INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 12/07/21 for the Period Ending 12/07/21

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, 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): **December 7, 2021**

InspireMD, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-35731	**26-2123838**
(Commission File Number)	(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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

Exhibit Number	Description
99.1	Slide Presentation of InspireMD, Inc. dated December 7, 2021
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: December 7, 2021

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Exhibit 99.1

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 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.

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 10 of 30 key markets globally

Evidenced based / Clinically Supported

CGuard™ EPS 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 CEO

Cordis
INTEGRA

Craig Shore
Chief Financial Officer

Pfizer

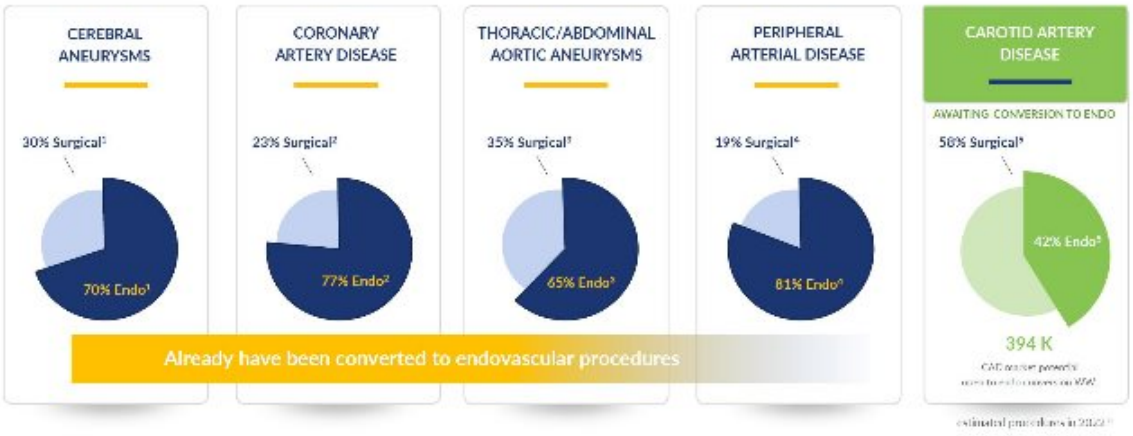
Andrea Tommasoli
SVP Global Sales & Marketing

INTEGRA
Abbott
ST. JUDE MEDICAL

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

Boston Scientific
BelVitge

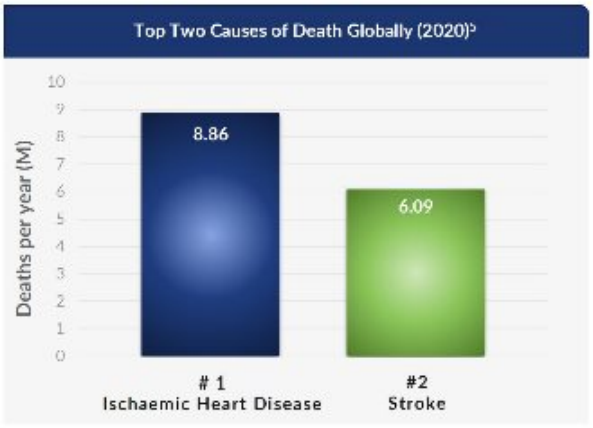
Endovascular Procedures: Landscape and InspireMD Potential



Stroke is the Second Biggest Cause of Death Globally

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

- 5 million deaths each year[2]
- 5 million people left permanently disabled[1]
- $46 billion associated with stroke management in the US alone[3]
- 87% 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



[1] https://www.cdc.gov/stroke/facts.htm
[2] https://www.who.int/health-topics/cardiovascular-diseases#tab=tab_1
[3] Centers for Disease Control and Prevention – Stroke Facts – 2021
[4] https://www.ninds.nih.gov/health-information/stroke/ischemic-stroke
[5] https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

THE PROBLEM: Risks with Existing Approaches to CAD

Conventional approaches come with risks

Carotid Endarterectomy (CEA)

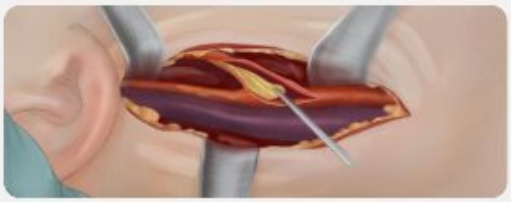
Surgical Approach

Risk of complications:

Myocardial infarction risk[1] (heart attack)

Cranial nerve injury risk[2] (vertigo, hearing loss, paralysis, etc)

Esthetic concern



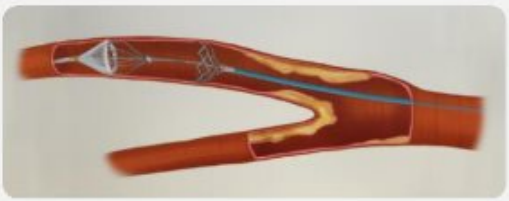
Carotid Artery Stenting (CAS)

Conventional Approach (Bare Stent)

Risk of complications:

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

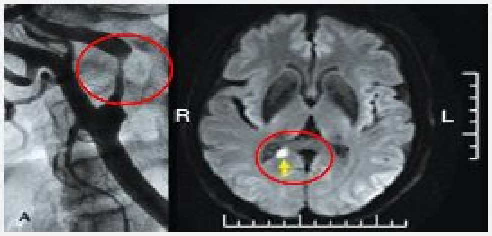
Bare stent deployment



THE PROBLEM: Risk of Embolism Following Conventional CAS

MRI reveals post-procedural cerebral embolization

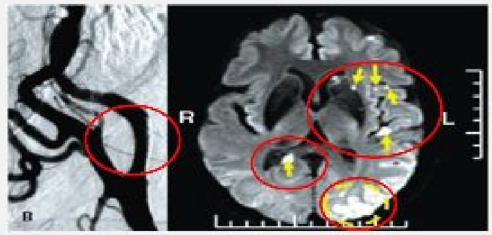
Pre-Procedure



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.[1]

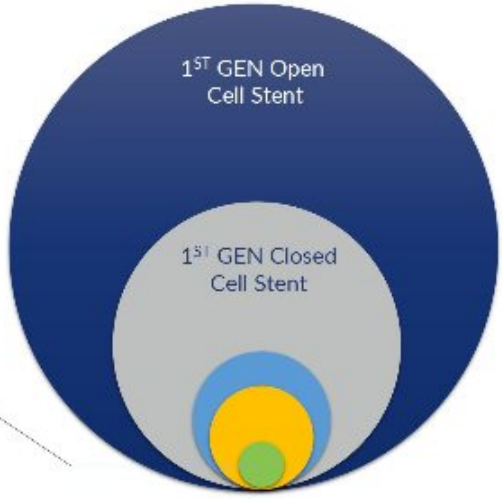
Mechanics Translate to Clinical Results

Pore size is an important differentiating factor in stent selection

2ND GEN Closed Stent

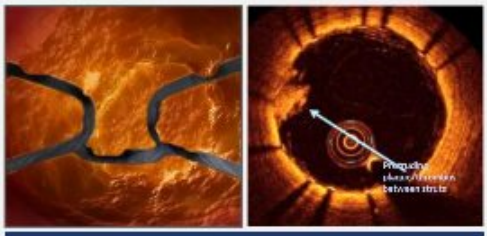
3rd GEN Closed Stent

CGuards's Pore size opening is ~1/12 or 8.5% that of a conventional open cell stent



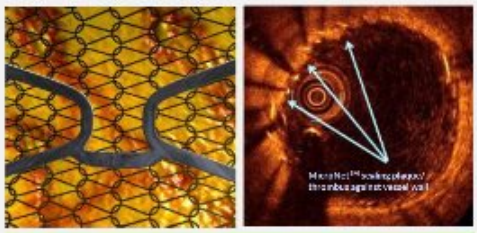
OUR SOLUTION: Proprietary MicroNet™ Technology[1]

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



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

VS.



CGuard Stent System (3rd 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

[1] Tenekidi E, University, P.D. Optical coherence tomography assessment of new generation mesh-covered stents after carotid stenting. EuroIntervention. 2017;13(10):1151 [published online]

Image: Prof. Vasilis Chatzis

Carotid Solution: Our Well Studied Mesh-Covered Technology

More than **1,500** 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	CARENET	Safety, Efficacy & Neuroprotection over other stents data	CGuard evaluated as new approach to CAS
2016	PARADIGM	All comers population: Excellent clinical results	
2017	CASANA	Large surgical center; Clinical results over conventional stents historical data	
2017	WISSCOTT	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	WISSCOTT 10MM	"One Size Fit All"(OSFA); 10 mm CGuard OSFA demonstrates safety and efficacy	
2019	IRON-GUARD 1	Real world multicentric 1y results; Excellent long-term results in multicentric	
2020	IRON-GUARD 2	Large real world multicentric; Large Multicentric Best-In-Class clinical results	CGuard demonstrates superiority to other stents
2021	CGuard-TCAS	CGuard Trans-Cervical excellent results	
2021	IRON-GUARD 2	12-month 733 pts clinical results	
2021	SIBERIA	Randomized Trial; CGuard demonstrates Neuroprotection vs Conventional stents	
2021	ONE SIZE-FIT-ALL	CGuard 150 pts 12m-FU	
2021-24	PARADIGM Extend	CGuard in all-comers 550 pts 30d/5y FU	
2021	Meta-Analysis	CGuard superior to Other Stents at 1y-FU	
2021	Meta-Analysis	CGuard superior to CEA at 1y-FU	CGuard demonstrates superiority to surgery
2021	OCTOPVS	OCT comparison CGuard vs CEA; CGuard superior post-intervention OCT than CEA	
2022	OPTIMA	IVUS assessment after CGuard; Anticipated Plaque exclusion demonstrated	
2022	FLOW-GUARD	Use of CGuard as flow diverter in very high-risk patients beyond carotids; Potential new CGuard indications	

Clinical Support Highlights / Call out

2015-2021

CARENET Trial

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

PARADIGM

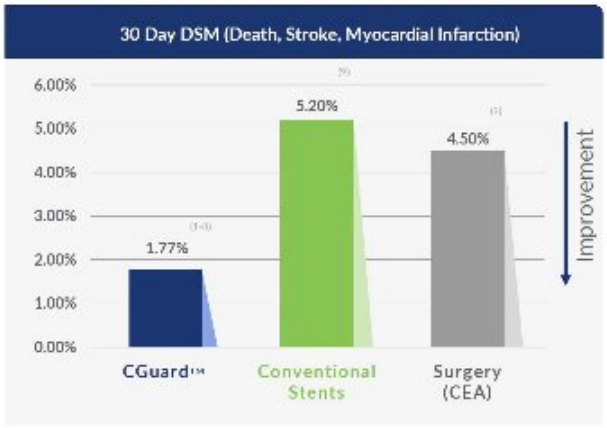
Opened CARENET study inclusion criteria and concluded the safety and clinical outcomes were applicable to others outside of high-risk

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

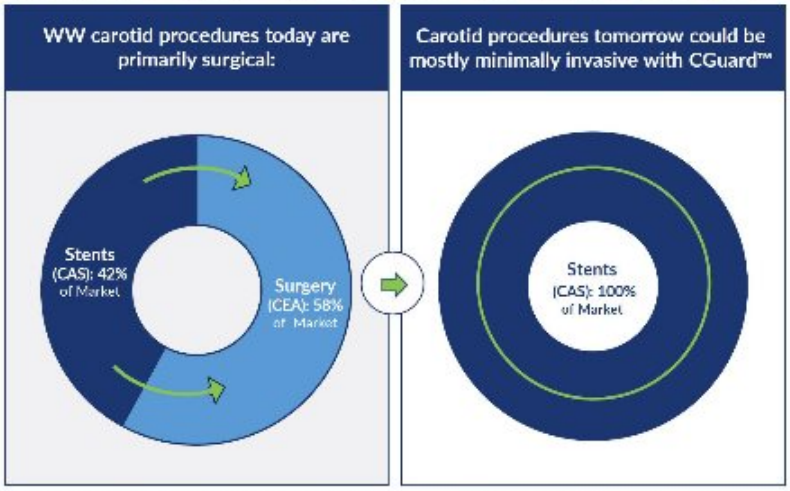


- **NO MAJOR STROKE** to date with CGuard (Minor stroke in 21/1,635 patients in 8 studies (1.28%)
- CGuard has a superior profile vs. historical data on both conventional carotid stents and surgery
- CGuard is a next-generation stent supported by a strong clinical data
- 8 completed clinical trials and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

[illegible]

Potential Multi Billion Dollar Market Opportunity

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



- **Current addressable market:**
  → **$666 million** [1]
  394K interventional procedures for HGCS (High Grade Carotid Stenosis)
- **Total Available Market:**
  → **$5 billion** [2]
  ~3 million* people diagnosed with HGCS w/ an additional ~ 13 million undiagnosed with carotid artery disease (CAD)

1. Procedures for Selected Nations, 2017 – 2025 prepared for InspireMD Inc. by Health Research International, Personal Medical Systems, Inc. Sept. 15, 2017

Commercial Footprint

- 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

155K

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

** [illegible]

Our Lead Product, CGuard™

Advancing Rapidly

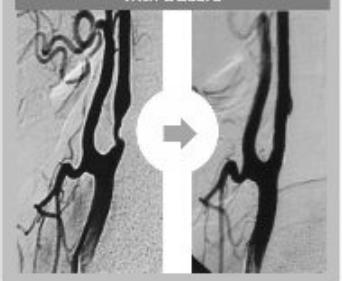
26,000+

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



Our Advancement Roadmap / Milestones

Our Key Value Drivers and Strategic Pathways

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

December 3, 2021

NASDAQ Capital Markets	NSPR
Stock Price	$3.29
Average 3 Month Volume	0.335M
Shares Outstanding	8.3M
Market Capitalization	$27.3M
Cash Balance – September 30th, 2021	$37.1M
Debt	$0M

Our Board of Directors

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.
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 Oaks 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 Kesler Director	Mr. Kesler is CFO of Kesler Search Group, Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies. He spent 26 years at KPMG LLP.
Gary Roubin, M.D., Ph.D. Director	Dr. Roubin was named to the board of Directors in October 2020. Dr. Roubin has co-authored more than 280 clinical publications and has contributed to 20 textbooks in the fields of Interventional Cardiology and Vascular Surgery. He was a key contributor in the CREST trial which has validated the use of carotid stents for the treatment of carotid artery stenosis.
Katie Arnold Director	Ms. Arnold was named to the Board of Directors in May 2021. Ms. Arnold founded and leads SPRIG Consulting, providing the entire spectrum of strategic marketing services to medical companies. Ms. Arnold is currently an adjunct professor at Northwestern University's Kellogg School of Business, where she teaches medical product commercialization and financing.


INSPIREMD
NASDAQ = NSPR