INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 03/29/17 for the Period Ending 03/29/17

Telephone	(888) 776-6804
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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): March 29, 2017

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)

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

(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))

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 March 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: March 29, 2017

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Investor Presentation

NYSE MKT: NSPR

March 2017

Forward Looking Statements

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.

About InspireMD

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:	34
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™

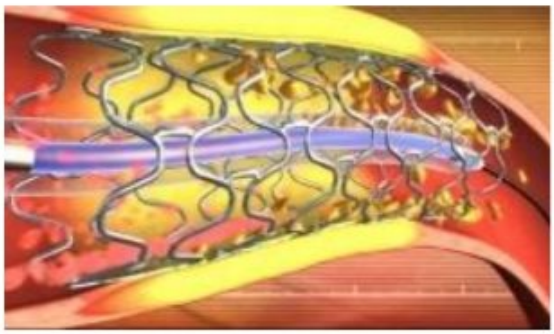
PVGuard™

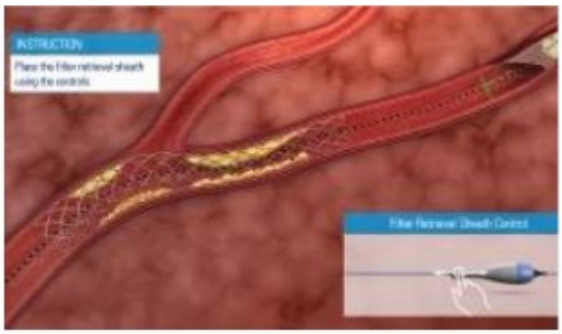
Investment Highlights

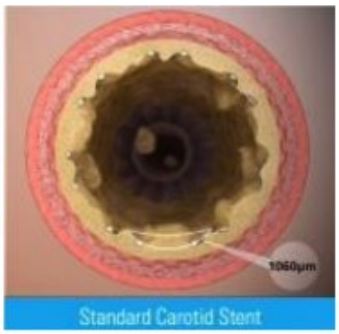
- Multi-billion dollar opportunity for MicroNet™ products for multiple vascular markets
  - Current stents do not adequately address the risk of post-procedural embolization
  - Consistent positive clinical trial results positioning CGuard™ as a potential standard-of-care in treating carotid artery disease
- Revenue growth driven by new commercialization strategy
  - Proven success with recent YOY sales growth of 67% in select markets with InspireMD managed regional distribution model
  - Transitioning from exclusive European distributor (18 countries) to established 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

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."*



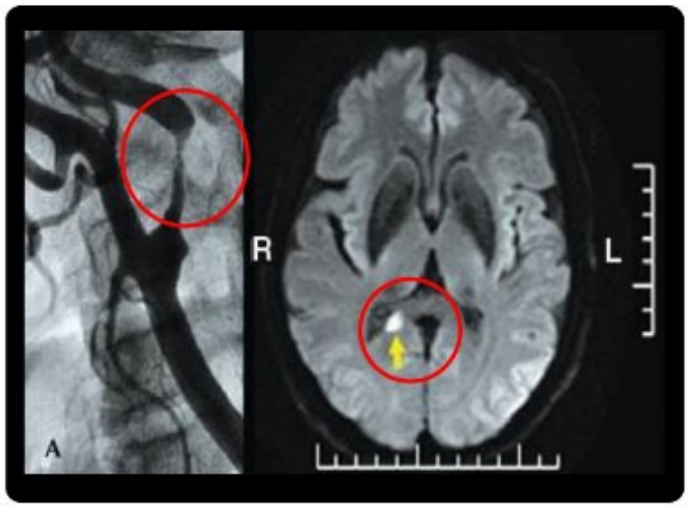




2/3 of CAS neurovascular events (stroke, TIA) are POST-procedural.**

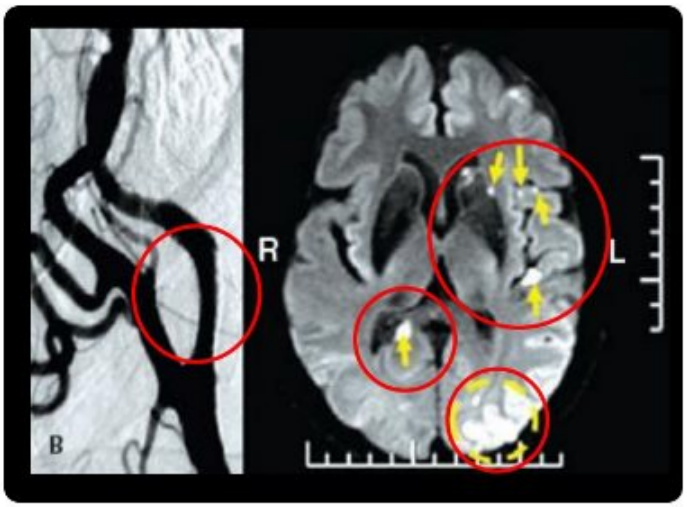
* Musialek, et.al. Eurointerventions 2016;12 August 2016.
** Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

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).



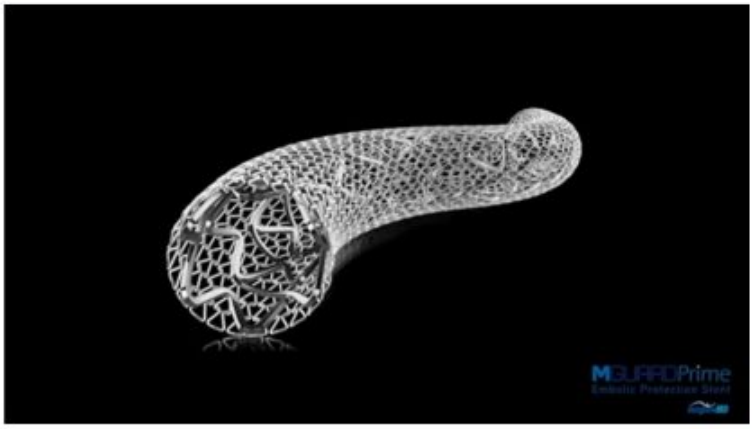
Post-Procedure

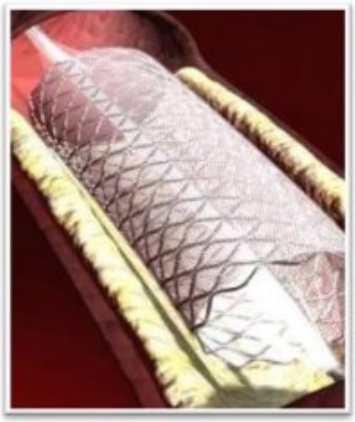
Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

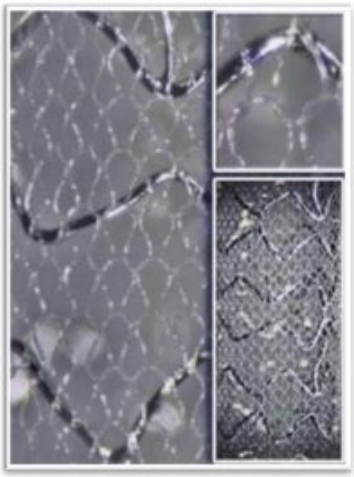
Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.

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

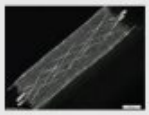






*PET – polyethylene terephthalate

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

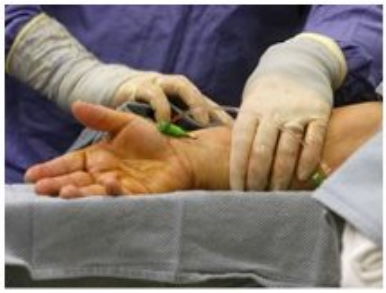
* MGuard™ global strategy focused on drug eluting stent OEM partnership

* MGuard is a bare metal stent scaffold

CGuard™ Product Development

- US FDA
  - Pre-IDE FDA submission for CGuard™ completed
  - Formal FDA meeting planned
  - 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

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, PROFI, ICSS
** Values extrapolated from event curves

Additional Independent Clinical Data Supports Use of CGuard™

Independent study conducted in 30 patients with internal carotid artery disease

Clinical results (2016)

- **100% success** in implanting the CGuard™ EPS
- No peri- or post-procedural complications
- **No deaths, major adverse events, minor or major strokes**, or new neurologic symptoms during the six months following the procedure
- All vessels treated with the CGuard™ system remained patent (open) at six months
- DW-MRI performed in 19 of 30 patients found **no new ipsilateral lesions after 30 days and after six months** compared with baseline DW-MRI studies

Clinical Investigation

ENDOVASCULAR THERAPY

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent

Christian Wissgott, MD[1], Wolfram Schmidt, PhD[2], Christoph Brandt-Wunderlich, MSc[2], Peter Behrens, MSc[2], and Reimer Andresen, MD[1]

Abstract

Purpose: To report early clinical outcomes with a novel double-layer stent for the internal carotid artery (ICA) and the in vitro investigation of the stent's mechanical properties. **Methods:** A prospective single-center study enrolled 30 consecutive patients (mean age 70.1±6.3 years; 27 men) with symptomatic (n=25) or high-grade (n=5) ICA stenoses treated with the new double-layer carotid CGUARD Embolic Prevention System (EPS) stent, which has an inner open-cell stented design with an outer closed-cell polyethylene terephthalate layer. The average stenosis of the treated arteries was 84.1%±7.9% with a mean lesion length of 14.4±2.1 mm. In the laboratory, 8×40-mm stents were tested in vitro with respect to their radial force during expansion, the bending stiffness of the stent system and the expanded stent, as well as the collapse pressure in a thin and flexible sheath. The wall adaptation was assessed using fluoroscopy after stent release in step and curved vessel models. **Results:** The stent was successfully implanted in all patients. No peri- or postprocedural complications occurred; no minor or major stroke was observed in the 6-month follow-up. The bending stiffness of the expanded stent was 63.1 N·mm² and (not unexpectedly) was clearly lower than that of the stent system (301.5 N·mm²). The normalized radial force during expansion of the stent, to 7.0 mm, correlated with in vitro sizing, was relatively high (0.016 N/mm), which correlates well with the collapse pressure of 0.17 bars. Vessel wall adaptation was harmonic and caused no straightening of the vessel after clinical application. **Conclusion:** Because of its structure, the novel CGUARD EPS stent is characterized by a high flexibility combined with a high radial force and very good plaque coverage. These first clinical results demonstrate a very safe implantation behavior without any stroke up to 6 months after the procedure.

Keywords

carotid artery stent, closed-cell design, double-layer stent, embolic filter, internal carotid artery, in vitro testing, mechanical behavior, nitinol, open-cell design, radial force, stenosis, stent

Introduction

Several studies have demonstrated that carotid artery stenting (CAS) of the ipsilateral internal carotid artery (ICA) is a well-established and equally good option for treating atherosclerotic carotid stenoses in comparison with carotid endarterectomy (CEA).[1–3] Although CEA is still considered the gold standard therapy in carotid stenoses[4–6] because of a lower risk of procedure-related and periprocedural cerebral embolizing stroke, stent implantation is a valuable treatment option because of its less invasive character.[7,8]

Despite the fact that procedure-related events can be caused by lesion crossing and pre-dilatation,[7] particular attention has been focused on the stent design because periprocedural diffusion-weighted magnetic resonance imaging (DW-MRI) lesions were more numerous in patients treated with an open-cell stent vs a closed-cell stent.[9,10]

The perfect stent should safely cover the plaque for sustained embolic protection like an ultra-closed-cell stent and show high flexibility and conformability like an open-cell stent.[11] The first reports of a closed-cell stent with double stacked layers showed promising clinical results with respect to an implantation failure rate based on the closed-cell design.[12,13] This article presents the clinical results

[1]Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westmecklenburg Klinik Academic Teaching Hospital of the Universities of Kiel, Lübeck and Hamburg, Heide, Germany
[2]Institute for Biomedical Engineering, Research University Medical Center Rostock, Germany

Corresponding Author
Christian Wissgott, Institute of Diagnostic and Interventional Radiology/Neuroradiology, Westmecklenburg Klinik Academic Teaching Hospital of the Universities of Kiel, Lübeck and Hamburg, Langenhahnstraße 10, 25746 Heide, Germany
Email: wissgott@wkk-hei.de

"CGuard EPS is an important new treatment option for both symptomatic and asymptomatic carotid artery stenosis patients."

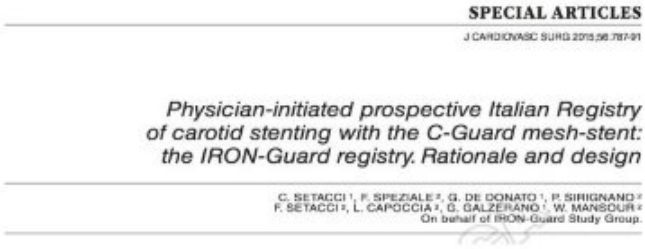
C. Wissgott, MD

Wissgott, et al. J Endovasc Ther 2016.

Additional Independent Clinical Data Presented at LINC 2017 Further Supports Use of CGuard™

The Iron-Guard Registry

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



SPECIAL ARTICLES

J CARDIOVASC SURG 2015;56:787-91

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

C. SETACCI [1], F. SPEZIALE [2], G. DE DONATO [1], P. SIRIGNANO [2], F. SETACCI [3], L. CAPOCCIA [4], G. SALZERANO [1], W. MANSOUR [2], On behalf of IRON-Guard Study Group.

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
  - PROFI reported 66% new lesions in 62 patients

"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. Spezaile, MD and P. Sirignano, MD

Sales & Marketing Strategy

Proven success with regionally strong local distributors; YOY sales growth 67%

Representative Regional Distributors

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

- Replacing Penumbra with regional distributors who target all 4 clinical specialties;
  - Penumbra's focus was primarily the interventional neuroradiology market, their key customer segment
- Focus on lager markets – Germany, Italy, and Spain
- Advanced discussions with distributors in Sweden, Poland, Belgium, Netherlands and Portugal
- Successfully attracting KOLs in each of the respective markets

Growing KOL Support Across Europe

PD Dr. Andrej Schmidt and Dr. Sven Bräunlich from the Department of Angiology, University Hospital Leipzig, Division of Interventional Angiology, Leipzig, Germany, perform a live stent endovascular interventional procedure featuring the CGuard™ EPS Carotid Stent at the Leipzig Interventional Course (LINC) 2017

Broad Platform Technology

* Planning & Development Phase

Near Term Growth Strategy

CGuard™

- Engaging distribution partners in countries with current/near-term regulatory approval
- Attracting leading KOLs from around the world
- Seeking additional regulatory approvals in countries that accept CE Mark
  - Recent approval in Russia with plan to launch in first half of 2017
- Plan to file US FDA IDE in 2018
- Plan to file CE Mark for next generation 5 French CGuard™ in 2018
- Partnership strategy targeting Asia Pacific region
  - CAS is the preferred treatment of carotid artery disease in China
  - Targeting distributors in Hong Kong, Taiwan, South Korea, Japan, and China

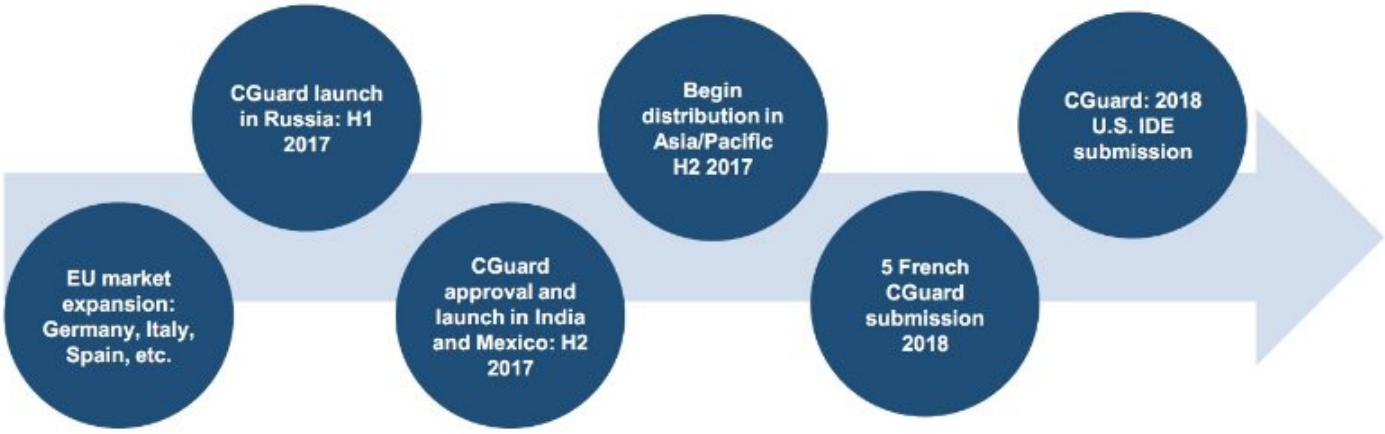
MGuard

- 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

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	17	1	19

Leadership

Significant track records of success

Dr. James Barry	President and CEO	Boston Scientific, Pfizer
Craig Shore	CFO	Pfizer, GE
Agustin Gago	CCO	Delcath Systems, Inc, angiodynamics, EZ EM
Dr. Sol Barer	Chairman	Celgene
Isaac Blech	Vice Chairman	cerecor, ContraFect, medgenics, sapience therapeutics
Michael Berman	Director	Boston Scientific, Velocimed, LUTONIX
Paul Stuka	Director	OSIRIS, Fidelity Investments
Dr. Campbell Rogers	Director	HeartFlow, Cordis, HARVARD MEDICAL SCHOOL
Thomas Kester	Director	Kester Search Group, KPMG

Financial Snapshot

InspireMD

NYSE MKT: NSPR

Stock Price (3/24/17):	**$0.92**
Average 3 Month Volume (3/24/17):	299 K
Shares Outstanding (3/24/17):	5.6 M
Shares Outstanding Including full conversion of preferred shares (3/24/17):	17.0M
Market Capitalization including full conversion of preferred shares (3/24/17):	$15.6 M
Total Cash (12/31/2016) adjusted for net cash received from March 2017 fund raising :	$13.5 M
Headquarters:	Tel Aviv, Israel
# of Employees (3/24/2017)	36

James Barry, Ph.D., President and CEO
888.776.6804
jimb@inspiremd.com

Craig Shore, CFO
888.776.6804
craigs@inspiremd.com