INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 07/08/20 for the Period Ending 07/08/20

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): July 8, 2020

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	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 7.01 Regulation FD Disclosure

Non-Deal Roadshow Presentation

Beginning on or about July 8, 2020, InspireMD, Inc. (the "**Company**") will make presentations to potential institutional and other investors as part of an ordinary course, non-deal "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 current investor presentation materials reflect certain updates relative to the last such presentation materials that had been furnished by the Company to the Securities and Exchange Commission (the "**SEC**"), as Exhibit 99.1 to the Company's Current Report on Form 8-K (a "**Form 8-K**") furnished on May 26, 2020. In particular, the current presentation updates the following:

- *Trial Results*: The current presentation reflects, in slide 13, a reduced 30-day rate of Death Stroke and Myocardial Infarction ("**DSM**") of 1.80% in the ongoing clinical trials for the Company's CGuard™ Embolic Prevention System (EPS) for the prevention of stroke caused by carotid artery disease treatment. The 30-day DSM had been 1.86% in the previous investor presentation materials. The reduction reflects the inclusion of the results of the SIBERIA randomized clinical trial of CGuard™ EPS, which were released on June 25, 2020 (as reported in the Form 8-K filed by the Company on that day). In that trial, none of the 50 patients treated with the CGuard™ EPS displayed any post-procedural evidence of DSM 30 days following the procedure, thereby reducing the overall 30-day DSM rate for the CGuard™ EPS.

- *Increased Cash Balances as of end of Q2 2020:* As a result of the public offering that the Company consummated on June 5, 2020, and the subsequent exercise of pre-funded warrants and a portion of ordinary warrants sold in that offering, the Company's cash balances stood at $13.9 million as of June 30, 2020, as reflected in slide 21 of the current investor presentation.

- *Increased Outstanding Share Capital as of end of Q2 2020*: The current presentation updates, in slide 21, the number of outstanding shares of the Company's common stock to 33,358,994 as of June 30, 2020. That reflects an increase relative to the previous investor presentation, resulting from the Company's issuance of additional shares of common stock (i) in the June 2020 public offering, as well as (ii) subsequently, upon the exercise of pre-funded warrants and a portion of ordinary warrants also sold in that public offering.

In addition to the foregoing updates, the current presentation materials contain certain projections of the Company's anticipated results of operations, or assumptions or estimates as to future events or outcomes. Those materials are 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 SEC 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 significantly from the potential results projected in the presentation materials, as a result of, among other things, changes in operations, factors affecting the Company's business and industry, and the degree and timing to which management is able to execute its currently proposed business plan.

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. The inclusion of that 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 July 8, 2020

SIGNATURES

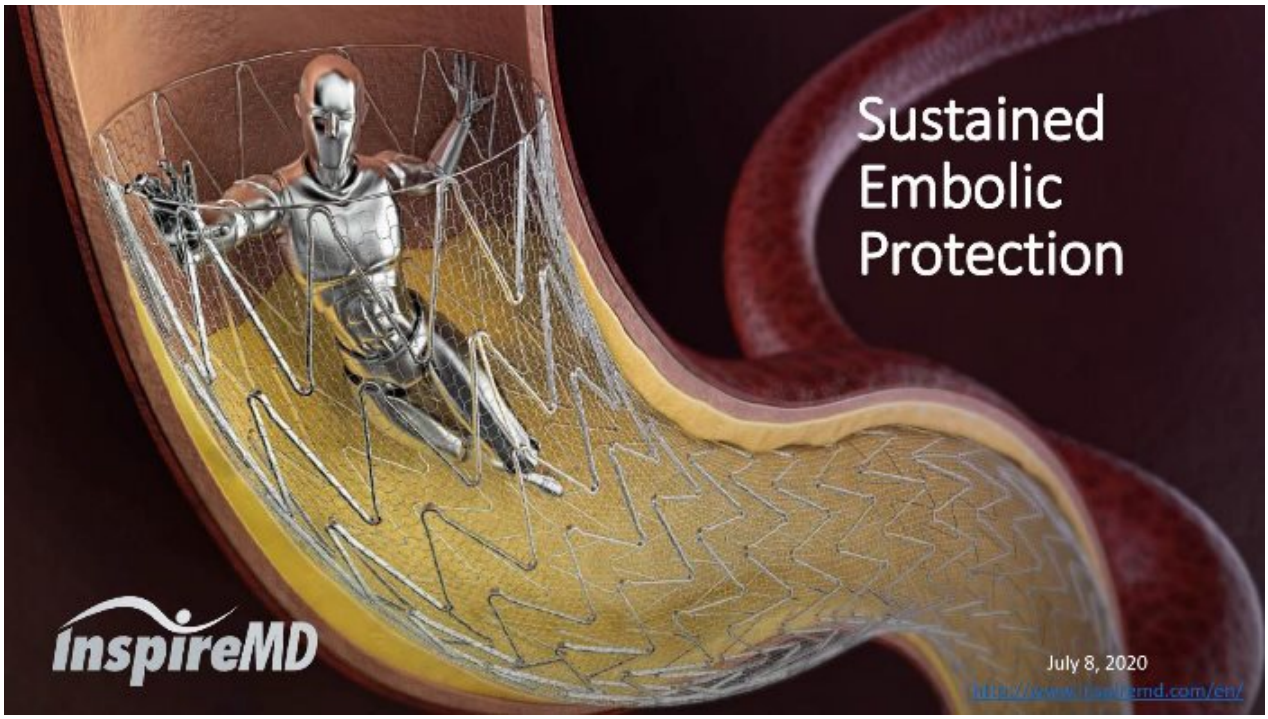
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

InspireMD, Inc.

Date: July 8, 2020

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

Exhibit 99.1



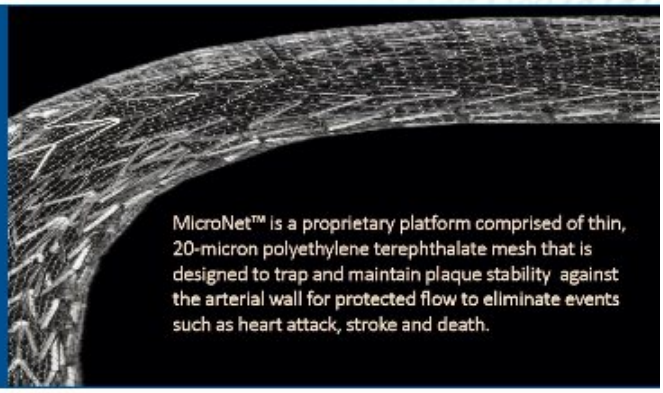
Disclaimers

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.



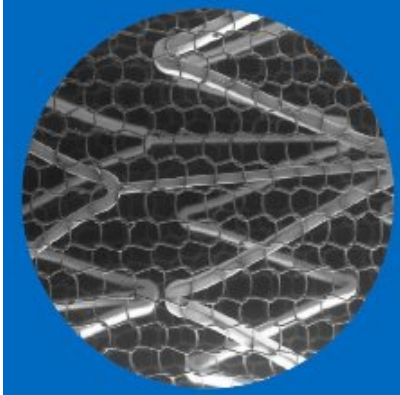
MicroNet™ is a proprietary platform comprised of thin, 20-micron polyethylene terephthalate mesh that is designed to trap and maintain plaque stability against the arterial wall for protected flow to eliminate events such as heart attack, stroke and death.

- The company develops, manufacturers and commercializes a portfolio of embolic protection systems
- MicroNet™, 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.
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 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.

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

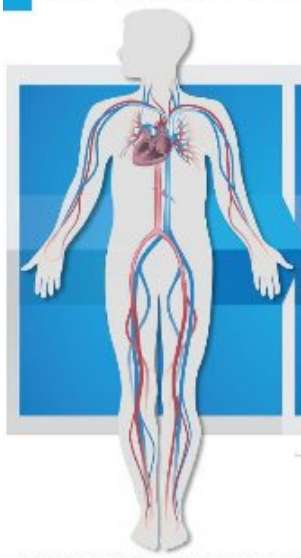
Carotid Treatment: CGuard™ EPS US; CGuard™ AV Shunt / Trans Cervical CAS

Peripheral Treatment: PGuard™ EPS US

Neuro Treatment: NGuard™

References: 1. Mustapha P et al. PARADIGM Extend Prospective Academic Trial: Accumulating long term evidence for MicroNet covered stent safety and stroke prevention efficacy. Presentation at LSC Congress 2019, Paris, France, 31 August 2019 to 4 September 2019. 2. Wissgott C et al. J Endovasc Ther 2017;24(1):130–137.

Endovascular Procedures: Landscape and InspireMD Potential



CEREBRAL ANEURYSMS	CORONARY ARTERY DISEASE	THORACIC/ ABDOMINAL AORTIC ANEURYSMS	PERIPHERAL ARTERIAL DISEASE (PAD)	CAROTID ARTERY DISEASE
70% Endo[1]	77% Endo[2]	65% Endo[3]	81% Endo[4]	20% Endo[5]
30% Surgical[1]	23% Surgical[2]	35% Surgical / Other[3]	19% Surgical[4]	80% Surgical[5]
				STILL AWAITING CONVERSION

Already have been converted to endovascular procedures

CAD market potential open to endo conversion WW:

614K

procedures in 2018 (estimated) [6]

1 Jacobs K, Gottlieb O, Su Y, et al. *Comparison of stapling and tubing incision patients with unruptured cerebral aneurysms.* J Neurosurg. 2017;126(3):811–818

2 Colantonio LD, Huguelet AD, Brown PR, , et al. *Trends in Coronary Revascularization Procedures Among Medicare Beneficiaries Between 2000 and 2012.* Circulation. 2015;132(4):362–70

3 Desai NM, 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

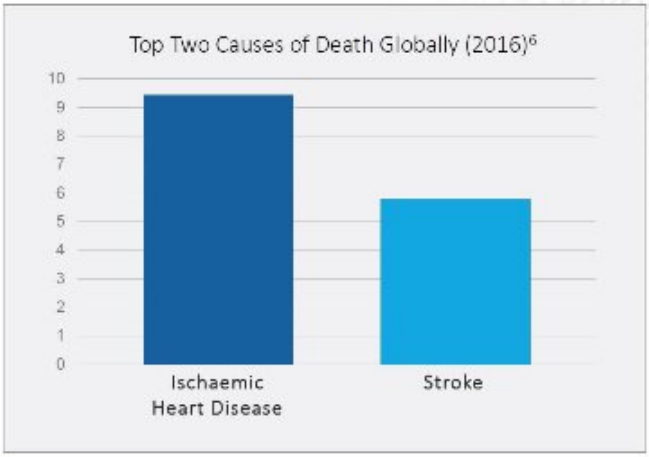
4 Guez, O., Himsberry, D. R., Gonsalves, C. F., Eschelman, D. J., Parker, L., Rao, V. M., & Lewis, D. C. *Recent Trends in Endovascular and Surgical Treatment of Peripheral Arterial Disease in the Medicare Population.* AJR Am J Roentgenol. 2020 May;214(5):1067–1076.

5 2017 Health Research International Market Report

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[2]
- $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/-/media/phd-files-public/@away/@ovs/@gmd/documents/downloadable/ucm_505431.pdf
[3] Center for Disease Control and Prevention – Stroke Facts – 2017
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4102827/?
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5861211/
[6] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

THE PROBLEM: Risks with Existing Approaches to CAD

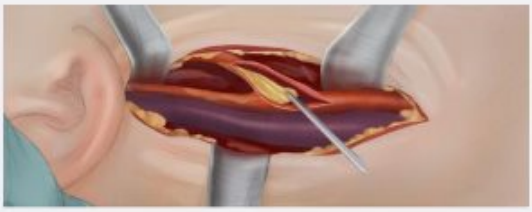
Surgery (CEA) and conventional Carotid Artery Stenting (CAS) both come with risks

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



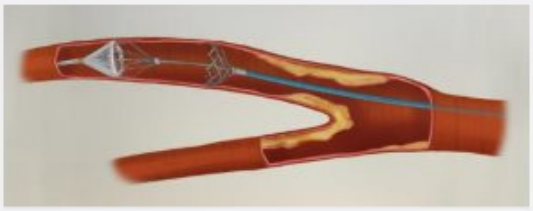
Carotid Artery Stenting (CAS)

Conventional Approach (Bare Stent)

Risk of complications:

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

Bare stent deployment

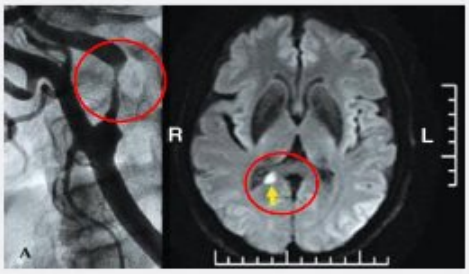
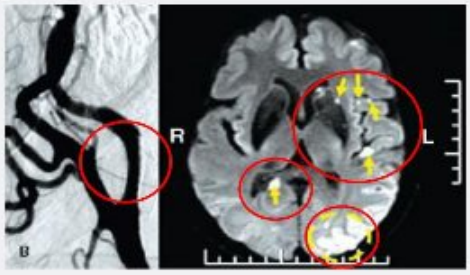


Based on the CREST clinical trial data[1], in which only conventional carotid stents were used vs surgery

[1] CREST Trial: N Engl J Med 2010;363:11-23
[2] Circulation. 2012;125:2250-2254

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	Successful opening of the carotid artery
MRI of a pre-existing white matter infarction (obstruction)	MRI reveals new multiple micro-infarcts (obstructions) due to liberation of embolic particles

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

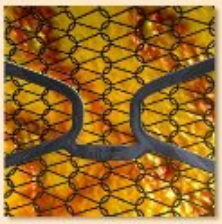
OUR SOLUTION: Proprietary MicroNet™ Technology

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

Conventional Stent:

Bare or dual layer approach, with plaque protrusion risk

Vs.



New Covered Stent:

Stents are covered in Micronet™

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

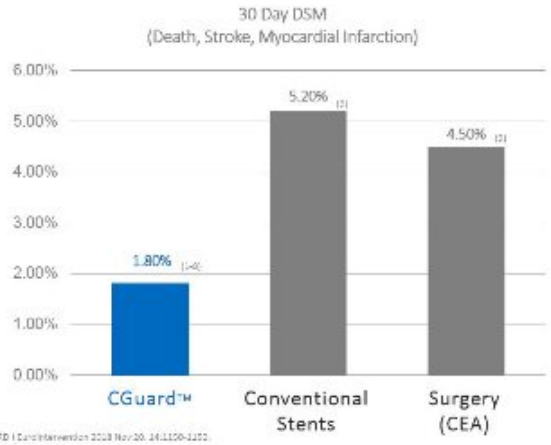
Timeline Growth: From Alternative Stent to New Gold Standard

YEAR	STUDY	PUBLICATION HIGHLIGHTS	CGUARD™'S STANDING (known & anticipated)
2015	CARLNET 30D	Safety, feasibility & neuroprotection; Neuroprotection over other stents data	☑ CGuard™ evaluated as new approach to CAS
2016	PARADIGM 101 30D	All commers population; Excellent clinical results	
2017	CASANA	Large surgical center; Excellent clinical results	
2017	WISSGOTT	Clinical & mechanical assessment; Mechanical advantages vs competitive stents	☑ CGuard™ demonstrates best performance in field
2018	WISGOTT 10MM	"One size fit all"; Safety & feasibility of a size fit all approach	
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	
2021	POLISH VASCULAR REGISTRY *	Large real world multicentric	☐ CGuard™ demonstrates superiority to other stents
2022	OCTOPVS *	OCT comparison CGuard™ vs CEA; to demonstrate CGuard™ superior procedural results than CEA	
2022	PARADIGM EXTEND *	Large long-term study for all commers; CGuard™ study of long-term results	☐ CGuard™ demonstrates superiority to surgery
2022	OPTIMA *	IVUS assessment after CGuard™; intended to demonstrate plaque exclusion	
2023	FLOW-GUARD *	Use of CGuard™ as flow diverter in very high-risk patients beyond carotids; Potential new CGuard™ indications	

* Expected

CGuard™ EPS Yields Superior Clinical Outcomes

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



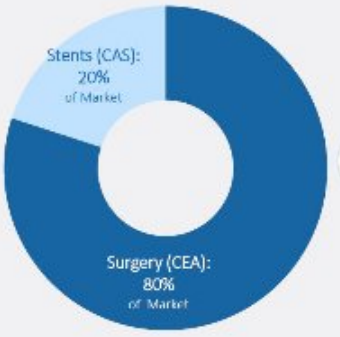
- CGuard™ has a superior profile versus historical data on both conventional carotid stents and surgery
- CGuard™ is a next-generation stent supported by a strong and growing body of clinical data
- 8 completed clinical trials and 3 ongoing trials
- NO MAJOR STROKE with CGuard™ (Minor stroke in 20/1,557 pts in 8 studies (1.28%)

1. (RONCUARD I Eurolnterv
2. (RONCUARD II, JVIC 2020
3. CNSVMA Eur J Vasc Endovasc Surg
4. WISCOTT J Endovasc Ther
5. WISCOTT II J Endovasc Ther
6. PARADIGM Edano, Eurolnterv
7. CARENET, JACC Cardiovasc Interv
8. SIBOTA, CardPCI e-Course, June 25, 2020.
9. CYCLE N Engl J Vasc Med

A Billion Dollar Market Opportunity

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

WW carotid procedures today are primarily surgical:



Carotid procedures tomorrow could be mostly minimally invasive with CGuard™

- 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

2017 Health Research International Market Report
CAS = Carotid Artery Stenting
CEA = Carotid Endarterectomy

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 (subject to FDA approval)

Our Lead Product, CGuard™ - Advancing Rapidly

31%

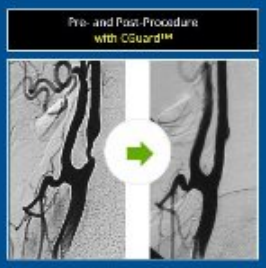
growth of CGuard™ portfolio in Q4 2019

18,000

Total protected stents sold to date with excellent clinical results

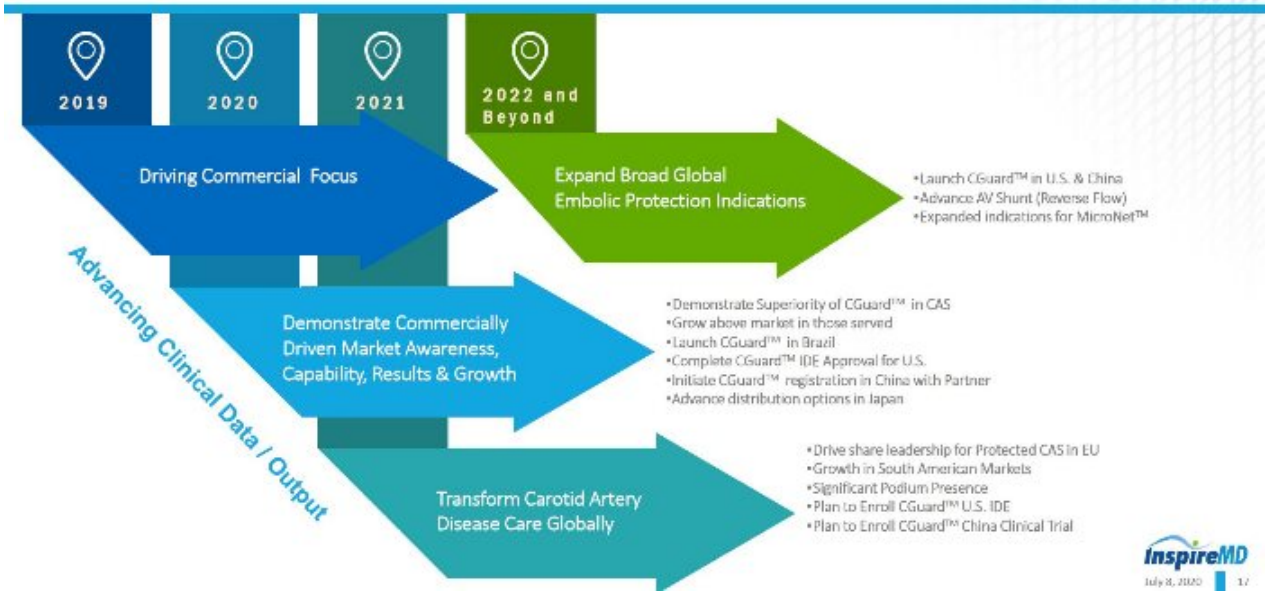
CGuard™ has potential to become the new standard-of-care for carotid indications

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



Our Advancement Roadmap / Milestones

Key Value Drivers and Strategic Pathways



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

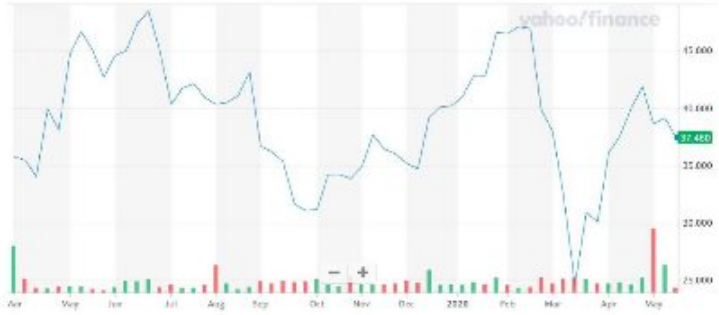
Our Business and Market Development

Strategic Targets for Merger or Acquisition

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



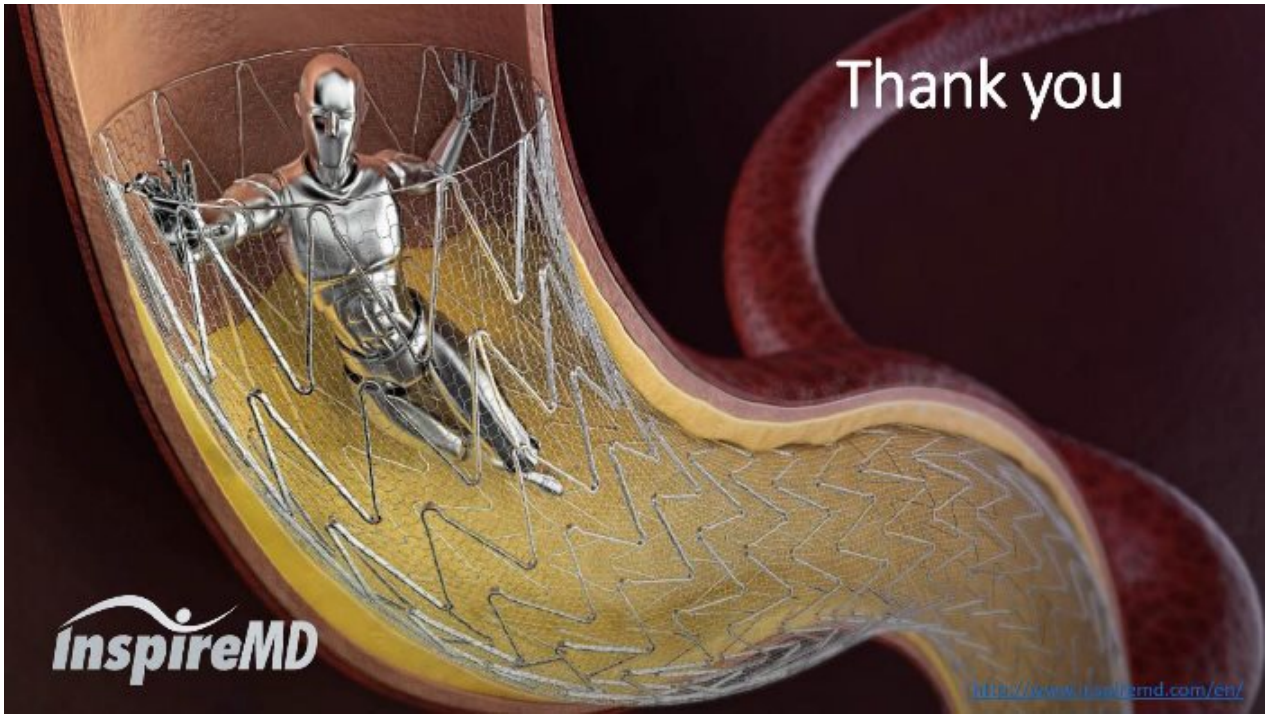
Summary Financials

NYSE AMERICAN	NSPR
Stock Price (7/6/20):	$0.48
Average volume:	3.9 M
Shares outstanding (7/6/20):	33.4 M
Shares outstanding including full conversion of preferred shares and prefunded warrants (7/6/20):	35.6 M
Market capitalization including full conversion of preferred shares and prefunded warrants (7/6/20):	$17.1 M
Cash (6/30/20)*:	$13.9 M

* Subject to PwC Q2 2020 review

Company Highlights

CGuard™ EPS	**Enabling a paradigm shift** (CAS) in the treatment of carotid artery disease and stroke prevention **Breakthrough platform:** Highly differentiated, with strong support from leading clinicians **MicroNet™ technology** that is elegantly simple, 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™ EPS sales increased 31% Q4/Q4 **Commercial model development:** Evaluating opportunities to go direct in key markets
$1B 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; Filed re-submission May 2020 • 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™ 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.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