INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 06/08/21 for the Period Ending 06/08/21

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): June 8, 2021

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)

(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	The Nasdaq Capital Market LLC
Series A Warrants, exercisable for one share of Common Stock	NSPRW	The Nasdaq Capital Market LLC
Series B Warrants, exercisable for one share of Common Stock	NSPRZ	The Nasdaq Capital Market LLC

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 June 8, 2021

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: June 8, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

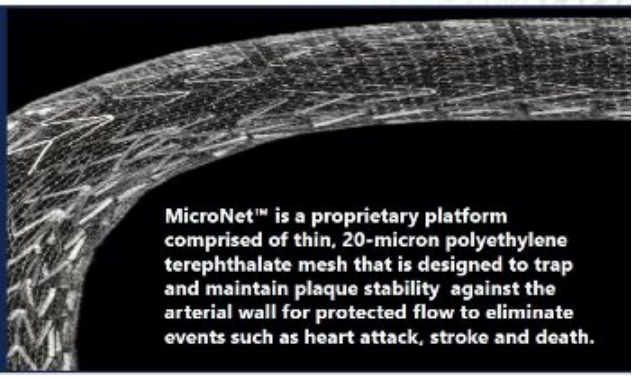
Disclaimers

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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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.

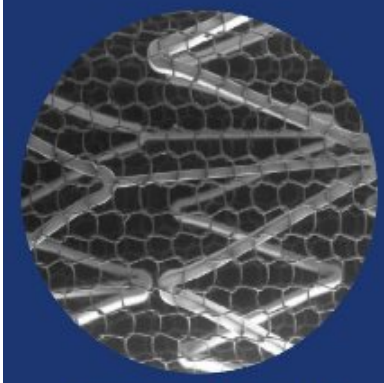
- The company develops, manufactures, and commercialized a portfolio of embolic protection devices
- MicroNet™, a key differentiator of InspireMD's commercial products, is revolutionizing the field of vascular stenting
- Today, InspireMD is a global company traded on NASDAQ under NSPR

INSPIREMD

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.
Gary Roubin, M.D., Ph.D. Director	Dr. Roubin was named to the board of Directors in October 2020. Dr. Roubin has co-authored more than 280 clinical publications and has contributed to 20 textbooks in the fields of Interventional Cardiology and Vascular Surgery. He was a key contributor in the CREST trial which has validated the use of carotid stents for the treatment of carotid artery stenosis.
Katie Arnold Director	Ms. Arnold was named to the Board of Directors in May 2021. Ms. Arnold founded and leads SPRIG Consulting, providing the entire spectrum of strategic marketing services to medical companies. Ms. Arnold is currently an adjunct professor at Northwestern University's Kellogg School of Business, where she teaches medical product commercialization and financing.

InspireMD Pipeline



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 Accessory Access / Delivery Devices

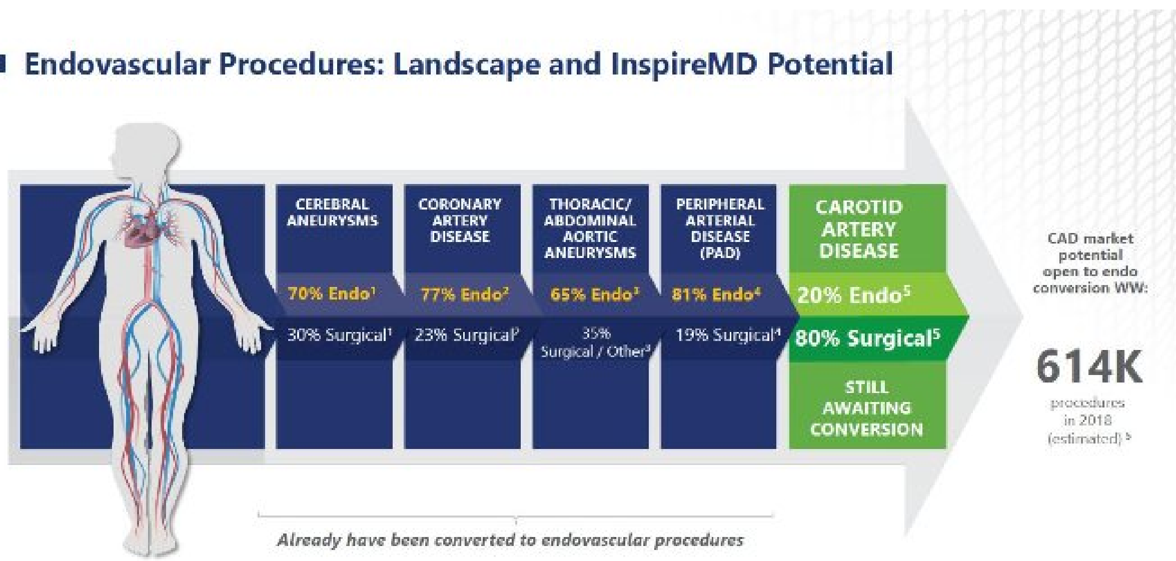
Expansion Opportunities

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. Wisquitt C et al. J Endovasc Ther 2017;24(1):130–137.

Endovascular Procedures: Landscape and InspireMD Potential



1 Bekelis K, Gottlieb DJ, Su Y, et al. Comparison of clipping and coiling in elderly patients with unruptured cerebral aneurysms. J Neurosurg. 2017;126(3):811-818
2 Culler SD, Kugelmass AD, Brown PP, et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2008 and 2012. Circulation. 2015;131(4):362-70
3 Beck AW, Sedrakyan A, Mao J, et al. Variations in Abdominal Aortic Aneurysm Care: A Report From the International Consortium of Vascular Registries. Circulation. 2016;134(24):1948-1958
4 Guez, D., Hansberry, D. R., Gonzalez, C. F., Eschelman, D. J., Parker, L., Rao, V. M., & Levin, D. C. Recent Trends in Endovascular and Surgical Treatment of Peripheral Arterial Disease in the Medicare Population. AJR Am J Roentgenol. 2020 May;214(5):962-966
5 2017 Health Research International Market Report

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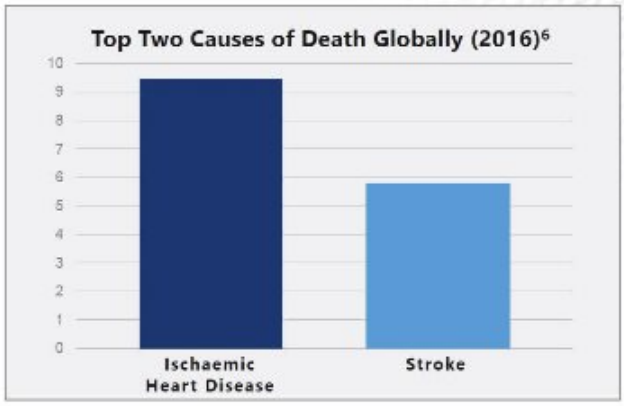
Stroke is the Second Biggest Cause of Death Globally

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

- 6.2 million deaths[2]
- 5 million people left permanently disabled[1]
- $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_505443.pdf
[3] Center for Disease Control and Prevention – Stroke Facts – 2017
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5562827/ 5
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5861911/
[6] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

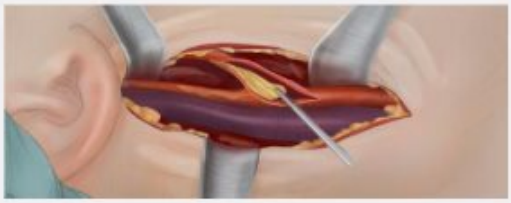
THE PROBLEM: Risks with Existing Approaches to CAD

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

Carotid Endarterectomy (CEA)
Surgical Approach

Risk of complications:

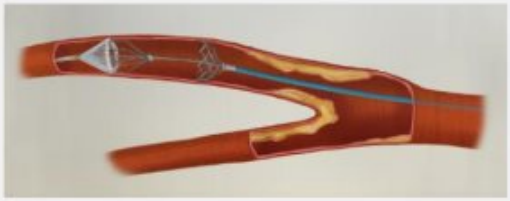
- **Myocardial infarction risk**[1] (heart attack)
- **Cranial nerve injury risk**[2] (vertigo, hearing loss, paralysis, etc)
- **Esthetic concern**



Carotid Artery Stenting (CAS)
Conventional Approach (Bare Stent)

Risk of complications:

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



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

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

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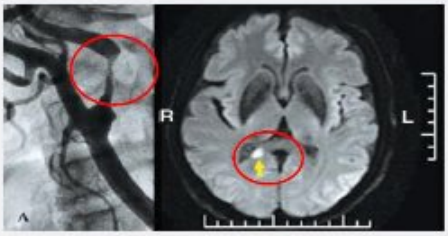
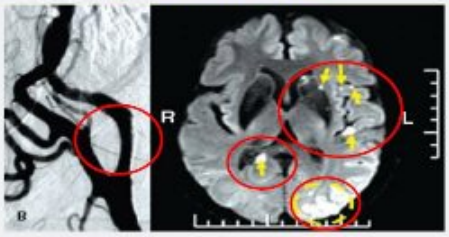
THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post procedural cerebral embolization

Pre-Procedure		Post-Procedure with Conventional Stent	
			
90% occlusion of the carotid artery	MRI of a pre existing white matter infarction (obstruction)	Successful opening of the carotid artery	MRI reveals new multiple micro infarcts (obstructions) due to liberation of embolic particles[1]

Approximately 2/3 of neurovascular events (stroke, TIA) occur after the procedure takes place.[2]

1. Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.
2. Ouriel et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

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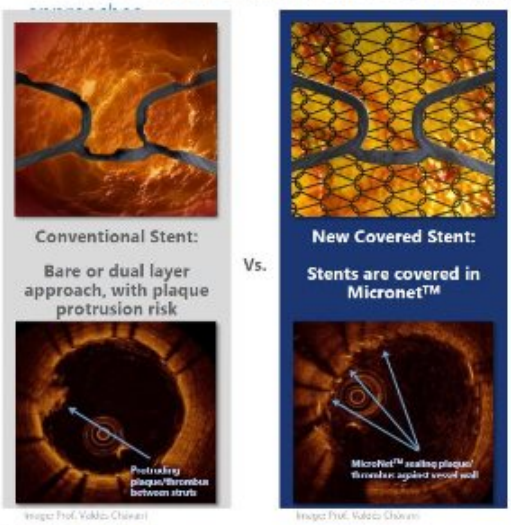
OUR SOLUTION: Proprietary MicroNet™ Technology

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



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**

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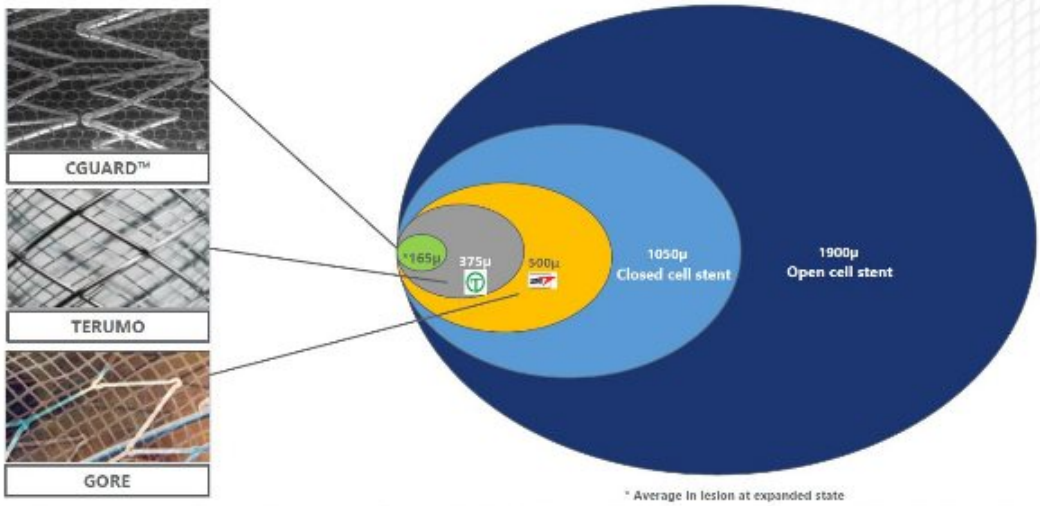
Mechanics Translate to Clinical Results



Muralek, Piotr; MD DFIBL. Mesh-Covered Stent for Carotid Intervention: Rationale, Device Design, Imaging and Data to Date . Presentation at TCT Congress 2015, San Francisco, California, 11 October 2015 to October 15 2015 .

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Carotid Solution: Our Well Studied Mesh-Covered Technology

More than 1,500 patients in Clinical Publications and Studies

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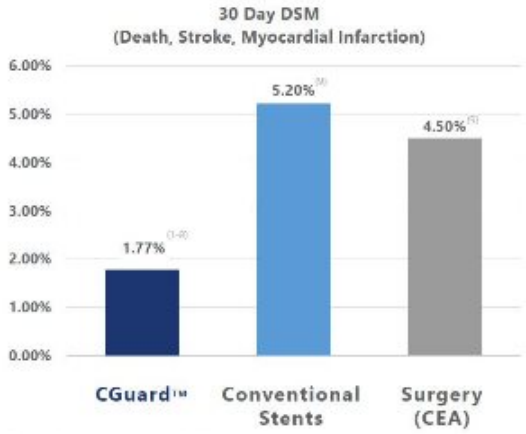
Timeline Growth: From Alternative Stent to New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (known & anticipated)
2015	CARENET	Safety, Efficacy & Neuroprotection over other stents data	✓ CGuard evaluated as new approach to CAS
2016	PARADIGM	All comers population; Excellent clinical results	
2017	CASANA	Large surgical center; Clinical results over conventional stents historical data	
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"(OSFA); 10 mm CGuard OSFA demonstrates safety and efficacy	
2019	IRON-GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric	
2020	IRON-GUARD 2	Large real world multicentric; Large Multicentric Best-In-Class clinical results	❑ CGuard demonstrates superiority to other stents
2021	CGuard-TCAS	CGuard Trans-Cervical excellent results	
2021	IRON-GUARD 2	12-month 733 pts clinical results	
2021	SIBERIA	Randomized Trial; CGuard demonstrates Neuroprotection vs Conventional stents	
2021	ONE SIZE FIT ALL	CGuard 150 pts 12m-FU	
2021-24	PARADIGM Extend	CGuard in all-comers 550 pts 30d/5y FU	
2021	Meta-Analysis	CGuard superior to Other Stents at 1y-FU	
2021	Meta-Analysis	CGuard superior to CEA at 1y-FU	❑ CGuard demonstrates superiority to surgery
2021	OCTOPVS	OCT comparison CGuard vs CEA; CGuard superior post-intervention OCT than CEA	
2022	OPTIMA	IVUS assessment after CGuard; Anticipated Plaque exclusion demonstrated	
2022	FLOW-GUARD	Use of CGuard as flow diverter in very high-risk patients beyond carotids; Potential new CGuard indications	

CGuard™ EPS Yields Superior Clinical Outcomes

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



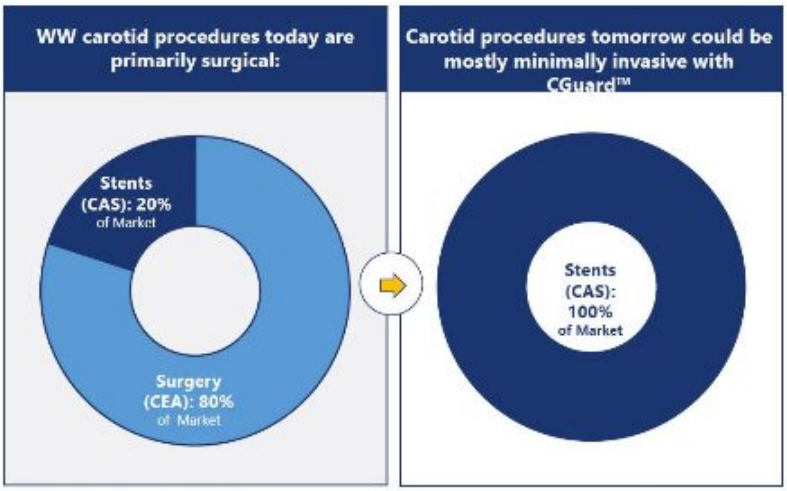
- CGuard™ has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
- 8 completed clinical trials and 3 ongoing trials
- **NO MAJOR STROKE** with CGuard™ (Minor stroke in 21/1,635 patients in 8 studies (1.28%)

1. IRONGUARD I. EuroIntervention 2018 Nov 20; 14(11):1150-1152.
2. IRONGUARD II. LINC 2020
3. CASPAR. Eur J Vasc Endovasc Surg 2017 Dec; 54(6):681-687.
4. WISSGDT I. J Endovasc Ther 2019 06; 26(3):378-382.
5. WISSGDT II. J Endovasc Ther 2017 02; 24(1):30-37.
6. PARAGRAM Extend. EuroIntervention 2016 Aug 05; 12(4):e569-75. Updated LINC 2020
7. CARENET JACC Cardiovasc Interv 2013 Aug 17; 6(12):1251-1258.
8. SIBERIA EuroPCR e-Course, June 25, 2020.
9. CREST N Engl J of Med 2010 July 1; 11-23.

INSPIRE MD

A Billion Dollar Market Opportunity

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



- 2.2M diagnosed (and potentially as many as 13 million undiagnosed) 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

Commercial Footprint

- Active selling in 33 countries
- Over 90% of sales are through channel partners/distributors with move to direct
- Signed agreement with Chinese distributor. Working toward distribution
- Exploring expansion opportunities Taiwan, Japan, and Korea
- U.S. Market IDF approval September 2020; targeting initiation of US trial Q3 2021

Growth Pathway to the U.S. Market

U.S. Market Opportunity*

- Size: 192K High Grade Carotid Artery Stenosis (HGCS) interventions in 2017
- Opportunity : At a price of $1,650 per stent, the addressable market is estimated to be approximately **$317 million**

Executing and Funded Approval of FDA PMA for U.S. Market Entry

- Estimated cost +/- $15MM
- The objective of this pivotal study is to evaluate the safety and efficacy of the CGuard™ Carotid Stent System in the treatment of carotid artery stenosis in **symptomatic and asymptomatic** patients undergoing carotid artery stenting (CAS) to a performance goal** developed from published CAS literature.
- **315 Patients** / 395 Total will Roll In
- Up to **40 Centers** (25% planned for European enrollment)
- 12–15-month enrollment, 12-month follow up
- Contracted CRO: **HCC (Health Care Consultants)** specializing in Carotid trial execution
- **Chris Metzger, M.D.** named as Primary Investigator
- Supporting advisory from **Christina Brennan, M.D.** and **Gary Roubin, M.D.** (InspireMD Director)

* 2017 Health Research International Market Report

** The primary endpoint of the study will be the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication or ipsilateral stroke from 31-360day follow up, based on Clinical Events Committee (CEC) adjudication.

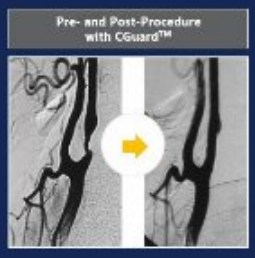
Our Lead Product, CGuard™ - Advancing Rapidly

23,000+

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 (SIBERIA)**



Our Advancement Roadmap / Milestones

Our Key Value Drivers and Strategic Pathways

INSPIREMD

Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Allowed	Pending
USA	15	1	4
Rest of World	38	1	6

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

Summary Financials – June 1st, 2021

NASDAQ Capital Markets	NSPR
Stock Price	$5.31
Average Volume	0.1M
Shares Outstanding	7.9M
Market Capitalization	$41.9M
Cash Balance – March 31st, 2021	$44.0M
Debt	$0M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NASDAQ = NSPR