

# INSPIREMD, INC.

# **FORM FWP**

(Free Writing Prospectus - Filing under Securities Act Rules 163/433)

## Filed 01/29/21

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



Filed Pursuant to Rule 433 Issuer Free Writing Prospectus dated January 29, 2021 Relating to Prospectus filed January 29, 2021 Registration Statement No. 333- 252199

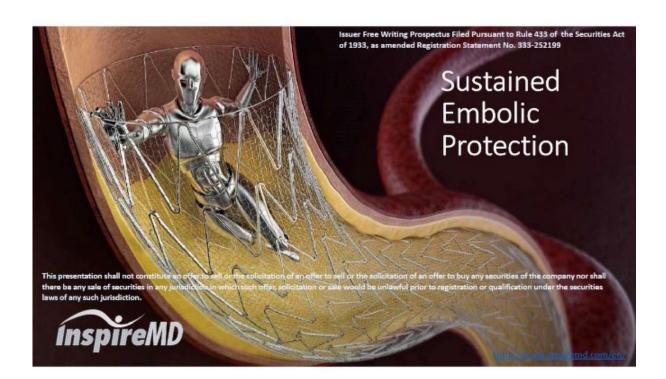


This presentation highlights basic information about InspireMD, Inc. and the offering. InspireMD, Inc. has filed a registration statement on Form S-1 (Registration No. 333-252199) (including a prospectus) with the U.S. Securities and Exchange Commission (the "SEC") for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including, among other things, risk factors described therein) and other documents the issuer has filed with the SEC for more complete information about InspireMD, Inc. and this offering. You may get these documents for free (including the preliminary prospectus dated January 29, 2021or any dealer participating in the offering will arrange to send you the prospectus if you request it by contacting A.G.P./Alliance Global Partners, 590 Madison Avenue, 28th Floor, New York, NY 10022, by calling (212) 624-2060 or emailing investmentbanking@alliance.com.

To review a filed copy of our current registration statement, click on the following link:

https://www.sec.gov/Archives/edgar/data/1433607/000149315220009800/forms-1a.htm





#### 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, (iii) 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, (viii) 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.



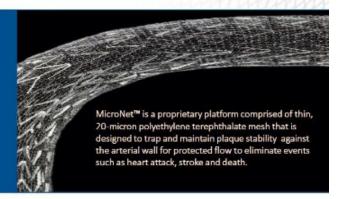
## Offering Summary

Issuer	InspireMD Inc.
Exchange: Ticker	NYSE American: NSPR
Offering Size	Up to \$15 million
Over Allotment	15%
Offering Details	Common Stock and/or Prefunded Warrants; 50% warrant coverage
Use of Proceeds	We plan to use the net proceeds of this offering to fund our anticipated CGuard $^{\text{TM}}$ FDA PMA Trial , working capital and other general corporate purposes.
Sole Book Runner	A.G.P. / Alliance Global Partners



#### 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.



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



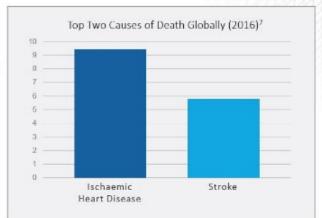
### Our Leadership

perience in financial management in the United States, Europe is senior financial and general management roles at General er Pharmaceuticals and Bristol Myers Squibb.  of Directors in August of 2011 and serves as Chairman of the Managing Member of Osiris Partners and a 30-year	Brisid Phers Squibb
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reneur within the medical device industry.  Is marketing activities until its merger with Boston Scientific as President of Boston Scientific/Scimed.	ston entific LUTONIX
CMO of HeartFlow, Inc., a company based in California.	leartFlow Cordis
n Group, Inc., a private in sales force placement for medical, dental He spent 28 years at KPMG LLP.	A Kester Search Group
d of Directors in October 2020, Dr. Roubin has co-authored	(13)
į	d of Directors in October 2020. Dr. Roubin has co-authored s and has contributed to 20 textbooks in the fields of cular Surgery. He was a key contributor in the CREST trial ortid stents for the treatment of carotid artery stenosis.

#### ■ Stroke is the Second Biggest Cause of Death Globally

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

- 6.2 million deaths<sup>2</sup>
- 5 million people left permanently disabled<sup>1</sup>
- \$34 billion associated with stroke management in the US alone<sup>3</sup>
- Requires immediate treatment: the brain deteriorates
   3.6 years for every hour untreated.<sup>4</sup>
- ~85% of all strokes are ischemic strokes, which result from a lack of blood flow to the brain<sup>3</sup>
- 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)<sup>6</sup>



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 Source II. Time is Brain -- Quantified Stress 2005-97-2.

https://www.ncti.nim.nih.gov/ncc/articles/PM/SSRIGEL//
https://www.who.ins/news-com/fact-cheess/decal/the-top-10-cause-of-death



#### ■ InspireMD Pipeline



References: 1. Mustalek 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, \$1 August 2019 to 4 September 2019. 2. Wissignit C et al. J Endowse. Ther 2017;24(3):139–197.



#### Endovascular Procedures: Landscape and InspireMD Potential



CAD market potential open to endo conversion WW:

614K

procedures in 2018 (estimated) s

Already have been converted to endovascular procedures

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### ■ 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<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 minor stroke risk<sup>1</sup>



Bare stent deployment



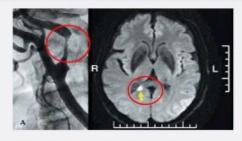
Based on the CREST clinical trial data<sup>1</sup>, in which only conventional carotid stents were used vs.surgery \*CREST Trief: N Engl J Med 2010;363:11-23 \* Circulation: 2012;126:2356-2264



#### ■ THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post-procedural cerebral embolization

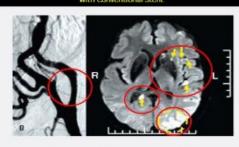




90% occlusion of the carotid artery

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

#### Post-Procedure with Conventional Stent



Successful opening of the carotid artery

MRI reveals new multiple microinfarcts (obstructions) due to liberation of embolic particles

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

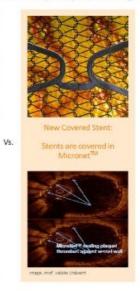
Cano et al. Rev Bras Cardol Invasiva 2013; 21(2): 159-64
 Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.,



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

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





# MicroNet<sup>™</sup>: 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



#### ■ Carotid Solution: Our Well Studied Mesh-Covered Technology

More than 1,650 patients in Clinical Publications and Studies



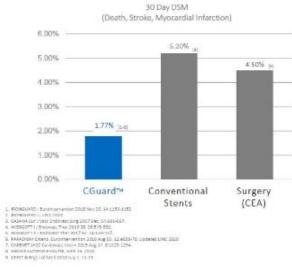
## ■ Timeline Growth: From Alternative Stent to New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD'S STANDING (known & articipated)	
2015	CARENET	Safety, Efficacy & Neuroprotection over other stents data	(Suard evaluated as new	
2016	PARADIGM	All corners population, Excellent clinical results	approach to CAS	
2017	CASANA	Large surgical center; Clinical results over conventional stents historical data	approach to CAS	
		Clinical & mechanical assessment; Mechanical advantages vs competitive stents	4	
		Real world multicentric 30d results; Excellent clinical results in multicentric	CGuard demonstrates best	
	WISSGOTT 10MM	"One-Size-Fit-All" (OSFA); 10 mm CGuard OSFA demonstrates safety and efficacy	performance in field	
	IRON-GUARD 1	Real world multicentric Sy results; Excellent long-term results in multicentric		
	IRON-GUARD 2	Large real world multicentric, Large Multicentric Best-in-Class clinical results		
		CGuard Trans Cervical excellent results		
	IRON-GUARD 2	12-month 733 pts clinical results	☐ CGuard demonstrates superiority	
	SIBERIA	Randomized Trial; CGuard demonstrates Neuroprotection vs Conventional stents		
	ONE SIZE-FIT-ALL	CGuard 150 pts 12m-FU	to other stents	
	PARADIGM Extend	CGuard in all-comers 550 pts 30d/5y FU		
	Meta-Analysis	CGuard superior to Other Stents at 1y+U		
	Meta-Analysis	CGuard superior to CEA at 1y-FU		
	OCTOPVS	OCT comparison CGuard vs CEA, CGuard superior post-intervention OCT than CEA	☐ CGuard demonstrates superiority	
	OPTIMA	IVUS assessment after CGuard; Anticipated Plaque exclusion demonstrated	to surgery	
		Use of CGuard as flow diverter in very high-risk patients beyond carotida; Potential new CGuard indications		



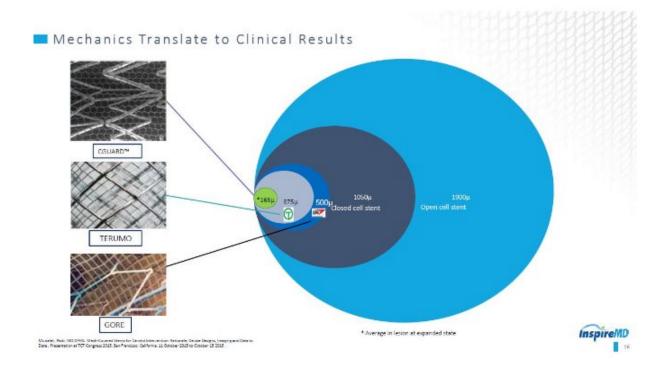
#### ■ CGuard™ EPS Yields Superior Clinical Outcomes

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

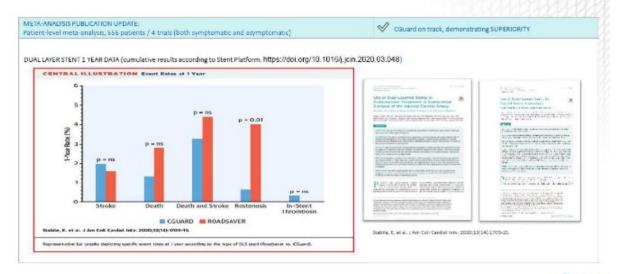


- . CGuard™ has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
- · 8 completed clinical trials and 3 ongoing trials
- . NO MAJOR STROKE with CGuard™ (Minor stroke in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





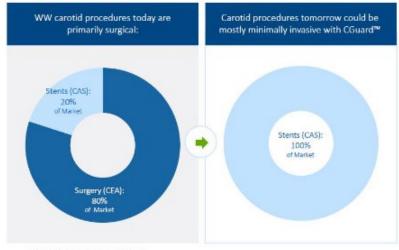
#### ■ CGuard™ Shows Superiority Over Terumo RoadSaver at 1yr





#### A Billion Dollar Market Opportunity

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



- CAS Carotid Artery Storting CEA Carotid Redarterscromy

- 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



## ■ Commercial Footprint (Dark Blue)



- Active Selling in 33 Countries
- Over 90% of sales are through channel partners / distributors
- Short Term Expansion Brazil and France
- New countries development include Japan, S Korea and China
- IDE approval in September 2020; targeting initiation of US trial in 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 on Approval of FDA PMA for U.S. Market Entry
  - Estimated cost +/- \$15MM
  - The objective of this privatal study is to evaluate the safety and efficacy of the CGuard<sup>IV</sup> 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
  - Primary Investigator Identified
  - Supporting advisory from Christina Brennan, M.D. and Gary Roubin, M.D. (InspireMD Director)

<sup>\*\*</sup> 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 Infaction (05/MI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication or ignilisteral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication.



<sup>\* 2017</sup> Health Research International Market Report

## ■ Our Lead Product, CGuard<sup>TM</sup> - Advancing Rapidly

31%

20,000+

growth of CGuard™ portfolio in Q4 2019 Total protected stents sold to date with excellent clinical results CGuard™ has potential to become the new standard-of-care for carotid indications

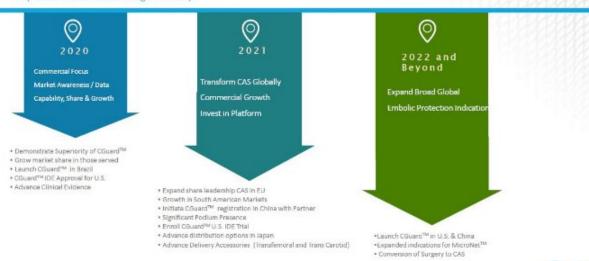
\*Achieved clinical milestones; neuroprotective vs other carotid artery stenting (SIBERIA)





## Our Advancement Roadmap / Milestones

Key Value Drivers and Strategic Pathways



InspireMD

# Our Robust Intellectual Property Portfolio Proprietary platform technology supported by IP

Patent Rights	Issued	Allowed	Pending
USA	14	1	3
Rest of World	38	0	3

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



#### Our Business and Market Development Strategic Players interested in Carotid advancement Synergy Johnson-Johnson Medtronic Scientific TERUMO stryker COOK Edwards CardinalHealth BIOSENSORS NIETHOUSE MERITA DIGAL BARD Teleflex **BIOTRONIK** ■ MicroPort SILKROAD> O<sub>INARI</sub> Penumbra 😱 LeMaitre **€**balt 60RE VENUSMEDTECH"

Concept Medical



**OSMT** 

## ■ The carotid space is seeing investment





## Capitalization Table

Capitalization Table (January 25, 2021)	# of shares	Face Value \$	Exercise Value \$	% of fully diluted
Common shares outstanding	71,455,570			75.7%
Series B Preferred	3,112,923	\$570,999		3.3%
Series C Preferred	46,714	\$14,995		0.0%
Warrants (\$0.495)	13,335,252		\$6,600,950	14.1%
Warrants (\$1.8)	2,972,221		\$5,349,998	3.1%
Warrants (\$15 and above)	770,352		N/A	0.8%
RSU's	1,357,668			1.4%
Options (\$1.10 and below)	1,396,148		\$584,028	1.5%
Options (Above \$1.10)	129		N/A	0.0%
Fully diluted shares outstanding	94,446,977		0.000	100%



