

# INSPIREMD, INC.

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

Filed 06/15/17 for the Period Ending 06/15/17

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

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): June 15, 2017

**InspireMD, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of incorporation)

001-35731

(Commission  
File Number)

26-2123838

(IRS Employer  
Identification No.)

4 Menorat Hamaor St.  
Tel Aviv, Israel

(Address of principal executive offices)

6744832

(Zip Code)

Registrant's telephone number, including area code: (888) 776-6804

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(Former name or former address, if changed since last report)

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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))

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.

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**Item 7.01 Regulation FD Disclosure.**

InspireMD, Inc. (the “Company”) intends, from time to time, to present and/or distribute to the investment community and utilize at various industry and other conferences a slide presentation, which is attached hereto as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
99.1	Slide Presentation of InspireMD, Inc. dated June 2017.

**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: June 15, 2017

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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Investor Presentation

NYSE MKT: NSPR

June 2017

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# Forward Looking Statements

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*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.*

InspireMD is a commercial-stage medical device company with proprietary and innovative embolic prevention systems (EPS)/thrombus management technologies and neurovascular devices that seek to overcome the harmful consequences of conventional stenting.

## COMPANY

**NYSE MKT:** NSPR  
**Founded:** 2005  
**Employees:** 36  
**Headquarters:** Tel Aviv  
**Manufacturing Facility:** Tel Aviv

## TECHNOLOGY

Proprietary MicroNet™ technology in multiple products seeking a superior solution for the treatment of complex vascular and coronary disease

## PRODUCTS

**Commercial:**  
CGuard™ Carotid EPS  
MGuard™ Coronary EPS

**Pipeline:**  
Next Gen CGuard™ - 5F  
NGuard™  
PVGuard™



# Embolization Following Carotid Artery Stenting



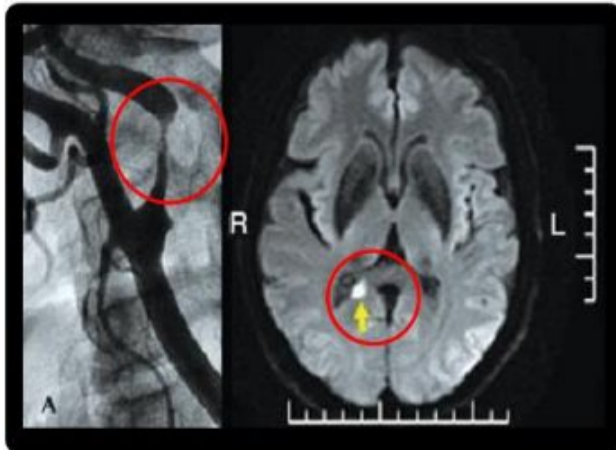
“Plaque protrusion through stent struts occurs in up to 65% of conventional carotid stents in relation to plaque morphology/symptomatic status and stent type, providing a mechanism for post carotid artery stenting (CAS) cerebral embolization, either directly or via additional thrombus formation.”\*



2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.\*\*

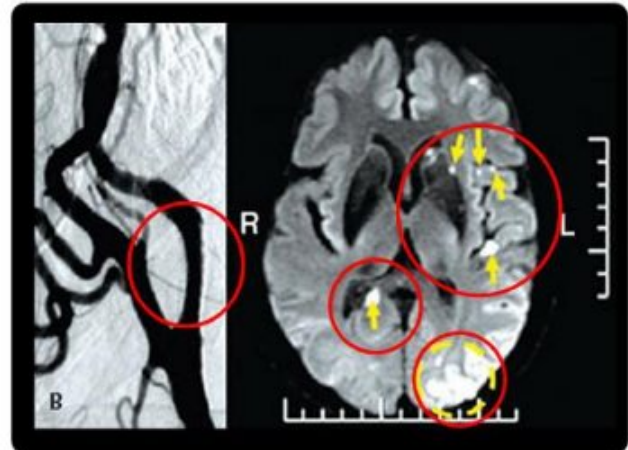
\* Musialek, et al. EuroIntervention 2016; 12 August 2016.  
\*\* Bossiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

# Consequences Range from Neurological Deficit to Stroke



Pre-Procedure

Pre-intervention showing 90% occlusion of the carotid artery and an MRI showing an old white matter infarction (obstruction).



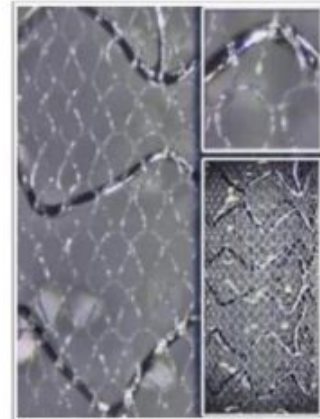
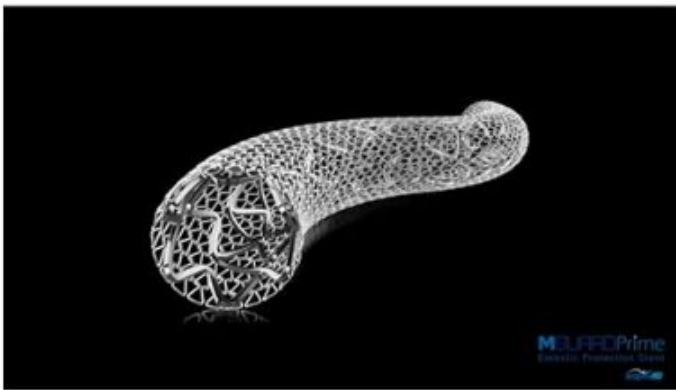
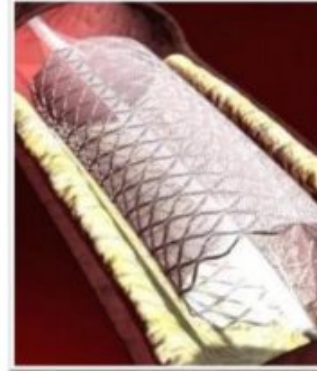
Post-Procedure

Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

# MicroNet™ Prevents Distal Embolization and Other Vascular Disease Challenges



- Ultrathin PET\* mesh provides meaningful clinical benefit versus conventional devices
- Provides revascularization benefit
- MicroNet™ acts as a “safety net” by offering greater vessel area coverage to prevent large plaque protrusion through the scaffold into the vessel lumen
- Made of a single fiber from a biocompatible polymer, widely used in other medical implants
- Stents incorporating MicroNet™ have identical deliverability to other stents



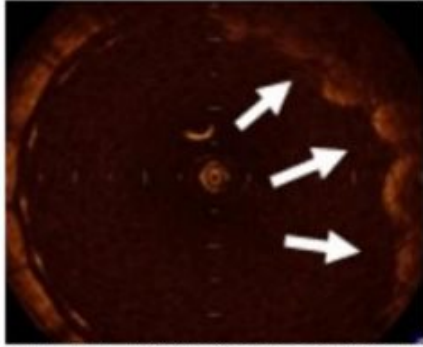
\*PET – polyethylene terephthalate

# Plaque Coverage in Carotid Stents

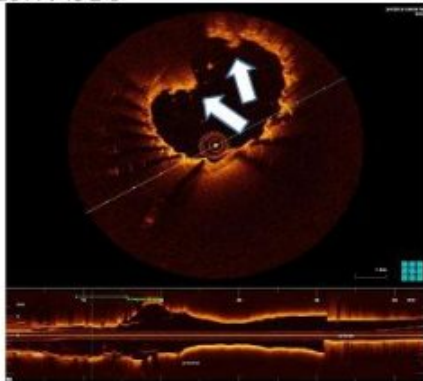


## Conventional Carotid Stents

No plaque coverage leading to vulnerable plaque protrusions or prolapse

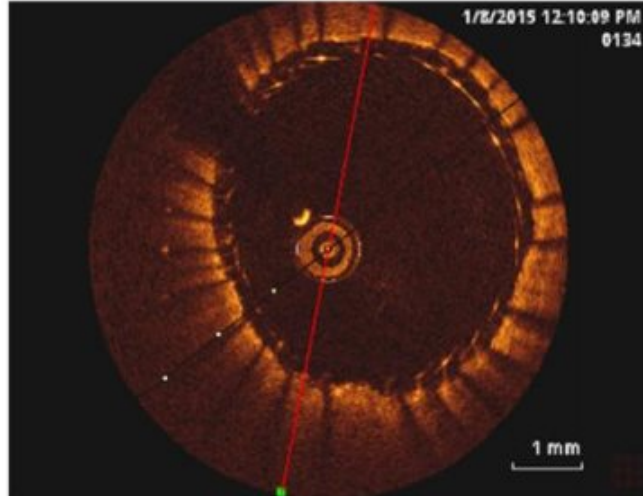


Yoshimura, et al. J A C C : Cardiovascular Imaging 4; 4, 2011 : 43 2-6



## CGuard™ EPS


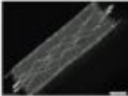

The MicroNet **permanently covers** thrombus that might be present and the plaque and prevents thrombus or “debris” from passing through the mesh and into the vessel lumen



Case reports courtesy Dr. Gianmarco de Donato, Department of Medicine Surgery and Neuroscience Università degli studi di Siena, Italy.

# Large & Growing Addressable Market



Embolic Prevention Products		Market Oppty	CE Mark	Focus Area
CGuard™		\$500M	✓	Carotid
MGuard™*		\$1.7B	✓	Coronary AMI & SVG
NGuard™		\$675M	Planned Submission TBD	Neurovascular
PVGuard™		\$1.7B	Planned Submission TBD	Peripheral

\* MGuard™ global strategy focused on drug eluting stent OEM partnership

\* MGuard is a bare metal stent scaffold

# Positive CGuard™ Clinical Experience



## CARENET Clinical Trial (2014)

- 30 Patient Safety and Efficacy clinical trial
- **Zero major adverse cardiac or cerebral events (MACCE)** at 30 days (Comparative data 5.72%\*)
- **50% fewer new ischemic lesions** with lesion volume being 10x times smaller compared to historical non-mesh carotid artery stenting data
- **All new ischemic lesions fully resolved at 30 days** except one
- 3.6% MACCE rate at 6 months (Comparative data 8.09%\*\*)
- **Zero strokes or stroke related deaths at 12 months**

## PARADIGM 101 Clinical Trial (2015 and 2016)

- 101 patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)
- **99.1% device success**
- **0% MACCE (Death/stroke/MI) @ 48 hr**
- **0% MACCE @ 30 day**
- **Zero strokes or stroke related deaths at 12 months**



*"CGuard can safely be used on more than 90% of all-comer patients that have carotid artery stenosis."*  
P. Musialek, MD

\* Trials included in analysis: ARChER pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVERIC 1+2, MAVERIC International, PRIAMUS, SAPPHIRE, SECURITY, PROF1, ICSS

\*\* Values extrapolated from event curves



### The Iron-Guard Registry

- Physician initiated
- 12 large Italian medical centers
- 200 patients

### Clinical Results

- **100% success** in implanting the CGuard EPS
- **No major adverse cerebrovascular cardiac events** at 30 days
- DW-MRI performed in 61 of 200 patients found **only 19% new lesions** between 24-72 hours
  - CARENET reported 37% new lesions in 30 patients
  - PROF1 reported 66% new lesions in 62 patients

#### SPECIAL ARTICLES

J CARDIOVASC SURG 2015;36:787-91

*Physician-initiated prospective Italian Registry of carotid stenting with the C-Guard mesh-stent: the IRON-Guard registry. Rationale and design*

C. SETACCI<sup>1</sup>, F. SPEZIALE<sup>2</sup>, G. DE DONATO<sup>1</sup>, P. SIRIGNANO<sup>2</sup>, F. SETACCI<sup>1</sup>, L. GAPOCCIA<sup>1</sup>, G. GALZERANO<sup>1</sup>, W. MANSOUR<sup>2</sup>  
On behalf of IRON-Guard Study Group



*"The IRON-Guard Registry shows promising results in this interim analysis with a low incidence of complications and the lowest reported rate of new MRDWI lesions*

F. Speziale, MD and P. Sirignano, MD





**Leipzig Interventional Course (LINC) January 2017**

PD Dr. Andrej Schmidt and Dr. Sven Bräunlich Department of Angiology, University Hospital Leipzig, Division of Interventional Angiology, Leipzig, Germany, perform a live stent endovascular interventional procedure featuring the CGuard™ EPS

**European Association of Percutaneous Cardiovascular Interventions (EuroPCR) May 2017**

Dr. Fausto Castriota and Dr. Antonio Micari Interventional Cardiovascular Units at GVM Care and Research, Maria Cecilia Hospital, Cotignola Hospital Cotignola, PAVENNA Italy perform a live stent endovascular interventional procedure featuring the CGuard™ EPS

# Peripheral Interventions: EuroPCR 2017 Highlights



- "We know that with the prior generation of [carotid] stents a lot of the [distal embolization] events happen after the procedure" (*Prof. Musialek*)
- "Here [with mesh covered stents] we have seen a lot of cases with control of IVUS and really there is no more plaque protrusion...this [mesh covered stents] is clearly a major advantage" (*Prof. Roffi*)

<https://www.youtube.com/watch?v=YI16rcFYdHs&feature=dir#t=3m00s>

Non-sponsored Video recorded at EuroPCR 2017 – ©Europa Organisation

**Proven success with regionally strong local distributors; YOY (2015-2016) sales growth 67%**

### Representative Regional Distributors

Market	YOY Growth
Colombia	100%
Israel	151%
Italy	59%
Slovenia	95%
Chile	233%

- Replacing exclusive European CGuard™ distributor with regional distributors who target all 4 clinical specialties
  - Vascular surgery, interventional cardiology, interventional neuroradiology, and interventional radiology
  - Penumbra's focus was primarily the interventional neuroradiology market, their key customer segment

**Proven success with regionally strong local distributors; 84% sequential increase in sales of CGuard™ in Q1 '17**

- Expanding global footprint
- Successfully attracting KOLs in each of the respective markets

### Latest Regional Distributors

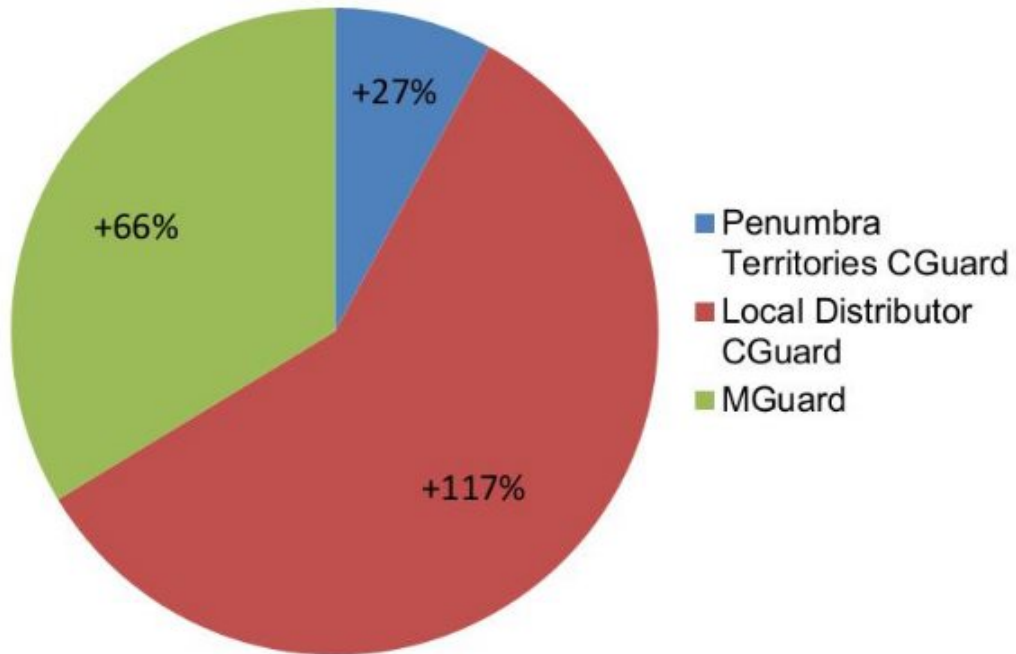
Former Distributor: Europe
Poland
Germany
Netherlands
Belgium
Austria
Estonia

Rest of World
Taiwan
Peru
Ecuador
Turkey
Hong Kong
Russia

## Revenue Growth - Q1 '17 vs Q4 '16



Total Sequential Growth of 77% using InspireMD Managed Local Distributor Model



- US FDA

- Pre-IDE FDA submission for CGuard™ February 2017
- Formal FDA meeting held April 2017
- Planned IDE submission in 2018



- Next generation CGuard™ - 5 French CGuard™



- Minimally invasive devices trending smaller for broader and easier usage
- Lower profile system for cases where pre-dilatation could be problematic
- Competitive advantage in the Asia/Pacific markets
  - Smaller anatomy particularly in the female population
- Transradial delivery (delivery from the wrist vs. femoral artery) gaining favor among interventionalists



\* Planning & Development Phase

# Near Term Growth Strategy



## CGuard™

- Engaging distribution partners in countries with current/near-term regulatory approval
- Seeking additional regulatory approvals in countries that accept CE Mark
- Plan to file US FDA IDE in 2018
- Plan to file CE Mark for next generation 5 French CGuard™ in 2018
- Expanding into the Asia Pacific region
  - CAS is the preferred treatment of carotid artery disease in China
  - Pursuing partnership strategy in China
  - Distributors identified and sales have commenced in Hong Kong and Taiwan
  - Identifying distributors/partners for South Korea, Japan, Australia and New Zealand
- Attracting leading KOLs from around the world

## MGuard

- Strategy focused on formation of strategic partnerships with stent manufacturers with approved drug eluting stents

## CGuard™ Approved Markets

Argentina	Ireland
Austria	Israel
Belarus	Italy
Belgium	Latvia
Chile	Lithuania
Colombia	Liechtenstein
Croatia	Luxemburg
Cyprus	Malta
Czech Republic	Norway
Denmark	Poland
Estonia	Portugal
Finland	Romania
France	Russia
Germany	Slovakia
Greece	Slovenia
Holland	Spain
Netherlands	Sweden
Hungary	Switzerland
Iceland	United Kingdom



# Recent/Upcoming Anticipated Milestones



*Continued market execution and revenue growth.*

# Intellectual Property Portfolio



- Proprietary platform technology supported by a robust intellectual property portfolio
- Continue to strengthen and broaden patent protection globally to enable future pipeline products

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
USA	6	0	12
Rest of World	18	2	19

# Leadership



Significant track records of success

<b>Dr. James Barry</b>	President and CEO				
<b>Craig Shore</b>	CFO				
<b>Agustin Gago</b>	CCO				
<b>Paul Stuka</b>	Chairman				
<b>Isaac Blech</b>	Vice Chairman				
<b>Michael Berman</b>	Director				
<b>Dr. Campbell Rogers</b>	Director				
<b>Thomas Kester</b>	Director				
<b>Sol Barer, Ph.D.</b>	Special Advisor to the Board				

- Multi-billion dollar opportunity for MicroNet™ products for multiple vascular markets
  - Current stents do not adequately address the risk of post-procedural embolization
  - Consistent positive clinical trial results positioning CGuard™ as a potential standard-of-care in treating carotid artery disease
- Revenue growth driven by new commercialization strategy
  - 84% sequential increase in sales of CGuard™ in Q1 '17
  - Completed transition from exclusive European distributor (18 countries) to InspireMD managed regional distributor model
  - Expanding CGuard™ users to a greater number of vascular surgeons, interventional cardiologists, and interventional radiologists
- Recent leadership changes focused on sales, marketing and high value pipeline development
- Strategic collaboration outreach expanding for multiple MicroNet™ product applications
- A broad portfolio of patent-protected assets

## NYSE MKT: NSPR

<b>Stock Price (6/13/17):</b>	<b>\$0.56</b>
Average 3 Month Volume (6/13/17):	447 K
Shares Outstanding (6/13/17):	7.5 M
Shares Outstanding Including full conversion of preferred shares (6/13/17):	17.0M
Market Capitalization including full conversion of preferred shares (6/13/17):	\$9.5 M
Total Cash (3/31/2017) :	\$8.6 M
Headquarters:	Tel Aviv, Israel
# of Employees (6/13/2017)	36



James Barry, Ph.D., President and CEO  
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