INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 11/15/16 for the Period Ending 11/15/16

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
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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): November 15, 2016

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.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (857) 305-2410

(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 November 2016

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: November 15, 2016

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer

Corporate Presentation

NYSE MKT: NSPR, NSPR.WS

November 2016

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 payers 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

Commercial-stage medical device company marketing and developing innovative embolic prevention systems (EPS), neurovascular devices and thrombus management technologies

COMPANY

NYSE MKT:	NSPR
Founded:	2005
Employees:	36
Headquarters:	Boston
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:

NGuard

PVGuard

Investment Highlights

- Revenue growth driven by broader EU sales and Latin American launch of CGuard™
- Strategic distribution partnership with Penumbra (NYSE: PEN)
- Multiple and consistent clinical trial results using CGuard in a broad patient population, including high risk patients
- Expanding opportunities in the growing neurovascular and peripheral vascular markets
- Strategic collaboration opportunities on multiple MicroNet™ product applications
- Broad portfolio of patent-protected assets
- Financial discipline in line with development and growth initiatives

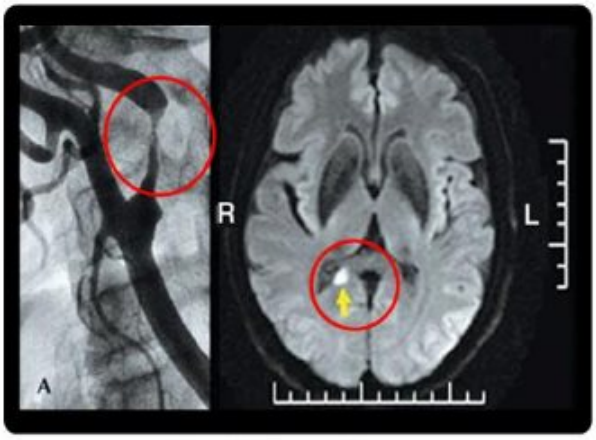
Embolization Following Carotid Artery Stenting

"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.**

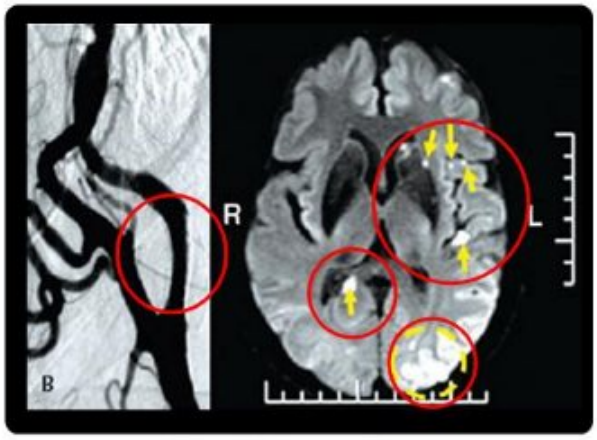
* Musialek, et.al. Eurointerventions 2016;12 August 2016.
** Bosiers et al. Eur J Vasc Endovasc Surg Vol 33, Feb 2007.

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).



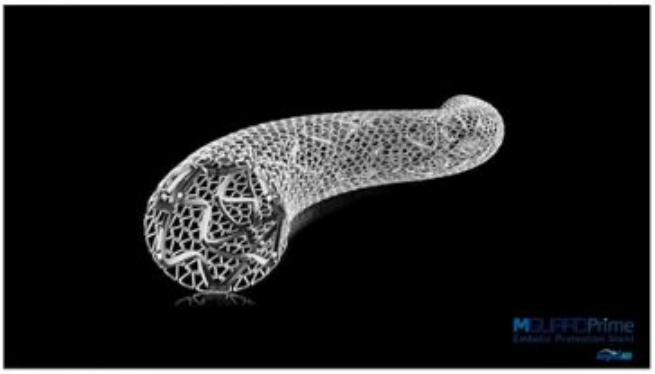
Post-Procedure

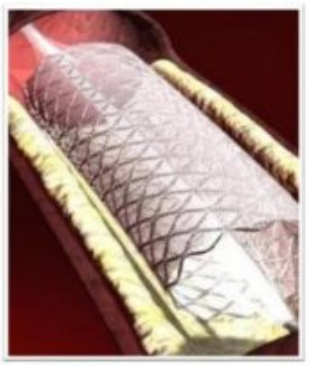
Post-intervention showing successful opening of the occluded carotid artery with conventional stenting and an MRI showing multiple micro-infarcts (obstructions) post-procedure due to liberation of embolic particles.

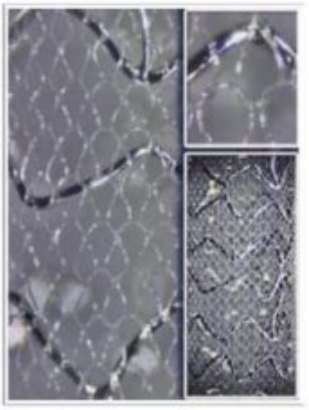
Cano et al. Rev Bras Cardiol Invasiva 2013; 21(2): 159-64.

MicroNet Prevents Distal Embolization and Other Vascular Disease Challenges

- Proprietary technology
- Ultrathin PET* mesh provides meaningful clinical benefit versus conventional devices
- Provides revascularization benefit
- MicroNet acts as “safety net” by offering greater vessel area coverage to prevent large debris protrusion through the scaffold
- Made of a single fiber from a biocompatible polymer, widely used in other medical implants

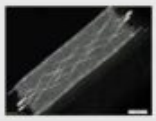






*PET – polyethylene terephthalate

Large Addressable Market

Embolic Prevention Products		Market Opportunity	CE Mark	Focus Area
MGuard™*		$1.7B	✓	Coronary AMI & SVG
CGuard™		$500M	✓ (FDA IDE draft protocol synopsis)	Carotid
NGuard™		$675M	2017E Planned Submission	Neurovascular
PVGuard™		$1.7B	2018E Planned Submission	Peripheral

* MGuard is a bare metal stent scaffold

Positive CGuard Data

Clinical trials support peri- and post-procedural safety and efficacy

- CARENET: 30-patient safety and efficacy clinical trial[1]
- Independent investigator-initiated clinical study: 30 patients with internal carotid artery stenosis[2]
- PARADIGM-101: 101-patient trial evaluating CGuard EPS in unselected, consecutive carotid patients (all-comers)[3,4]
- Ease of placement

Laboratory engineering evaluations[2]

- CGuard EPS provides high radial force and strong support in long stenotic lesions
- Structure adapted well to changes in vessel diameter and direction
- MicroNet mesh of CGuard EPS did not cause any measurable changes to specific mechanical parameters of the underlying stent

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

[1]Musialek P. The CARENET All-Comer Trial Using the CGuard™ MicroNet Covered Embolic Prevention Stent. Presented at the Leipzig International Course (LINC) 2015.
[2]Wissgott C. Clinical Results and Mechanical Properties of a Novel Double-Layered Carotid Stent (CGuard). J Endovasc Ther. 2016.
[3]Musialek P. Twelve-month Safety and Efficacy of CGuard™ Micronet-Covered Embolic Prevention Stent System: Routine Use to Perform Carotid Revascularization in Symptomatic and Increased Stroke Risk Asymptomatic Patients: The PARADIGM All-Comer Prospective Academic Study. Presented at the Transcatheter Cardiovascular Therapeutics 2016 Scientific Symposium.
[4]Mazurek M. Highly Calcific Carotid Lesions Endovascular Revascularizaton Using a Novel Dual-layer Carotid Stent System CGuard™: Analysis from the PARADIGM Study. Presented at the Transcatheter Cardiovascular Therapeutics 2016 Scientific Symposium.

CGuard Data Presentation at TCT 2016

12-month follow up data of PARADIGM-101 Study of CGuard EPS

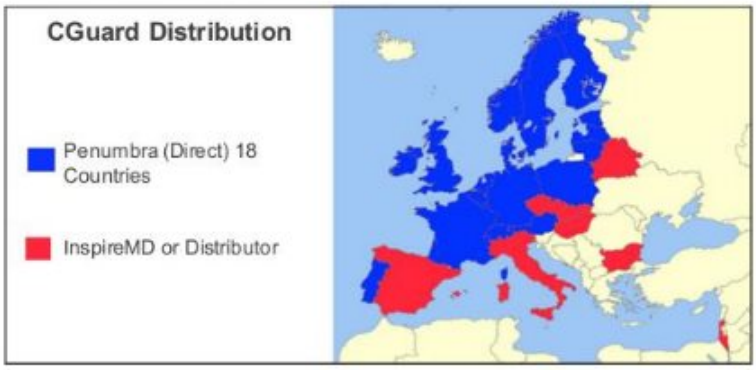
- No device-related adverse events at 12 months
- Vessel narrowing was reduced from 83±9% to only 6.7±5% ($p<0.001$) by independent core lab analysis
- Peri-procedural death/major stroke/myocardial infarction (MI) was 0%
- At 12 months the device showed a normal healing profile, and the patency of the external carotid artery was normal

* Mustalek, P, 2016. Data presented at TCT 2016.

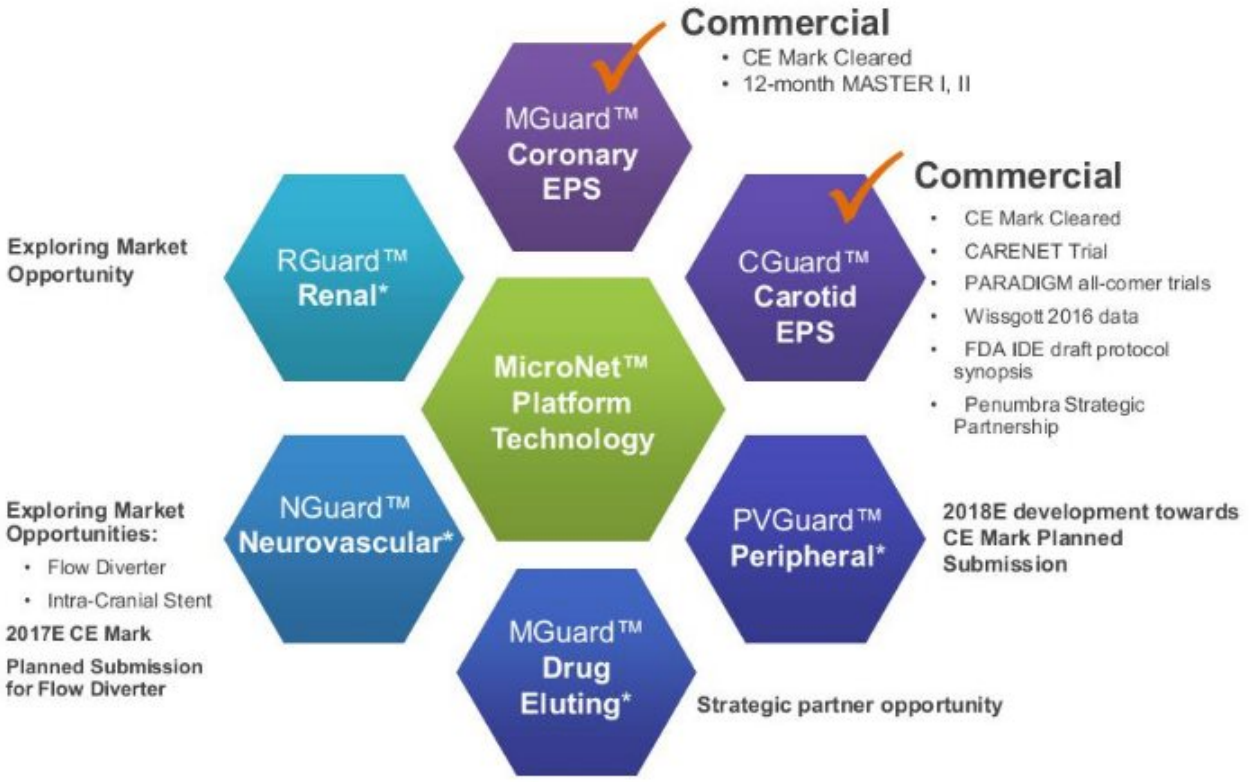
Broad EU Commercialization Support from a Growing Neurovascular Leader

Penumbra

- Strategic distribution agreement with Penumbra
- 18 European markets with opportunity to expand
- Comprehensive neurovascular product portfolio
- CGuard is a synergistic product offering
- Growing direct sales force throughout Europe
- Establishing a direct sales force focused on peripheral vascular



Expanding Pipeline Opportunities with MicroNet



* Planning & Development Phase

Flow Diversion for Neurovascular Aneurysms

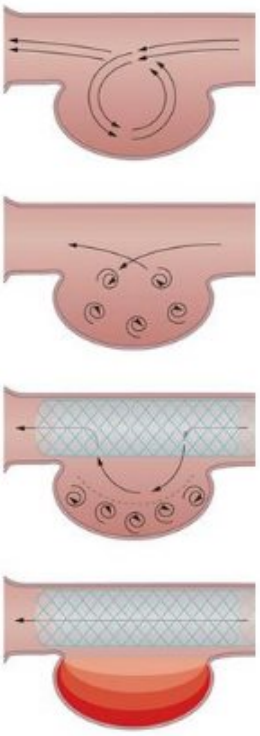
InspireMD

Objective

- Seal the aneurysm and prevent rupture

Current device therapies

- Coils to pack the aneurysm
- Flow diverters
  - Highly flexible, dense metal "tube"
  - Placed in main artery to seal off aneurysm and cause aneurysm thrombosis
  - Precise delivery required to avoid blocking other vessels



http://www.nature.com/nrcardio/journal/v11/n2/full/nrcardio.2013.196.html

Innovation Enables Growth in the Neurovascular Market

Flow Diversion for Unruptured Brain Aneurysms

Next Generation Technology

- Aneurysm Therapy (all types): $550M*
- Flow diverters are estimated to be 25% of the aneurysm market
- Neurovascular products: estimated 15% CAGR from 2010-2016

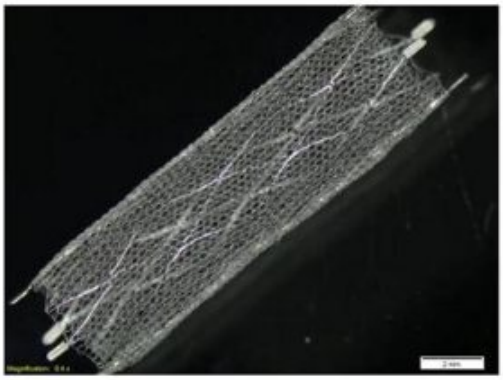
Global Flow Diversion - $125M**

Competitive Landscape:

Product	Company	Approval
Pipeline	Medtronic/Covidien	CE Mark 2014 FDA 2011
Surpass	Stryker	CE Mark 2010
Silk	Balt Extrusion	CE Mark 2008

* 2013 MRG Neuro Report, 2010 Ev3 Revenue Data ** 2014 projection based on 2013 actuals

InspireMD Flow Diverter Advantage



- Low profile, flexible, open cell scaffold = Easy to deliver
- Low metal ratio = Potential for reduced anti-thrombosis medication
- Re-accessible through MicroNet = Allows for further treatment, if needed which is impossible with current flow diverters
- Can be placed in side branches and bifurcations = Will not block blood flow into major side vessels, which is impossible with current technology
- Published success with MicroNet in coronary and carotid aneurysms

Intellectual Property Portfolio

- Proprietary platform technology supported by a robust intellectual property portfolio.
- Continue to strengthen and broaden patent protection globally.
- Progress over the last year imparts important rights on existing products and technologies and will enable future pipeline products.

PATENT RIGHTS	ISSUED	ALLOWED	PENDING
US	4	**2**	12
Rest of World (ROW)	16	**1**	14

Upcoming Anticipated Milestones

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

NYSE MKT: NSPR, NSPR.WS

Stock Price (11/11/16):	$2.45
Average Volume (3 Months):	358 K
Shares Outstanding (9/30/16):	1.4 M
Shares Outstanding Including Future Pref. Stock Conv. (9/30/16):	3.6 M
Market Capitalization (10/14/16):	$2.7 M
Total Cash:	$10.5 M as of 9/30/2016
US Headquarters:	Boston, MA
International Headquarters:	Tel Aviv, Israel
# of Employees (9/30/2016):	36

Investment Highlights

- **Revenue growth** driven by broader EU and Latin American launch of **CGuard**
  - Strategic distribution partnership with Penumbra (NYSE: PEN)
  - Strong, and growing, direct sales teams across key countries
  - Multiple and consistent clinical trial results using CGuard in a broad patient population, including high risk patients
- **Expanding opportunities** in the growing neurovascular and peripheral vascular markets
  - 2017E CE Mark Submission for NGuard
- **Broad portfolio** of patent-protected assets
- **Strategic collaboration opportunities** on multiple **MicroNet** product applications
- **Financial discipline** in line with development and growth initiatives
- Planned CGuard FDA IDE submission in 2017

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