

# INSPIREMD, INC.

## **FORM 8-K** (Current report filing)

Filed 01/10/22 for the Period Ending 01/10/22

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, DC 20549**

**FORM 8-K**

**CURRENT REPORT PURSUANT  
TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): **January 10, 2022**

**InspireMD, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**001-35731**

(Commission File Number)

**26-2123838**

(IRS Employer Identification No.)

**4 Menorat Hamaor St.**

**Tel Aviv, Israel**

(Address of Principal Executive Offices)

**6744832**

(Zip Code)

**(888) 776-6804**

(Registrant's Telephone Number, Including Area Code)

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	NSPR	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 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

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Slide Presentation of InspireMD, Inc. dated January 10, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**INSPIREMD, INC.**

Date: January 10, 2022

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

---



# Sustained Embolic Protection

Investor Presentation I January 2022



INSPIREMD

---

## Disclaimers

### Forward Looking Statement

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. For example, the Company is using forward-looking statements when it discusses the potential commercialization and market opportunities for its products and product candidates, its cash runway, its expected unaudited cash balance as of Dec. 31, 2021, and its anticipated future milestone Company events. 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.

The Company is providing its estimated unaudited cash balance as of December 31, 2021, in this presentation, rather than the specific amount, primarily because the financial closing process and review are not yet complete and, as a result, the Company's results upon completion of its closing process and review may vary from this preliminary estimate.

## Investment Highlights



### MicroNet™ Proprietary Platform Technology

Highly differentiated profile for treatment of carotid artery disease and stroke prevention clinicians



### Expanding Commercial Footprint

Evaluating opportunities to sell direct in 18 of 30 key markets globally



### Evidenced based / Clinically Supported

CGuard™ FPS 8 clinical trials completed with >1,600 patient procedures and 3 ongoing clinical trials



### Financial Discipline

Well capitalized, with cash runway into 2H 2023



### Experienced Management Team

Industry leaders with extensive healthcare expertise



### Deep Pipeline

Leverage MicroNet™ platform technology into other Carotid Artery Diseases treatments utilizing a multi generational development plan

## Our Leadership



**Marvin L. Slosman**  
President and CLO



**Craig Shore**  
Chief Financial Officer



**Andrea Tommasoli**  
SVP Global Sales & Marketing

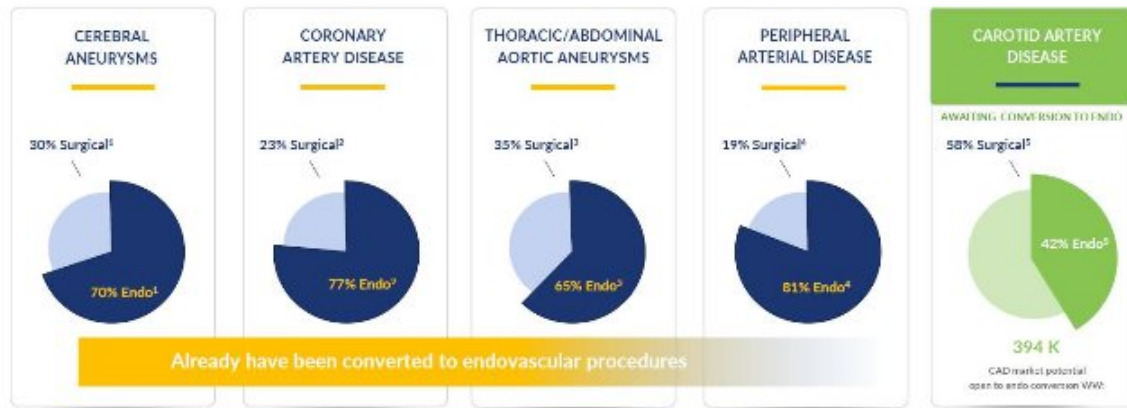


**Juan Rigla, M.D., Ph.D.**  
Medical Director





# Endovascular Procedures: Landscape and InspireMD Potential



estimated procedures in 2022<sup>2</sup>

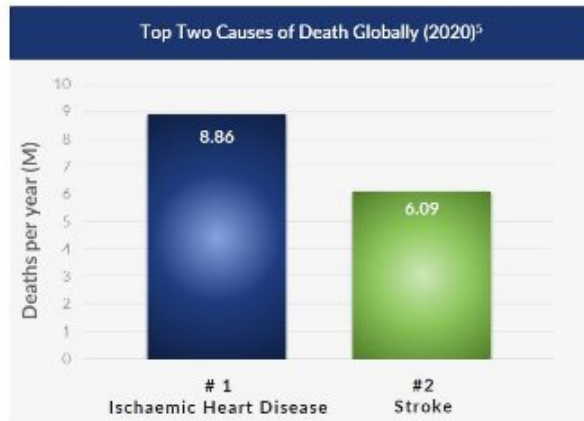
<sup>1</sup>Delgado G, Gottlieb DJ, Su Y, et al. Comparison of clipping and coiling in elderly patients with unruptured saccular aneurysms. *J Neurosurg*. 2017;126(3):633-638.  
<sup>2</sup>Chellier-D, Sughrue SD, Devan RP, et al. Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2003 and 2012. *Circulation*. 2015;132(19):362-70.  
<sup>3</sup>Deek AW, Sedrakyan A, Mo J, et al. Variations in Abdominal Aortic Aneurysm Care: A Report From the International Consortium of Vascular Surgeons. *Circulation*. 2016;134(5):1240-1250.  
<sup>4</sup>Kovic D, Haidich A, D. M, Gorenker C, P., Balkrishnan D, J, Malhotra L, Rao V, M, S Levin D, C. Round. Trends in Endovascular and Surgical Treatment of Thoracic Aortic Disease in the Medicare Population. *ART Res J* [http://www.artsjournal.com/2020/Mar/21/28/192-196].  
<sup>5</sup>Source: InspireMD Medical Analytics, 2022; provided to InspireMD, Inc. by health research international Personal Medical Systems, Inc. Sept. 13, 2022.



## Stroke is the Second Biggest Cause of Death Globally

An estimated 15 million people suffer from stroke annually<sup>1</sup>

- 5 million deaths each year<sup>2</sup>
- 5 million people left permanently disabled<sup>1</sup>
- \$46 billion associated with stroke management in the US alone<sup>3</sup>
- 87% of all strokes are ischemic strokes, which result from a lack of blood flow to the brain<sup>4</sup>
- Carotid artery disease (CAD) is a major risk factor for stroke



<sup>2</sup> <https://www.who.int/news-room/fact-sheets/detail/stroke>  
<sup>3</sup> <https://www.heart.org/en/health-topics/stroke/about-stroke>  
<sup>4</sup> <https://www.heart.org/en/health-topics/stroke/about-stroke>  
<sup>5</sup> <https://www.who.int/news-room/fact-sheets/detail/stroke> - Stroke Facts - 2018

<sup>5</sup> <https://www.who.int/news-room/fact-sheets/detail/stroke>  
<sup>6</sup> <https://www.who.int/news-room/fact-sheets/detail/stroke> (December 2018)

## THE PROBLEM: Risks with Existing Approaches to CAD

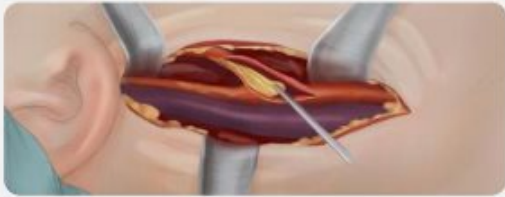
Conventional approaches come with risks

### Carotid Endarterectomy (CEA)

Surgical Approach

#### Risk of complications:

- Myocardial infarction risk<sup>1</sup> (heart attack)
- Cranial nerve injury risk<sup>2</sup> (vertigo, hearing loss, paralysis, etc)
- Esthetic concern



### Carotid Artery Stenting (CAS)

Conventional Approach (Bare Stent)

#### Risk of complications:

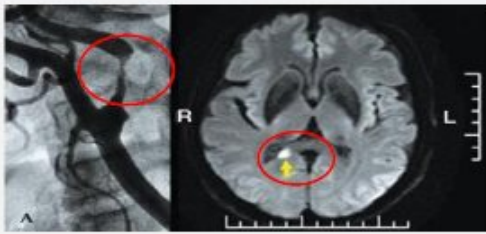
- Procedural and post-procedural increase in minor stroke risk<sup>1</sup>



## THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post-procedural cerebral embolization

### Pre-Procedure

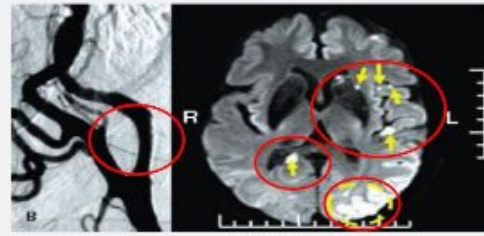


90% occlusion of the carotid artery

MRI of a pre-existing white matter infarction (obstruction)

### Post-Procedure

with Conventional Stent



Successful opening of the carotid artery

MRI reveals new multiple micro-infarcts (obstructions) due to liberation of embolic particles

Approximately 2/3 of neurovascular events (stroke, TIA) occur after the procedure takes place.<sup>2</sup>

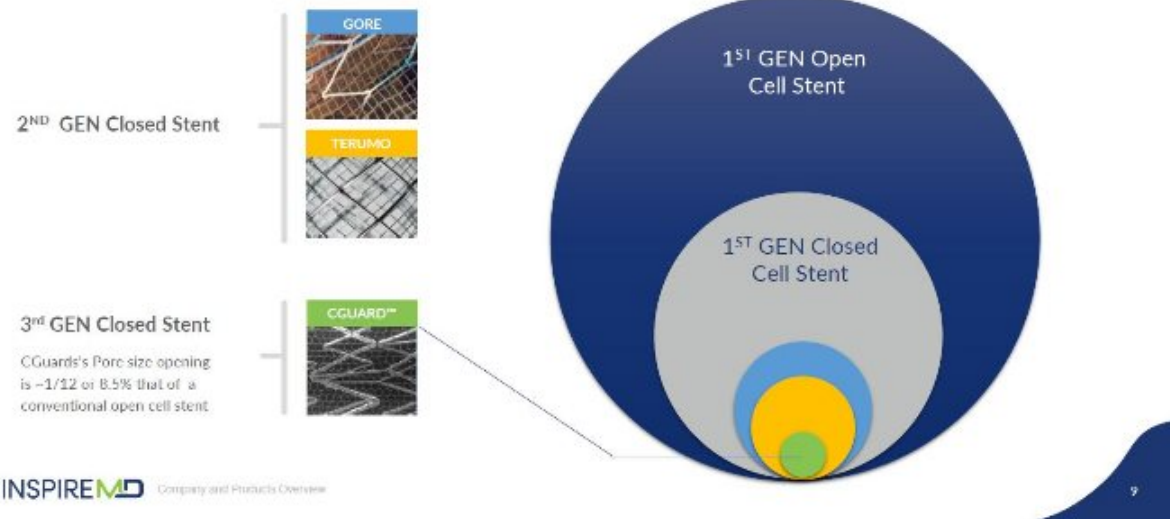
<sup>1</sup> Cere et al. *Neuro-Spine* 2013; 21(2): 155-64. <sup>2</sup> Beal et al. *Dir J Vasc Endovasc Surg* 1993; 1(8): 2367.

**INSPIREMD**

Company and Products Overview


## Mechanics Translate to Clinical Results

Pore size is an important differentiating factor in stent selection



## OUR SOLUTION: Proprietary MicroNet™ Technology<sup>1</sup>

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



**Conventional Open Cell Stent (1<sup>st</sup> GEN):**  
Bare or dual layer approach, with plaque protrusion risk

**CGuard Stent System (3<sup>rd</sup> GEN):**  
Stents are covered in MicroNet

### An Embolic Prevention System (EPS) for Ultimate Thrombus Protection

MicroNet captures and locks thrombus & plaque materials against the arterial wall, deterring debris from entering the bloodstream while also acting as a mechanical barrier to prevent plaque protrusion.

<sup>1</sup> [Coronary Intervention 2012](#), Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting, compared to conventional stents, 1348-1355 (published online before print, 2012, 01/24/12)

# Carotid Solution: Our Well Studied Mesh-Covered Technology

More than  
**1,600**  
patients in  
Clinical  
Publications &  
Studies



## Timeline Growth: From Alternative Stent to Potential New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (Known & Anticipated)
2015	CARENE I	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): 20 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 /33 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	OCTOPUS	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	



## Clinical Support Highlights / Call out

2015-2021



**CARENET Trial**  
First in Man Study-  
Demonstrated Safety,  
Efficacy, &  
Neuroprotection over  
other stents data



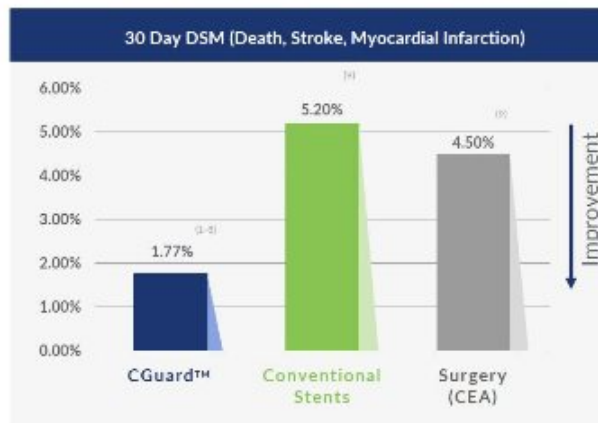
**PARADIGM**  
Opened CARENET study  
inclusion criteria and  
concluded the safety and  
clinical outcomes were  
applicable to others  
outside of high-risk



**SIBERIA**  
Randomized Trial; CGuard  
vs. Conventional Stent  
(Acculink); CGuard  
demonstrates  
Neuroprotection vs  
Conventional Stent

## CGuard™ EPS Yields Superior Clinical Outcomes

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

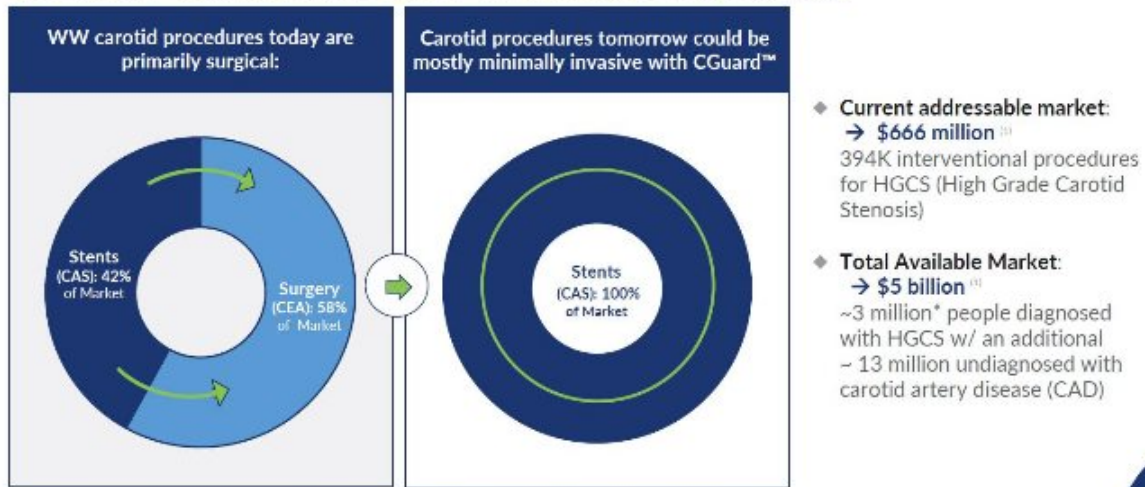


- **NO MAJOR STROKE** to date with CGuard (Minor stroke in 21/1,635 patients in 8 studies (1.28%))
- CGuard has a superior profile vs. historical data on both conventional carotid stents and surgery
- CGuard is a next-generation stent supported by a strong clinical data
- 8 completed clinical trials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

1. (COMPELLER) I EuroIntervention 2016; Nov 01. 14:1150-1152. 2. (COMPELLER) I, BMC 2020. 3. CASABA Part 1 Vasc Endovasc Surg 2017; Dec. 5:661-667. 4. WISSEDT I J Endovasc Ther 2019; 08: 76:578-582. 5. WISSEDT I J Endovasc Ther 2017; 02: 24:130-137. 6. PARADIGM External, EuroIntervention 2016; Aug 05. 12:e598-70. Updated UNC 2020. 7. CARBET JACC Cardiovasc Interv 2013; Aug 17. 8:1229-1234. 8. SIBERIA EuroPCR e Course, June 23, 2020. 9. CHEST N Engl J Med 2010; July 1. 31: 28.

## Potential Multi Billion Dollar Market Opportunity

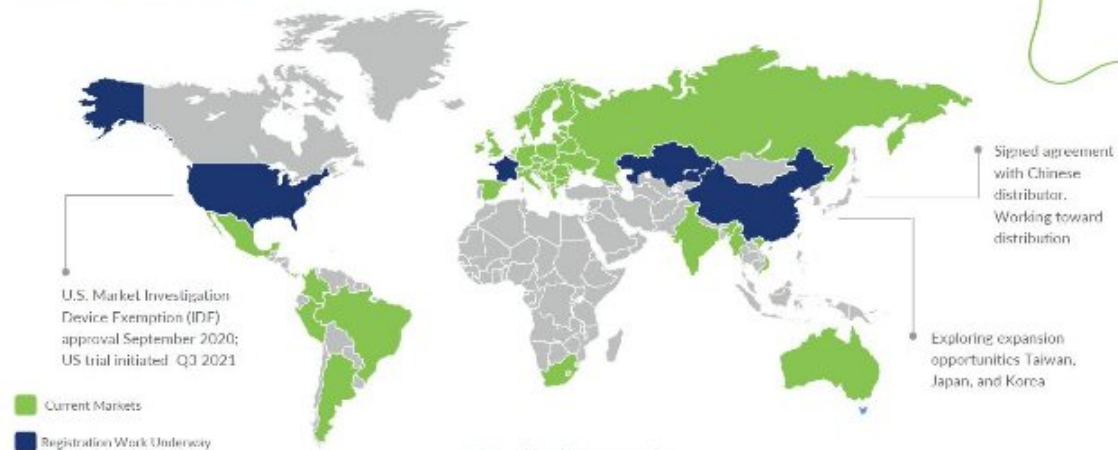
Our MicroNet™ covered stents like CGuard™ could become the new gold standard



1. Procedures for Selected Nations, 2017 - 2025 presented to InspireMD, Inc. by Health Research International Personal Medical Systems, Inc. Sept. 13, 2021

INSPIREMD Company and Products Overview

## Commercial Footprint



- Current Markets
- Registration Work Underway

- Active selling in 33 countries
- Over 90% of sales are through channel partners/distributors with move to direct

## Growth Pathway to the U.S. Market



### U.S. Market Opportunity\*

Size: 155K High Grade Carotid Artery Stenosis (HGCS) interventions estimated in 2021

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 Premarket Approval (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.
- **Chris Metzger, M.D.** (Ballard Health) named as Primary Investigator
- **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
- Supporting advisory from **Christina Brennan, M.D.** and **Gary Roubin, M.D.** (InspireMD Director)

\* 2021 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 (MI) through 30-days post-endo procedure, based on the clinical events committee (CEC) adjudication or ipsilateral stroke from 31-365day follow-up, based on Clinical Events Committee (CEC) adjudication.

## Our Lead Product, CGuard™

Advancing Rapidly

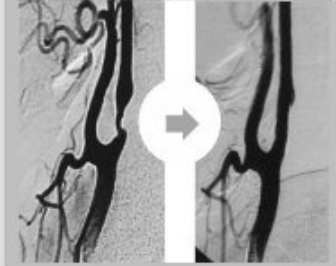
26,000+\*

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)

Pre- and Post-Procedure with CGuard



\* As of September 30, 2021

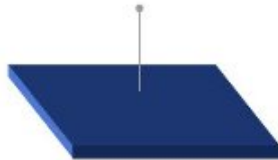
# InspireMD Pipeline



# Our Advancement Roadmap / Milestones

## Our Key Value Drivers and Strategic Pathways

- USA IDE trial approved
- Brazilian regulatory approval
- R&D projects advancing
- New leadership and directors
- Commercial Focus



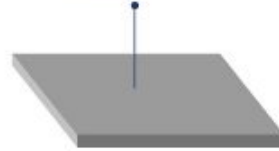
2020

- Commercial growth
- Uplisting to NASDAQ
- Significant fundraising
- USA trial enrollment
- French regulatory approval



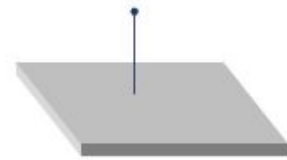
2021

- CGuard Prime Launch
- Asia Expansion
- Chinese trial enrollment
- USA reimbursement initiative
- SwitchGuard Launch



2022

- USA regulatory approval
- China regulatory advancement
- Neuro Guard launch



2023





## Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP



Patent Rights	Issued	Allowed	Pending
USA	16	1	6
Rest of World	37	1	6

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








## Summary Financials

January 7, 2022

NASDAQ Capital Markets	NSPR
Stock Price	\$2.94
Average 3 Month Volume	0.224M
Shares Outstanding	8.3M
Market Capitalization	\$24.4M
Cash Balance - December 31 <sup>st</sup> , 2021*	\$34.0M
Debt	\$0M

\* The Company is providing its estimated unaudited cash balance as of December 31, 2021, in this presentation, rather than the specific amount, primarily because the financial closing process and review are not yet complete and, as a result, the Company's results upon completion of its closing process and review may vary from this preliminary estimate.

## Our Board of Directors

<p><b>Marvin L. Slosman</b> President and CEO</p>	<p>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.</p>	
<p><b>Paul Stuka</b> Chairman</p>	<p>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 Oskis Partners and a 30-year investment industry veteran.</p>	
<p><b>Michael Berman</b> Director</p>	<p>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.</p>	
<p><b>Campbell Rogers, M.D.</b> Director</p>	<p>Dr. Rogers currently serves as the CMO of HeartFlow, Inc., a private cardiovascular diagnostics company based in California.</p>	
<p><b>Thomas Kester</b> Director</p>	<p>Mr. Kester is CEO 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.</p>	
<p><b>Gary Roubin, M.D., Ph.D.</b> Director</p>	<p>Dr. Roubin was named to the board of Directors in October 2020. Dr. Roubin has co-authored more than 200 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.</p>	
<p><b>Katie Arnold</b> Director</p>	<p>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.</p>	

INSPIRE MD



NASDAQ = NSPR