Pre-Procedure



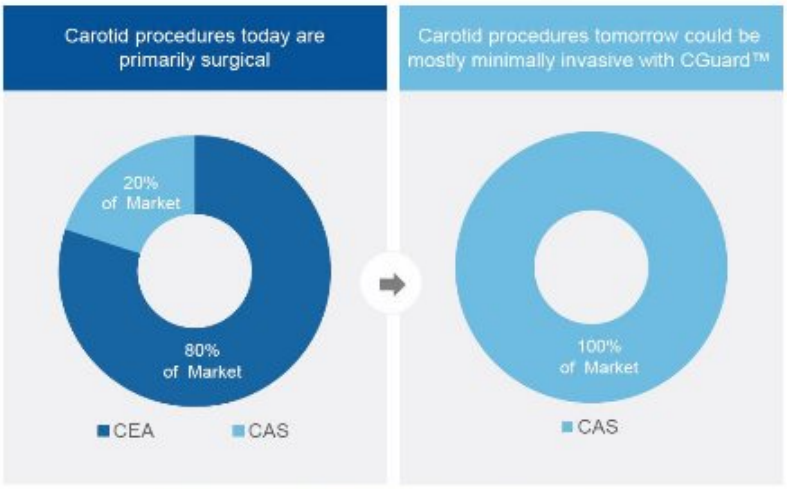
Pre-intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction).

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

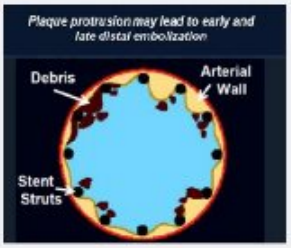


- 2.2M diagnosed with carotid artery disease
- 2017: ~600,000 patients with high grade carotid stenosis (HGCS) require interventions for CAD
- At present, ~80% are surgically treated with carotid endarderectomy (CEA)
- At a price of $1,650 per stent, the addressable market is estimated to be more than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

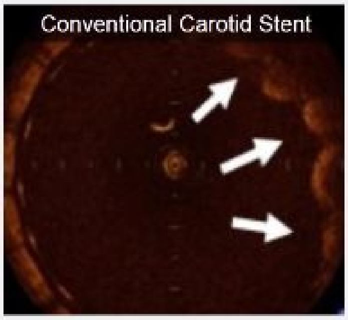
- The MicroNet™ **permanently covers** plaque and stops "debris" from passing through the mesh.
- Ultrathin PET mesh made of a single 20 micron fibre from a biocompatible polymer - widely used in other medical implants
- MicroNet™ acts as a "safety net" with greater vessel area coverage to prevent plaque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

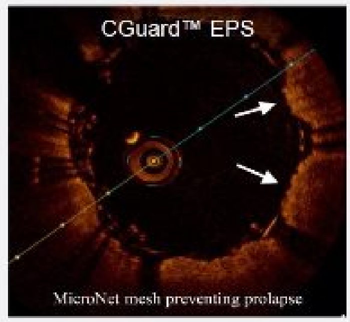
CGuard™ EPS has been shown to prevent embolic debris passing into the carotid artery and traveling to the brain

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 2-6
2. Umemoto et al. Eurointervention 197 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 and PARADIGM Extend Clinical Trials (2015, 2016, 2018, and 2019)
402 patients, 436 devices ongoing registry evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)
99.1% device success in PARADIGM 101
0% major stroke @ 30 days (0-402) **<1% any stroke (minor), death or myocardial infarction (4/402)**
0 strokes from 30 days to 1 year (n=311) **0 ipsilateral (device related) strokes from 30 days to 2 years (n=205)** **1 ipsilateral stroke at 3 years (1/108)** **1 ipsilateral stroke at 4 years (1/61)**
1 case of instent restenosis at 1 year (1/106)

"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, CARENET, CREATE, EMPIRE, EPIC, MAVERIC 1+2, MAVERIC International, PRIMUS, SAPPHIRE, SECURITY, PARIS, ICSS

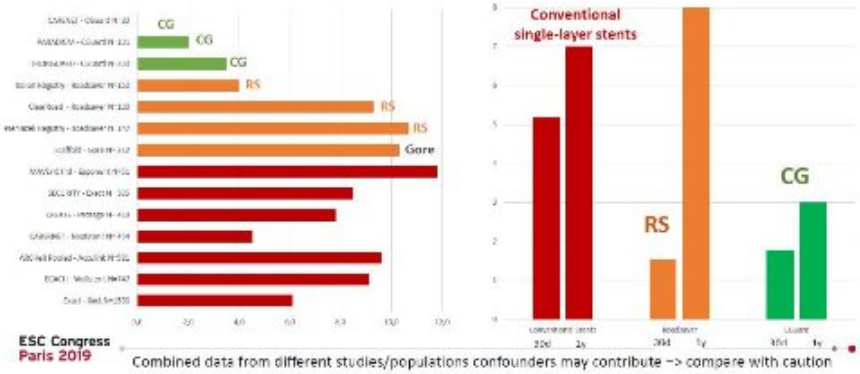
** Values extrapolated from event curves

*** Musialek, Presentation at the 2019 Joint Congress of the World Heart Federation and the European Society of Cardiology, Paris FR

Analysis of Published Carotid Stent Trial Data

Comparative analysis of the carotid stent data available in public domains
(Journal publications plus congress presentations published on-line)

Cumulative Incidence of Death/Stroke/MI @ 30 days *plus* 1-year ipsilateral stroke rate



ESC Congress
Paris 2019

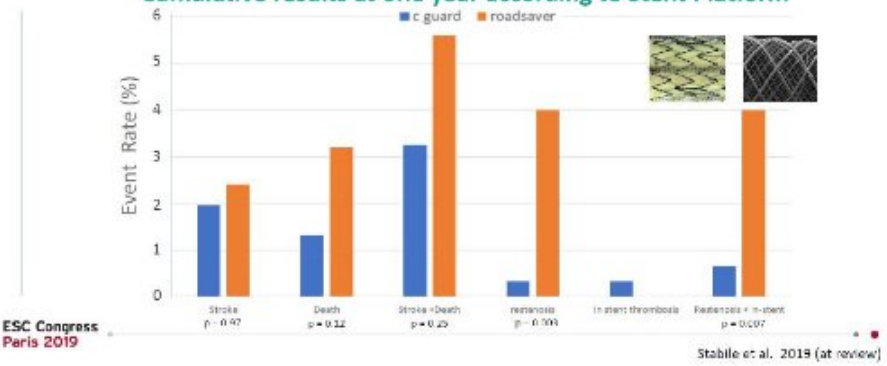
Combined data from different studies/populations confounders may contribute -> compare with caution

Analysis of Published Next Generation Carotid Device Trial Data*

Patient-level meta-analysis
556 patients / 4 trials
(both symptomatic and asymptomatic) **

Dual-layer stents
1-year data

Cumulative results at one year according to Stent Platform

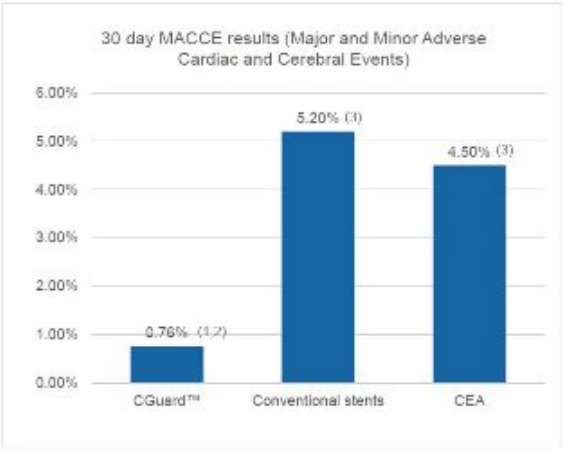


ESC Congress
Paris 2019

Stabile et al. 2019 (at review)

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



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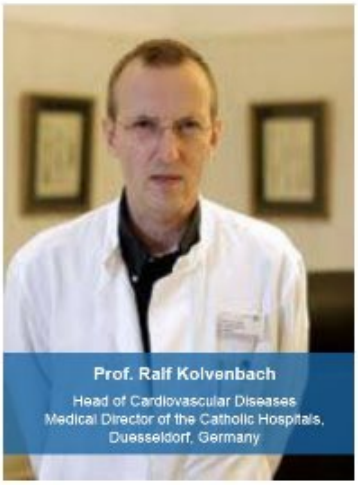
NOTE: ROW-GUARD, Wingspan and Cassiva trials are not included in the calculation of the CGuard data as these trials were not independently monitored.
1. JACC Cardiovasc Interv 2010 Aug 17; 8:1229-1234 2.EuroIntervention 2016 Aug 05; 638-70 3.N Engl J of Med 2010 July 1; 11-23

A Leading Vascular Surgeon's View



Prof. Ralf Kolvenbach

Head of Cardiovascular Diseases
Medical Director of the Catholic Hospitals,
Duesseldorf, Germany

"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"

Commercial Strategy

Transition current users of carotid stents to CGuard™ EPS

Continued communication of CGuard™ EPS clinical data

Continue to support investigator initiated clinical registries

Continue to develop network of KOLs, broaden centers of excellence to multiple clinical disciplines

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

Expand footprint in existing geographical areas

Focus limited resources on larger markets with highest opportunities – Germany, Italy, Spain, Poland

Support regional clinical and clinical specialty registries to build on the clinical database and broaden support

Evaluating further market growth via direct sales in key regional markets

Continue geographical expansion where strategically relevant

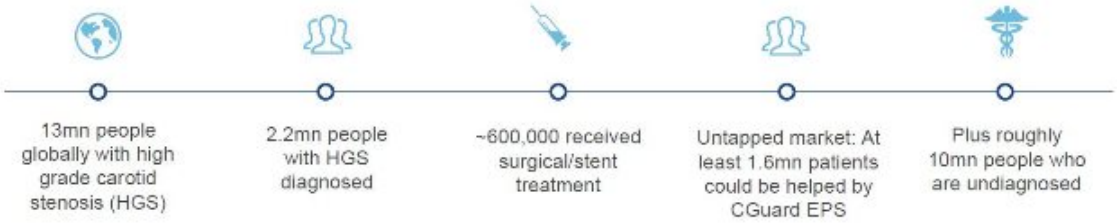
Ongoing discussions with partners to bring CGuard To Japan and China

Obtain US IDE approval

CGuard™ EPS Product Development

US FDA	• IDE FDA submission for CGuard™ EPS July 2019 • Additional request from FDA for information in support of application August 2019 • Working closely with FDA to resolve additional requests for information • Critical step in commencing human trial in the USA
Innovative Pipeline Developments	• CGuard continuous improvements (including COGS) • Peripheral vascular products • Neurovascular
Evaluating external opportunities	• Proactively evaluating synergistic opportunities to further broaden the product portfolio and take advantage of the global distribution network that has been developed • Add BD resources to effectively assess inbound queries and implement a more focused and proactive BD strategy

Addressable Stroke Prevention Device Market



2017: ~600,000 patients with high grade carotid stenosis (HGS) 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

Intellectual Property Portfolio

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	13	2	6
Rest of World	47	0	19

Proprietary platform technology supported by a robust intellectual property portfolio

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

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, Medtronic, 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

Summary Financials

NYSE AMERICAN	NSPR
Stock Price (10/31/19):	$1.13
Average last month daily trading volume:	242 K
Shares outstanding (10/31/19):	3.6 M
Shares outstanding including full conversion of preferred shares and prefunded warrants (10/31/19):	4.9 M
Market capitalization including full conversion of preferred shares and prefunded warrants (10/31/19):	$5.5 M
Cash (9/30/19):	$7.2 M

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
- Increasingly more presentations and live clinical cases with CGuard™ EPS are featured at major and regional clinical conferences
- Following the sterilizer event in Q1, company made a solid recovery and has returned to normal operations
- Increased focus, positive large clinical trials and significant investment in minimally invasive treatment of carotid artery disease is creating a tailwind for CGuard™ EPS
- Product pipeline to support continued growth in all geographies, including the United States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