

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 05/26/20 for the Period Ending 05/26/20

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): May 26, 2020

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-21238	838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Empl Identificatio	2
4 Menorat Hamaor St. Tel Aviv, Israel		6744832	
(Address of principal executive offices)		(Zip Code)	
(Registr	(888) 776-6804 rant's telephone number, including area c	ode)	
(Former Na	N/A me or former address, if changed since las	st report)	
Check the appropriate box below if the Form 8-K filing is in provisions:	ntended to simultaneously satisfy the fili	ing obligation of the registrant unde	er any of the following
[] (Written communications pursuant to Rule 425 under the	Securities Act (17 CFR 230.425		
[] (Soliciting material pursuant to Rule 14a-12 under the Exc	change Act (17 CFR 240.14a-12		
[] ((Pre-commencement communications pursuant to Rule 14	4d-2(b) under the Exchange Act (17 CFR	240.14d-2(b	
[] ((Pre-commencement communications pursuant to Rule 1.	3e-4(c) under the Exchange Act (17 CFR	240.13e-4(c	
Securities	s registered pursuant to Section 12(b) of the	ne Act:	
Title of each class	(Trading		exchange on which registered
Common Stock, par value \$0.0001 per share	NS		SE American
Warrants, exercisable for one share of Common Stock Series B Warrants, exercisable for one share of Common Stock	NSPF K NSPR		SE American SE American
Indicate by check mark whether the registrant is an chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 Emerging growth company []	emerging growth company as defined in (§240.12b-2 of this chapter).	n Rule 405 of the Securities Act of	1933 (§230.405 of this
If an emerging growth company, indicate by check mark if t revised financial accounting standards provided pursuant to Se	=	extended transition period for comp	lying with any new or

Item 7.01 Regulation FD Disclosure

Beginning on May 26, 2020, InspireMD, Inc. (the "Company") will make presentations to potential institutional and other investors as part of a "road show," during which the Company will provide an overview of its business. A copy of the presentation materials to be shown to potential institutional and other investors is furnished herewith as Exhibit 99.1.

The presentation materials contain certain projections of the Company's anticipated results of operations, or assumptions or estimates as to future events or outcomes. It is intended to speak only as of the date of this Report and should not be construed as representing projections of the Company's anticipated results of operations, or assumptions or estimates as to future events or outcomes, as of any subsequent date. By furnishing the projections and other information in the presentation materials, the Company is not undertaking, and the Company expressly disclaims, any obligation to furnish updated or revised projections of the Company's projected results of operations, or assumptions or estimates as to future events or outcomes, to reflect any events or circumstances occurring or existing at any time after the date hereof (irrespective in any such case of whether the projections, assumptions or estimates set forth in the presentation materials, in light of events or circumstances occurring or existing at any time after the date hereof, shall have ceased to have a reasonable basis). Consequently, the projections of the Company's anticipated results of operations, assumptions and estimates set forth in the presentation materials furnished hereby should not be regarded as a representation by the Company that the projected results of operations can or will be achieved, only that the Company has concluded in good faith that they may be achieved based on many assumptions. The Company's regular annual and quarterly financial statements, and the accompanying discussions and analyses of its financial condition and results of operations, contained in the Company's Annual Reports on Form 10-K and its Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission after the date of this Report will contain disclosure regarding the Company's actual results of operations for fiscal periods covered by the projections in the presentation materials. The Company's actual results could, and likely will, vary

Please refer to page 2 of Exhibit 99.1 for a cautionary note regarding certain forward-looking statements included therein and the risks and uncertainties related thereto.

This information is being furnished pursuant to Item 7.01 of this Report and the exhibit being furnished as Exhibit 99.1 hereto shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference and regardless of any general incorporation language in such filing. This inclusion of such information in this Report will not be deemed an admission as to the materiality of any information in this Report that is being disclosed pursuant to Regulation FD.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit	
Number	Description
99.1	Presentation of InspireMD, Inc., as furnished on May 26, 2020
	-2-

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: May 26, 2020

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer

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Filed Pursuant to Rule 433 Issuer Free Writing Prospectus dated May 26, 2020 Relating to Prospectus filed May, 26, 2020 Registration Statement No. 333- 238247

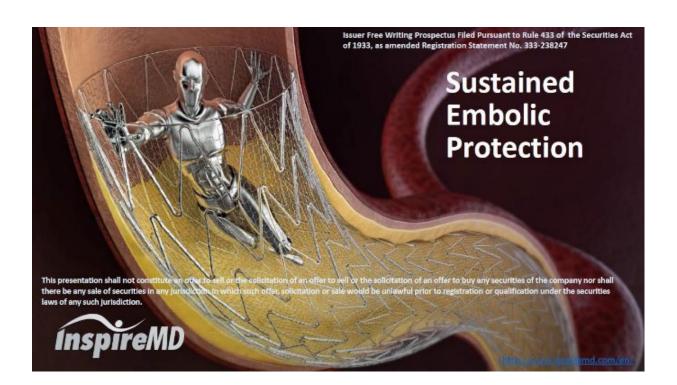


This presentation highlights basic information about InspireMD, Inc. and the offering. InspireMD, Inc. has filed a registration statement on Form S 1 (Registration No. 333-238247) (including a prospectus) with the U.S. Securities and Exchange Commission (the "SEC") for the offering to which this presentation 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 May 26, 2020, and subsequent amendments) by visiting EDGAR on the SEC website at www.sec.gov Alternatively, InspireMD, Inc. or any underwriter or 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, (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 forwardlooking 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.



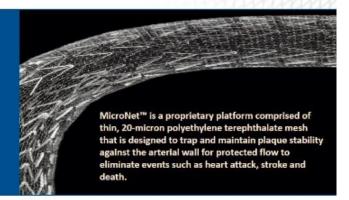
Offering Summary

Issuer	InspireMD Inc.
Exchange: Ticker	NYSE American: NSPR
Offering Size	Up to \$10 million
Over Allotment	15%
Offering Details	Common Stock and/or Prefunded Warrants
Use of Proceeds	We plan to use the net proceeds of this offering for research and development, sales and marketing, and 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
- MicroNetTM, 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

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.	Cordis, INTEGRA
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.	Briss-Novo Squide
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.	OSIRIS OSIRIS
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.	Separatific Scientific LUTONIX
Campbell Rogers, M.D. Director	Dr. Rogers currently serves as the CMO of HeartFlow, Inc., a private cardiovascular diagnostics company based in California.	HeartFlow Cordis,
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.	KPMG Kester Search Group*

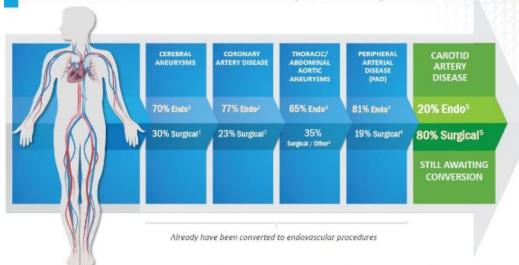
InspireMD Pipeline



References: 1. Mustalek Plet al. PARADIGNEs tend Prospective Academic Trial: Accumulating long-term evidence for MicroNet-covered stent safety and stroke prevention efficacy. Presentation at ESC Congress 2019, Paris, Prance, 31 August 2019 to 4 September 2019. 2. Wissgott Clet al. J Endovasc Ther 2017;24(1):130-137.



Endovascular Procedures: Landscape and InspireMD Potential



CAD market potential open to endo conversion ww:

614K

procedures in 2018

Debails K, Garrish DJ, Sv Y, et al. Comparison of display and miling in elsely potients with unsuprand coverage consequence. I Neurocourp. 2017;12(2):0011-310.

Ladie 13, Negatives AD, Rosen PF, et al. Transa in Coronery Researchitation Procedures Among Meditures Societies and Selection 2008 and 1012 Consolvins. 2017;25(1):036-70.

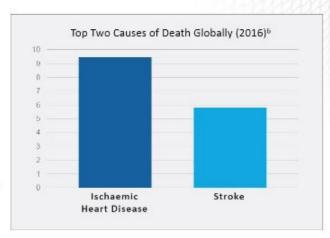
Linch AM, Secretages A, Miles I, et al. Variations in Attachmical Acritic Research Select A Report Price the Terrenotional Consortium of Value for Registrate. Circulation. 2018;134(4):1349-1353



Stroke is the Second Biggest Cause of Death Globally

An estimated 15 million people suffer from stroke annually¹

- 6.2 million deaths²
- 5 million people left permanently disabled1
- \$34 billion associated with stroke management in the US alone³
- ~85% of all strokes are ischemic strokes, which result from a lack of blood flow to the brain⁴
- 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



Imms // www.erms.who.ins/health-explor/moke-cereamwarulan-accident/holes hami.
Imms // fundossense.neur-nogfisig von spidsmanta nakis // flavor/flavor-flavo

*https://www.nchi.nlm.nlh.gov/pmc/articles/PMC4562827/5 https://www.nchi.nlm.nlh.gov/pmc/articles/PMC5861011/ *https://www.who.int/news-toom/fact-sheets/detal/the-tog-10-causes-of-seath



■ 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 risk1 (heart attack)
- Cranial nerve injury risk² (vertigo, hearing loss, paralysis, etc)
- · Esthetic concern





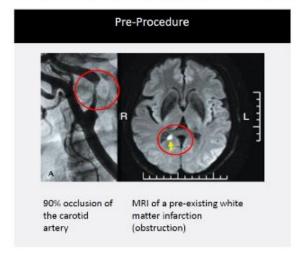
Based on the CREST clinical trial data¹, in which only conventional carotid stents were used vs.surgery

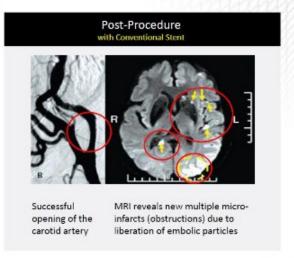
*CREST Trial: N Engl J Med 2010;963:11:23 * Circulation: 2012;125:2256-2264



■ THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post-procedural cerebral embolization





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



■ OUR SOLUTION: Proprietary MicroNetTM 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



Carotid Solution: Our Well Studied Mesh-Covered Technology

More than 1,500 patients in Clinical Publications and Studies

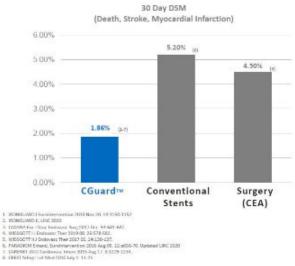


■ Timeline Growth: From Alternative Stent to New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD™'S STANDING (known & anticipated)
2015	CARENET 300	Safety, feasibility & neuroprotection; Neuroprotection over other stents data	☑ CGuard™ evaluated as new
2016	PARDIGM 101 30D	All commers population; Excellent clinical results	✓ CGuard™ evaluated as new approach to CAS
2017	CASANA	Large surgical center; Excellent clinical results	approach to cas
2017	WISSCOTT	Clinical & mechanical assessment; Mechanical advantages vs competitive stents	
2017	IRON GUARD 1	Real world multicentric 30d results; Excellent clinical results in multicentric	☑ CGuard™ demonstrates best
2018	WISGOTT 10MM	"One xize fit all"; Safety & feasibility of a size fit all approach	performance in field
2019	IRON-GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric	
2020	IRON-GUARD 2 *	Large real world multicentric	
2020	SIBERIA *	Randomized Trial; CGuard neuroprotection vs conventional stents	☐ CGuard™ demonstrates
2021	POLISH VASCULAR REGISTRY *	Large real world multicentric	superiority to other stents
2022	OCTOPVS *	OCT comparison CGuard** vs CEA; to demonstrate CGuard** superior procedural results than CEA	
1022	PARADIGM EXTEND *	Large long-term study for all commers; CGuard™ study of long-term results	
2022	OPTIMA *	IVUS assessment after CGuard ^{ru} ; intended to demonstrate plaque exclusion	☐ CGuard™ demonstrates superiority to surgery
0023	FLOW-GUARD *	Use of CGuard™ as flow diverter in very high-risk patients beyond carotids; Potential new CGuard™ Indications	superiority to surgery
	* Expected		Inspir

■ CGuard™ EPS Yields Superior Clinical Outcomes

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



- CGuard™ has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
- · 7 completed clinical trials and 4 ongoing
- . NO MAJOR STROKE with CGuard™ (Minor stroke in 17/1,507 pts in 7 studies (1.13%)



A Billion Dollar Market Opportunity

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



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



201,7 Health Research International Market Report

CAS - Caroni Arten sterling

Commercial Footprint (Dark Blue)



- Active Selling in 39 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 progressing with FDA; targeting initiation of US trial in 2021 | Market Internal approval



■ Our Lead Product, CGuardTM - Advancing Rapidly

growth of CGuard™

portfolio in Q4 2019

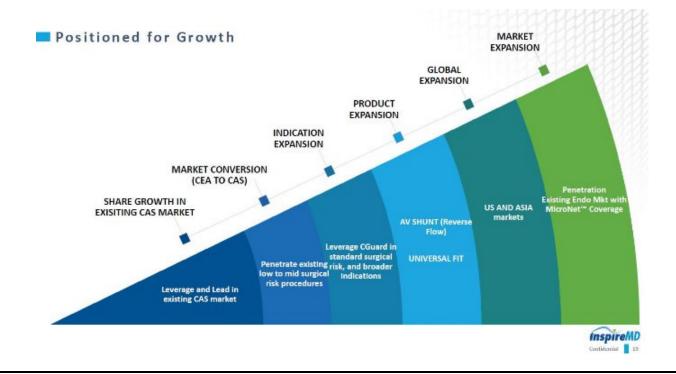
31% 18,000

Total protected stents sold to date with excellent clinical results CGuard[™] has potential to become the new standard-ofcare for carotid indications

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







Key Value Drivers and Strategic Pathways 0 0 0 0 2022 and Beyond 2019 2020 2021 Expand Broad Global **Driving Commercial Focus** *Launch CGuardTM in U.S. & China *Advance AV Shunt (Reverse Flow) *Expanded indications for MicroNetTM **Embolic Protection Indications** Advancing Clinical Data | Output *Demonstrate Superiority of CGuardTM in CAS *Grow above market in those served *Launch CGuard^{IM} In Brazil *Complete CGuard^{IM} EDE Approval for U.S. *Initiate CGuard^{IM} registration in China with Partner *Advance distribution options in Japan **Demonstrate Commercially** Driven Market Awareness, Capability, Results & Growth Prive share leadership for Protected CAS in EU Growth in South American Markets Significant Podium Presence Plan to Enroll CGuardTM U.S. IDE Plan to Enroll CGuardTM China Clinical Trial **Transform Carotid Artery Disease Care Globally** InspireMD Confidential 20

Our Advancement Roadmap / Milestones

Our Robust Intellectual Property Portfolio

Proprietary platform technology supported by IP

Patent Rights	Issued	Allowed	Pending
USA	14	0	3
Rest of World	33	4	14

 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 Synergy Medtronic Scientific CardinalHealth Edwards BIOSENSORS TERUMO Abbott COOK Teleflex BANRID M MERITARDICAL Meiil SILKROAD> OINARI GORE / **C**balt VENUSMEDTECH* **BIOTRONIK** Concept Medical @SMT

InspireMD

Silk Road- Comparison

- Ticker SILK
- \$120 Million IPO (\$20 per share) April 2019
- Valuation at time of IPO \$600 Million
- Current Stock Price \$37. 46
- Market Value today \$1.3 Billion
- Revenue in 2019 \$63.4 Million (United States Only)
 Silk Road Stock Performance since IPO





Capitalization Table

Capitalization Table (May 13, 2020)	# of Shares	WAEP-\$	Face Value \$	Exercise Value \$	% of Fully Diluted
Common Shares Outstanding	4,338,910				46,60%
Series B Preferred	555,138		\$570,999		5.96%
Series C Preferred	94,428		\$167,971		1.01%
Warrants (\$1.80-\$2.25)	3,166,665	\$1.83		\$5,787,497	34.01%
Warrants (\$6.25-\$188)	846,283	\$15.44		N/A	9.09%
Warrants (\$200 and above)	3,649	\$5,587.23		N/A	0.04%
RSU's	182,381				1.96%
Options	60,929	\$1.10		\$67,022	0.65%
Unit Purchase Option	63,402	\$1.29		\$81,510	0.68%
Fully Diltued Shares Outstanding	9,311,785				100%



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 TM technology that is elegantly simple, propriety and easily leveraged to other medical devices	
Benefits Demonstrated in Multiple Trials	Clinical evidence / data driven: 7 clinical trials completed with >1,500 patient procedures and 4 ongoing clinical trials Differentiation versus conventional carotid stents and surgery with both short- and long-term results Outcomes based: No device related major adverse events. No major strokes or deaths related to device. Sustainable results: Long term benefit reported in all-comer population	
Commercial Growth	Expanding existing footprint: Deeper penetration within key markets (18,000 devices sold to date.) Results: 2019 CGuard TM EPS sales increased 31% Q4/Q4 Commercial model development: Evaluating opportunities to go direct in key markets	
\$18 Global Market Opportunity	Expansion into OUS markets: Near term: Brazil; strategic partners discussions in Japan and China United States: • IDE FDA submission for CGuard [®] EPS July 2019 • Critical step in commencing human trial in the USA	
Capital Structure	Recapitalized the company to clean up the capital structure and prepare for growth Capital use focused on commercial execution and pipeline	
Pipeline and Strategic Opportunities	Leverage MicroNet TM into other pipeline opportunities in other neurovascular and peripheral techniques and treatments Proactively seek synergistic product opportunities Add BD resources to effectively assess inbound queries and implement a more focused and proactive BD strategy.	InspireML Confidential 25

