

# INSPIREMD, INC.

## FORM 8-K (Current report filing)

Filed 08/05/15 for the Period Ending 08/05/15

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

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): August 5, 2015

**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.)

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

02116  
(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

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(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))
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**Item 1.01 Entry into a Material Definitive Agreement.**

On August 5, 2015, InspireMD, Ltd. (“InspireMD”), a wholly owned subsidiary of InspireMD, Inc. (the “Company”), entered into a distribution agreement (the “Distribution Agreement”) with Penumbra, Inc. (“Penumbra”), pursuant to which Penumbra will act as the exclusive distributor of the Company’s CGuard carotid embolic prevention system products (the “Products”) in Austria, France, Sweden, Denmark, Norway, Finland, Estonia, Lithuania, Portugal, Switzerland and the United Kingdom and Ireland (the “Exclusive Territory”). The territory covered by the Distribution Agreement also includes non-exclusive rights to distribute the Products in Latvia, Benelux, Germany and Poland (together with the Exclusive Territory, the “Territory”).

Under the terms of the Distribution Agreement, InspireMD will use all commercially reasonable efforts to obtain all required permits, licenses and other approvals necessary to import, market or sell the Products in the Territory. Within 60 days after receipt of all such required approvals in a given Territory, Penumbra shall place its initial stocking order for the Products, for which Penumbra will pay one-half of the purchase price upon placing such order and the remainder of the purchase price 30 days after receipt of the Products and InspireMD’s invoice for such Products. If, in InspireMD’s reasonable discretion, Penumbra fails to order a sufficient quantity of Products to successfully commercialize the Products in the applicable Territory, then InspireMD may reduce the Territory covered by the Distribution Agreement upon providing 60 days’ notice to Penumbra.

The Distribution Agreement requires Penumbra to use commercially reasonable efforts to purchase Products in certain minimum target amounts agreed to by the parties for the 2015 and 2016 calendar years. For all subsequent calendar years during the term of the Distribution Agreement, the parties will agree to the minimum annual purchase targets at least 30 days prior to the commencement of such calendar year, which shall be determined in good faith by mutual agreement, taking into account various relevant factors, such as the sales attained during the preceding calendar year and prevailing market conditions, among others. The parties have fixed the initial prices to be paid by Penumbra for Products through December 31, 2015, which remain subject to certain reductions for inventory shelf life and other adjustments to be negotiated by the parties.

The initial term of the Distribution Agreement ends on December 31, 2018, unless sooner terminated pursuant to the termination rights set forth therein. Either party may terminate the Distribution Agreement (i) without cause upon providing 60 days’ notice to the other party, (ii) upon the other party’s material breach of the Distribution Agreement, which is not cured 30 days after written notice thereof from the non-breaching party and (iii) immediately without notice upon the bankruptcy, insolvency, dissolution, assignment for the benefit of creditors or similar event with respect to the other party. InspireMD may also terminate the Distribution Agreement if it reasonably believes that Penumbra, or any party acting on its behalf, has violated the United States Foreign Corrupt Practices Act of 1977. In addition, if at any time during the term of the Distribution Agreement, Penumbra distributes or offers for sale products that, in InspireMD’s reasonable judgment, compete with any of the Products, then InspireMD may terminate the Distribution Agreement or change the exclusive rights granted to non-exclusive rights upon providing 30 days’ notice to Penumbra.

Pursuant to the Distribution Agreement, InspireMD is subject to customary covenants and other continuing regulatory, record-keeping and reporting obligations.

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The Distribution Agreement also contains a limited three year warranty for the Products and other mutual confidentiality and indemnification obligations for InspireMD and Penumbra.

The foregoing summary of the Distribution Agreement is not complete, and is qualified in its entirety by reference to the full text of such Distribution Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015.

#### **Item 2.02 Results of Operations and Financial Condition.**

On August 5, 2015, the Company issued a press release announcing its financial and operating results for the fiscal quarter ended June 30, 2015. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "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, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### **Item 7.01 Regulation FD Disclosure.**

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 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2, shall not be deemed "filed" for the purposes of Section 18 of 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 8.01 Other Events.**

On August 5, 2015, the Company issued a press release announcing that InspireMD has entered into the Distribution Agreement with Penumbra. A copy of the press release is attached hereto as Exhibit 99.3, and is incorporated herein by reference.

#### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
*99.1	Earnings release dated August 5, 2015.
*99.2	Slide Presentation of InpsireMD, Inc. dated August 2015.
99.3	Press release dated August 5, 2015.

\*This exhibit is furnished pursuant to Item 2.02 or Item 7.01, as applicable, and shall not be deemed to be "filed."

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**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.

Date: August 5, 2015

**InspireMD, Inc.**

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer



## InspireMD Reports Financial Results for the Second Quarter Ended June 30, 2015

**BOSTON, MA** – August 5, 2015 – [InspireMD, Inc.](#) (NYSE MKT: NSPR) (“InspireMD” or the “Company”), a leader in stent embolic prevention systems (“EPS”), today announced its financial and operating results for the second quarter ended June 30, 2015.

The Company is in the second full quarter of a strategic transition into penetrating the carotid and neuro intervention markets utilizing its proprietary MicroNet™ technology. MicroNet technology has the potential to improve the clinical outcomes for patients who are at risk of embolization during Carotid Artery Stenting (CAS), a highly attractive \$500 million dollar global market segment within the interventional medical device industry. Early clinical results of the CGuard™ Embolic Prevention System have been highly positive in the CARENET and PARADIGM data sets.

Alan Milinazzo, CEO of InspireMD, commented, “As previously stated, 2015 is a transition year for InspireMD, as we continue to execute on our strategic plan with a sense of urgency and the resources to deliver on key milestones. We remain on course to drive increased market adoption of our carotid platform and look forward to a full European market launch with our new strategic distribution partner, Penumbra Inc. We also advanced our development program for our neurovascular platform and we look forward to broader collaboration discussions, including those facilitated by our Penumbra partnership.”

### Recent Operating Highlights:

#### COMMERCIAL

- Secured a CGuard strategic distribution agreement with Penumbra Inc., a market leader in the interventional neuroradiology and peripheral vascular markets.
- Reported sequential revenue increases of 182% for carotid and 24% for coronary product sales in the quarter.
- On track for full Penumbra commercial launch of CGuard in Q4 of 2015.

#### REGULATORY / CLINICAL / PRODUCT DEVELOPMENT

- Reported positive results from the investigator led PARADIGM trial in an all comers patient population.
  - Advanced our next generation neurovascular flow diverter program for a 2016 CE Mark submission.
  - Received CE approval for MGuard Prime in Brazil.
  - Awarded 2015 Frost and Sullivan European Innovation Award for Product Development.
  - Received an OEM (Original Equipment Manufacturer) partnership proposal to develop a next generation coronary DES (Drug Eluting Stent) platform with MicroNet technology.
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## FINANCIAL

- Comprehensive cash management, with steady, measured declines in monthly cash use.
- Continued implementation of cost containment activities while supporting key development programs.

### Quarter Ended June 30, 2015 Financial Results

Revenue for the second quarter ended June 30, 2015 increased \$0.5 million to \$0.7 million compared to \$0.2 million during the same period in 2014. The 2015 period included an increase in sales of MGuard™ Prime EPS, our coronary product, due to the suspension of sales that occurred in the three months ended June 30, 2014 due to our voluntary field corrective action (“VFA”) which began on April 30, 2014, as well as sales of our new product CGuard™ EPS, our carotid product, which was launched in October 2014.

The Company's gross loss for the quarter ended June 30, 2015 was \$0.2 million compared to a gross loss of \$0.4 million for the same period in 2014. The improvement of 45.8% was largely attributable to the increase in product revenues and no costs associated with our VFA, which occurred during the three months ended June 30, 2014. This improvement was partially offset by write-offs and other related adjustments of MGuard™ Prime EPS inventory due to the trend of increased usage of drug eluting stents rather than bare metal stents in STEMI patients.

Total operating expenses for the quarter ended June 30, 2015 were \$3.4 million, a decrease of 50.9% compared to \$6.8 million for the same period in 2014. This decrease was primarily due to a reduction of expenses related to MGuard™ Prime EPS's MASTER II trial, which was suspended in October 2014, a decrease in compensation related expenses and other savings associated with our cost reduction plans.

The loss from operations for the quarter ended June 30, 2015 was \$3.6 million, a decrease of 50.6% compared to a loss of \$7.2 million for the same period in 2014.

Financial expenses for the quarter ended June 30, 2015 remained flat at \$0.3 million compared to the same period in 2014.

The net loss for the quarter ended June 30, 2015 totaled \$3.9 million, or \$0.05 per basic and diluted share, compared to a net loss of \$7.6 million, or \$0.22 per basic and diluted share, in the same period in 2014.

Non-GAAP net loss for the quarter ended June 30, 2015 was \$2.9 million, or \$0.04 per basic and diluted share, a decrease of 55.6% compared to a non-GAAP net loss of \$6.5 million, or \$0.19 per basic and diluted share, for the same period in 2014. The non-GAAP net loss for the quarter ended June 30, 2015 primarily excludes \$1.0 million of share-based compensation. The non-GAAP net loss for the quarter ended June 30, 2014 primarily excludes \$1.1 million of share-based compensation.

### Six Months Ended June 30, 2015 Financial Results

Revenue for the six months ended June 30, 2015 decreased \$0.5 million to \$1.2 million compared to \$1.7 million during the same period in 2014. The 2015 period included an expected decline in sales of MGuard™ Prime EPS associated with the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients and the impact of the transition to a new commercial strategy built on using third party distributors for our products offset by sales of our new product CGuard™ EPS, which was launched on a limited basis in October 2014.

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The Company's gross loss for the six months ended June 30, 2015 was \$0.2 million, a decrease of 153.4% compared to a gross profit of \$0.5 million for the same period in 2014. The decrease was largely attributable to the decrease in product revenues and write-offs of inventory due to the trend of increased usage of DES stents in STEMI patients, longer shelf life requirements and the transition to the rapid exchange delivery system for CGuard from the over the wire platform.

Total operating expenses for the six months ended June 30, 2015 were \$8.2 million, a decrease of 37.9% compared to \$13.2 million for the same period in 2014. This decrease was primarily due to a reduction of expenses related to MGuard's MASTER II trial, a decrease in compensation related expenses and other savings associated with our cost reduction plans.

The loss from operations for the six months ended June 30, 2015 was \$8.5 million, a decrease of 33.7% compared to a loss of \$12.8 million for the same period in 2014.

Financial expenses for the six months ended June 30, 2015 decreased 14.9% to \$0.6 million from \$0.7 million during the same period in 2014. This decrease was primarily due to a decrease in interest expenses.

The net loss for the six months ended June 30, 2015 totaled \$9.1 million, or \$0.14 per basic and diluted share, compared to a net loss of \$13.5 million, or \$0.40 per basic and diluted share, in the same period in 2014.

Non-GAAP net loss for the six months ended June 30, 2015 was \$6.7 million, or \$0.11 per basic and diluted share, a decrease of 41.3% compared to a non-GAAP net loss of \$11.4 million, or \$0.34 per basic and diluted share, for the same period in 2014. The non-GAAP net loss for the six months ended June 30, 2015 primarily excludes \$2.0 million of share-based compensation and \$0.3 million of expense related to an impairment of a royalties buyout asset. The non-GAAP net loss for the six months ended June 30, 2014 primarily excludes \$2.1 million of share-based compensation.

#### **Cash and Cash Equivalents**

As of June 30, 2015, cash and cash equivalents were \$9.8 million, compared to \$6.3 million as of December 31, 2014.

#### **Quarterly Conference Call Details**

The Company has scheduled a conference call to discuss the second quarter 2015 financial results for today at 4:30 PM Eastern. To participate in the conference call, please dial (866) 652-5200 (United States) or (412) 317-6060 (International) and request the InspireMD call. A live webcast of the call will also be available on the Investor Relations section of the Company's website at [www.inspire-md.com/site\\_en/for-investors](http://www.inspire-md.com/site_en/for-investors). Please allow 10 minutes prior to the call to visit this site to download and install any necessary audio software.

An archive of the webcast will be available approximately two hours after completion of the live event and will be accessible on the Investor Relations section of the Company's website at [www.inspire-md.com/site\\_en/for-investors](http://www.inspire-md.com/site_en/for-investors) for a limited time. A dial-in replay of the call will also be available to those interested until August 19, 2015. To access the replay, dial (877) 344-7529 (United States) or (412) 317-0088 (International) and enter code: 10068462.

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## About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

## Forward-looking Statements

*This press release 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.*

## Investor Contacts:

### InspireMD, Inc.

Craig Shore  
Chief Financial Officer

Phone:  1-888-776-6804 FREE  
Email: [craigs@inspiremd.com](mailto:craigs@inspiremd.com)

## PCG Advisory

Vivian Cervantes  
Investor Relations  
Phone: (212) 554-5482

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**CONSOLIDATED STATEMENTS OF OPERATIONS <sup>(1)</sup>**  
(U.S. dollars in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
<b>Revenues</b>	\$685	\$193	\$1,162	\$1,675
Cost of revenues	897	584	1,411	1,209
<b>Gross Profit (Loss)</b>	(212)	(391)	(249)	466
Operating Expenses:				
Research and development	747	2,448	2,099	5,025
Selling and marketing	995	1,948	2,012	3,224
General and administrative	1,587	2,448	3,557	4,987
Restructuring and impairment expenses	32	-	546	-
Total operating expenses	3,361	6,844	8,214	13,236
Loss from operations	(3,573)	(7,235)	(8,463)	(12,770)
Financial expenses	322	325	628	738
Loss before tax expenses	(3,895)	(7,560)	(9,091)	(13,508)
Tax expenses (Income)	(17)	2	(1)	22
<b>Net Loss</b>	<b>\$(3,878)</b>	<b>\$(7,562)</b>	<b>\$(9,090)</b>	<b>\$(13,530)</b>
Net loss per share – basic and diluted	\$(0.05)	\$(0.22)	\$(0.14)	\$(0.40)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	76,035,721	34,115,814	63,067,454	34,083,936



**RECONCILIATION OF NON-GAAP NET LOSS <sup>(2)</sup>**

(U.S. dollars in thousands, except per share data)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2015	2014	2015	2014
<b>GAAP Net Loss</b>	\$(3,878)	\$(7,562)	\$(9,090)	\$(13,530)
Non-GAAP Adjustments:				
Share-based compensation expenses	970	1,080	1,999	2,099
Impairment of royalties buyout	-	-	316	-
Royalties buyout expenses and amortization	22	25	58	40
Non-cash financial expenses (income) <sup>(3)</sup>	-	(41)	-	(47)
<b>Total Non-GAAP Adjustments</b>	<b>992</b>	<b>1,064</b>	<b>2,373</b>	<b>2,092</b>
<b>Non-GAAP Net Loss</b>	<b>\$(2,886)</b>	<b>\$(6,498)</b>	<b>\$(6,717)</b>	<b>\$(11,438)</b>
Non-GAAP net loss per share – basic and diluted	\$(0.04)	\$(0.19)	\$(0.11)	\$(0.34)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	76,035,721	34,115,814	63,067,454	34,083,936



CONSOLIDATED BALANCE SHEETS <sup>(4)</sup>  
(U.S. dollars in thousands)

ASSETS	June 30, 2015	December 31, 2014
Current Assets:		
Cash and cash equivalents	\$9,768	\$6,300
Accounts receivable:		
Trade	728	635
Other	193	359
Prepaid expenses	76	150
Inventory	1,229	1,924
<b>Total current assets</b>	<b>11,994</b>	<b>9,368</b>
Non-current assets:		
Property, plant and equipment, net	546	622
Deferred issuance costs	119	153
Funds in respect of employee rights upon retirement	495	498
Long term prepaid expenses	30	66
Royalties buyout	378	752
<b>Total non-current assets</b>	<b>1,568</b>	<b>2,091</b>
<b>Total assets</b>	<b>\$13,562</b>	<b>\$11,459</b>

**LIABILITIES AND EQUITY (CAPITAL DEFICIENCY)**

	<b>June 30, 2015</b>	<b>December 31, 2014</b>
<b>Current liabilities:</b>		
Accounts payable and accruals:		
Trade	\$491	\$909
Other	2,654	3,576
Advanced payment from customers	169	179
Current maturity of loan	4,015	3,809
<b>Total current liabilities</b>	<b>7,329</b>	<b>8,473</b>
<b>Long-term liabilities:</b>		
Liability for employees rights upon retirement	698	687
Long term loan	3,159	5,086
<b>Total long-term liabilities</b>	<b>3,857</b>	<b>5,773</b>
<b>Total liabilities</b>	<b>11,186</b>	<b>14,246</b>
<b>Equity:</b>		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 76,048,385 and 41,368,889 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	118,870	104,620
Accumulated deficit	(116,501)	(107,411)
<b>Total equity (capital deficiency)</b>	<b>2,376</b>	<b>(2,787)</b>
<b>Total liabilities and equity (less capital deficiency)</b>	<b>\$13,562</b>	<b>\$11,459</b>



(1) All 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission, all 2014 financial information is derived from the Company's 2014 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) Our non-GAAP net loss is presented as management uses this supplemental non-GAAP financial measure to evaluate performance period over period, analyze the underlying trends in our business, and establish operational goals and forecasts that are used in allocating resources. We believe by presenting this additional measurement, we are providing investors with greater transparency to the information used by our management for our financial and operational decision-making, as well as allowing investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

(3) Non-cash financial income relates to the issuance of shares as a result of the anti-dilution rights of our March 2011 investors.

(4) All June 30, 2015 financial information is derived from the Company's 2015 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2014 financial information is derived from the Company's 2014 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2014 filed with the Securities and Exchange Commission.

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NYSE MKT: NSPR

August 2015





# 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 control of InspireMD, Inc. (the "Company"), 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 the Company's 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 the Company's products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) product malfunctions, (vii) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payors for the Company's products, (ix) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) the Company's reliance on single suppliers for certain product components, (xii) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain, (xiii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing it 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 and (xiv) the escalation of hostilities in Israel, which could impair the Company's ability to manufacture its products. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements are set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Transition Report on Form 10-K/T and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these reports free of charge on the Securities and Exchange Commission's web site at [www.sec.gov](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.

*An emerging medical device company developing and commercializing advanced technology for interventional cardiology and other vascular procedures*

## NYSE MKT: NSPR

<b>Stock Price (8/3/15):</b>	\$0.28
<b>52 Week Range:</b>	\$0.18 - \$2.57
<b>Average Volume:</b>	1,248K
<b>Shares Outstanding (8/3/15):</b>	78 M
<b>Market Capitalization (8/3/15):</b>	\$21.8 M
<b>Analyst Coverage:</b>	Cowen Group: Josh Jennings Empire Asset Management: Cathy Reese
<b>Total Cash (8/3/2015):</b>	\$9.8 M
<b>US Headquarters:</b>	Boston, MA
<b>International Headquarters:</b>	Tel Aviv, Israel
<b># of Employees (8/3/2015):</b>	46



# Investment Highlights

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- 2015 return to revenue growth driven by the full launch of carotid platform through strategic distribution partnership with Penumbra, Inc.
- Operating and financial realignment inline with development and growth initiatives.
- Advancing into highly valued Neuro and Peripheral markets to leverage MicroNet technology into high growth segments.
- Expanding collaboration activities on multiple MicroNet technology applications.

## Leadership: Significant Track Records of Success

### EXECUTIVE TEAM

**Alan Milinazzo**, President, CEO & Director

- Medtronic
- Boston Scientific

**Craig Shore**, CFO

- Pfizer
- General Electric

**Dr. James Barry**, COO

- Boston Scientific
- Howmedica Division of Pfizer

**Eli Bar**, CTO

- Nicast

**Gwen Bame**, VP Corporate Development

- Boston Scientific
- Covidien

**David Blossom**, VP Global Marketing & Strategy

- Boston Scientific
- Covidien

### BOARD OF DIRECTORS

**Dr. Sol Barer**, Chairman

- Former Chairman and CEO, Celgene

**Alan Milinazzo**, President, CEO & Director

- Medtronic
- Boston Scientific

**Dr. James Barry**

- SVP Corporate Technology Development at Boston Scientific
- Howmedica Division of Pfizer

**Michael Berman**

- Pres. Boston Scientific/Scimed
- Founder, Velocimed and Lutonix

**James Loughlin**

- KPMG
- Celgene Audit Chair

**Paul Stuka**

- Founder, Osiris
- Fidelity Management and Research

**Dr. Campbell Rogers**

- CMO, Heartflow
- CSO, Cordis/JNJ
- Associate Professor, Harvard School of Medicine



U.S. NEWS

# Stents Boost Stroke Recovery, Study Finds

Using Devices to Pull Clots From Brain Arteries Can Help Patients

By THOMAS M. BURTON

Using a device to extract blood clots from brain arteries can significantly improve patients' ability to rebound from a stroke, according to a landmark study published Wednesday.

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**The New York Times** Times Essentials Search:  Capital One

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**Precious Hours, Then Lives, Lost in Stroke's Wake**



**Well** Take Better Care of Yourself

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- Think Like a Doctor: Snag Off Her Teeth** February 13, 2014

**The IBM Cloud**

**TIME** BUSY? MULTITASKING? IS YOUR MIND UNLATCHED?

**THE SECRET KILLER**

• The surprising link between INFLAMMATION and HEART ATTACKS, CANCER, ALZHEIMER'S and other diseases  
• What you can do to fight it



# Technology: MicroNet™

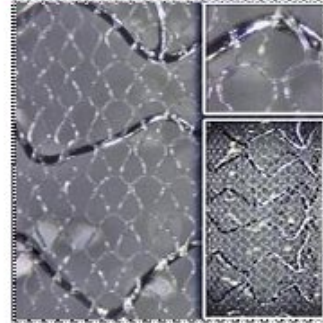
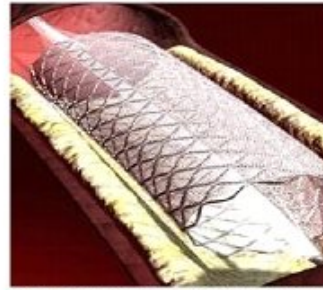


*Beyond Stenting: MicroNet Mesh for Embolic Prevention*

## **MicroNet Platform**

*Combines stent and embolic protection in a single device*

- Stent platform provides revascularization benefit
- MicroNet then acts as safety net by offering greater surface area coverage to prevent large debris flow
- Mesh configuration allows perfusion to vessel wall
- Made of a single fiber from a biocompatible polymer, widely used in medical implantations



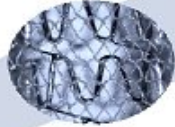
# Large Addressable Markets



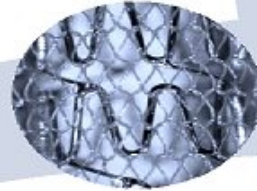
Expanding the MicroNet™ Platform



- MGuard™**
- ✓ \$1.7B Market
  - ✓ CE Mark Cleared
  - ✓ Coronary AMI, SVG



- CGuard™**
- ✓ \$500M Market
  - ✓ CE Mark Cleared
  - ✓ Carotid



- NVGuard**
- ✓ \$125M Flow Diversion Market
  - ✓ \$550M Aneurysm Market
  - ✓ 2016E CE Mark Planned Submission for Flow Diverter
  - ✓ Neurovascular

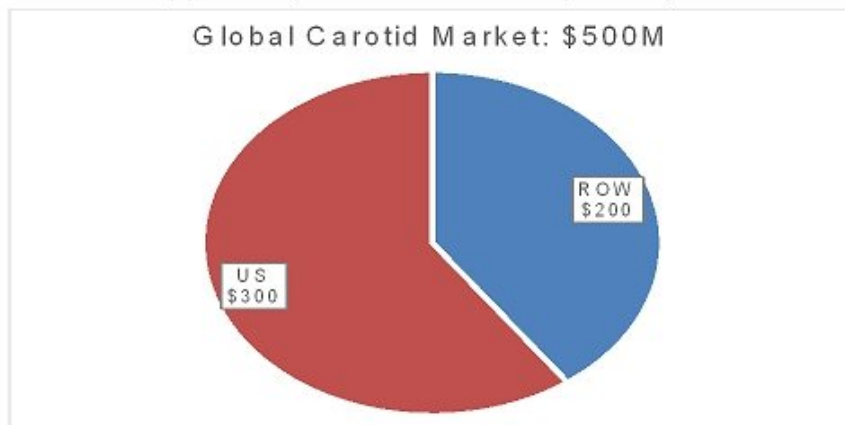
- PVGuard**
- ✓ \$1.7B Market
  - ✓ 2017E CE Mark Planned Submission
  - ✓ Peripheral

# Carotid Market Opportunity



*An Enhanced Minimally Invasive Solution*

- Standard of care: Open surgery: Carotid EndArterectomy (CEA)
- Current stents have not improved on CEA stroke rates (CREST)
- Mesh covered stent category has the potential to convert CEA to CAS
- CARENET 30-day and 6-mo data show CGuard better than previous technology/therapy
- PARADIGM physician-initiated trial validated benefits of CGuard in an all-comer population
- Immediate commercial opportunity with revenue ramp throughout 2015



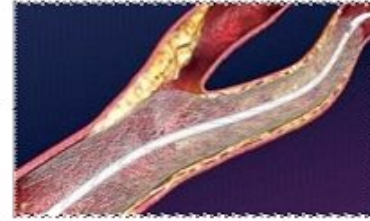
Source: JMP Securities, 2014



## **CGuard™ Embolic Prevention System**

*Combines stent and embolic protection in a single device*

- Stent platform provides revascularization benefits
- MicroNet acts as safety net by offering greater plaque scaffolding to prevent prolapse related to late embolization



- CE marked
- Self-expanding nitinol stent
- Global market valued at \$500M\*
- Strong CARENET FIM data released 9/14 and 1/15
- Impressive all-comer data from PARADIGM presented 5/15
- First commercial orders (LMR) received Q4 2014

\*Source: JMP Securities, 2014

### **CARENET (CARotid Embolic protection using microNET) FIM\* Clinical Trial**

- 30 Patient Safety and Efficacy clinical trial
- Prospective, multi-center, multispecialty, non-randomized single arm study
- DWMRI follow ups at 48hrs and 30 days for “gold-standard” neurological analysis

### **CARENET Highlights: 30 day Results Announced at TCT 2014**

- Achieved primary end point
- 100% procedural success
- Zero MACCE at 30 days
- 50% fewer new ischemic lesions compared to historical non-mesh carotid artery stenting data
- Average lesion volume per patient 10 times smaller compared to historical non-mesh carotid artery stenting data

### **CARENET Highlights: 6 mo Results Announced at LINC 2015 and EuroPCR 2015**

- 3.6% MACCE rate at 6 months (Comparative data 8.09%)
- 6 month ultrasound analysis was indicative of healthy healing without restenosis concern with patent external and internal carotid arteries

\* FIM , First in Man

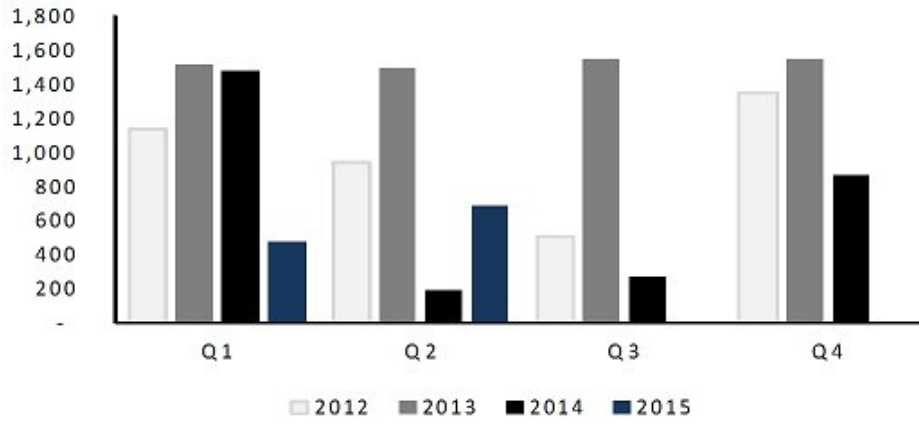
**PARADIGM (Prospective evaluation of All-comer percutaneous carotid revascularization in symptomatic and increased-risk asymptomatic carotid artery stenosis using CGuard™ Mesh-covered embolic prevention system) Physician Initiated All-Comers Study**

- Objective: To evaluate feasibility and outcome of routine anti-embolic stent system in unselected, consecutive carotid patients (all-comers)
- Investigator-independent neurological and angiographic evaluation
- 71 CGuard devices placed in 68 pts
- Device success: 100%; Procedure success: 100%
- MACCE (Death/stroke/MI) @ 48 hr: 0% @ 30 day: 0%
- Conclusions:
  - "> 90% all-comer carotid artery stenosis pts, including >50% symptomatic pts, can be treated using CGuard."
  - "Endovascular revascularization with routine use of the CGuard in an unselected patient population is extremely safe"
  - "Use of the CGuard enables endovascular reconstruction of the diseased carotid artery across a wide lesion spectrum in absence of clinical complications."

# Commercial Profile



Revenue Growth Driven by CGuard™ RX



## Strategic Distribution Partnership

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*Rationale: Predictable, Sustainable & Profitable Revenue Growth*

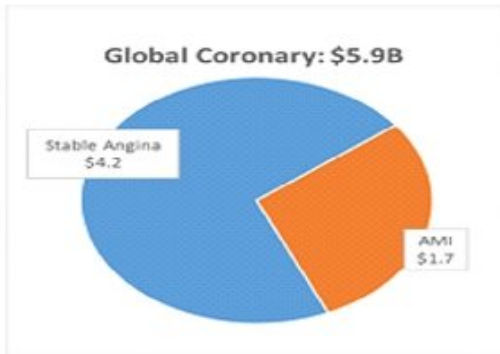
### Penumbra

- Founded in 2005 as a Neurovascular company with a clinically-driven product development strategy
- Reputation as the innovation leader in the neurovascular field
- Extending success beyond stroke into the periphery and neurosurgical markets
- Track record of consistent, profitable growth
- Management team with decades of vascular experience
- Entering carotid market to complement their stroke portfolio

# Coronary MGuard™ EPS

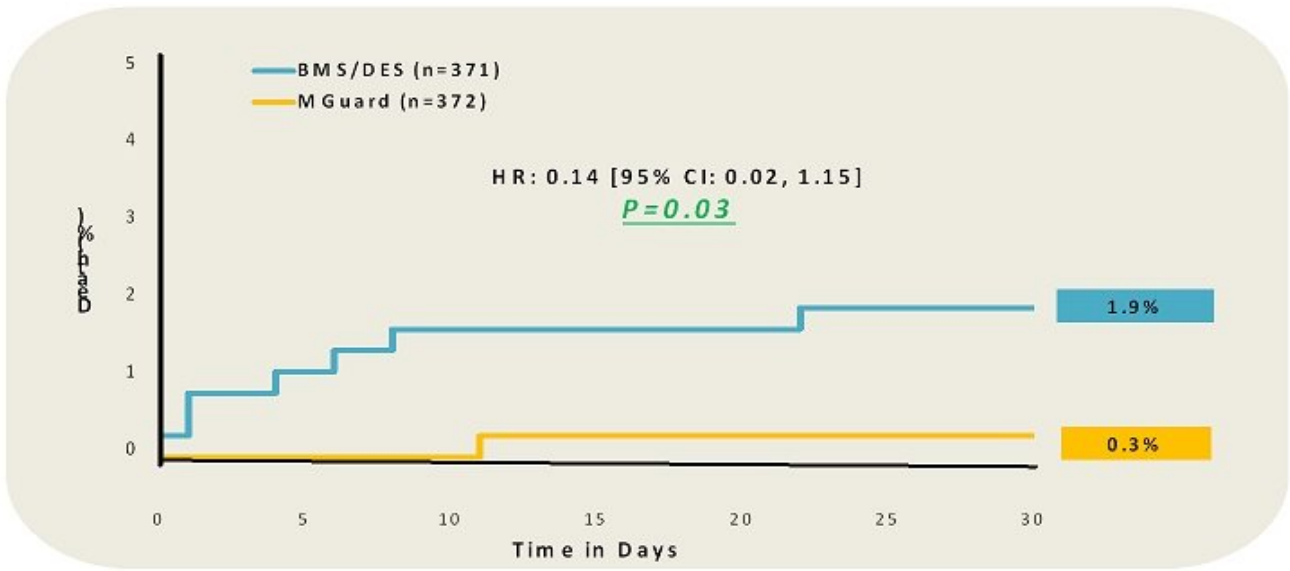


Improving AMI Patient Outcomes



- Current stents not specifically designed for AMI
- Distal embolization occurs in up to 73% of cases\*
- Majority of AMI market is outside of the U.S. (~60%)
- MGuard clinical experience including two randomized trials MASTER I and MASTER II with data showing sustained mortality rates
- Coronary market to be pursued with strategic partner support

MASTER I & II Pooled: All Cause Mortality at 30 days (743 patients)



# Robust Pipeline



Expanding Indications with MicroNet™



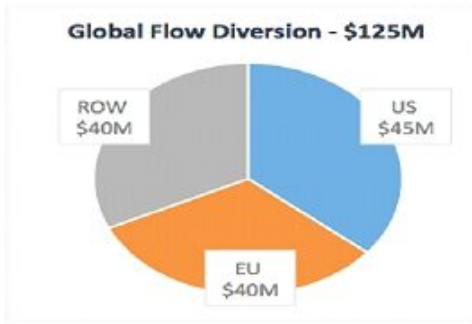
\*Planning & Development Phase



## The Flow Diversion System

*The preferred solution for unruptured aneurysm treatment*

- Current designs have sub-optimal trackability and in vessel flexibility
- MicroNet meets need to simultaneously manage thrombosis of the aneurysmal sac while preserving the patency of the adjacent small vessels



**2014 Competitive Landscape: Relatively Fewer Players with Limited Innovation**

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

*Differentiation Yields Increased Utility*

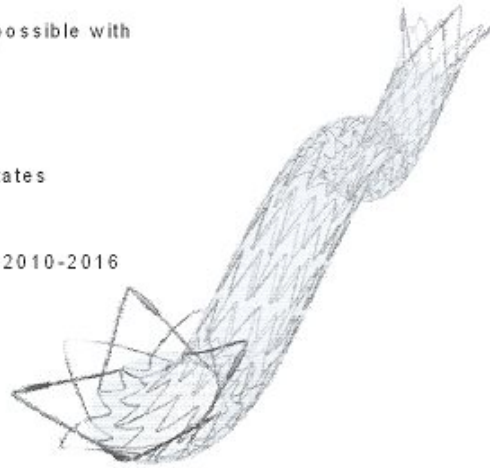
## **Our Significant Advantage Over Existing Flow Diverters**

- MicroNet aperture & size
- Low metal to artery ratio
- Can be placed in side branches and bifurcations, which is impossible with current technology

## **Total Aneurysm Market Value: \$946M**

- Aneurysm Therapy (all types): \$550M
- Aneurysms account for 74% of neuroendovascular disease states
- Estimated that flow diverters can treat 25% of all aneurysms
- Wide-neck Aneurysm Procedures: \$350M
- Non-coil neurovascular products: estimated 12% CAGR from 2010-2016

*"Devices in the European neurovascular device market will face significant competition from emerging treatments, such as INR flow diversion"*



# PVGuard™ Peripheral



Enabling a New Solution: Peripheral Embolic Protection



## The Embolic Prevention System

A new stent category as the preferred solution for peripheral intervention

- Current stents not specifically designed for embolic protection
- Mesh covered stent category emerging as immediate opportunity
- Strong global growth profile with increased clinical complexity

Market Landscape 2014	
Company	EU Market Share
Abbott Laboratories	15%
Boston Scientific	15%
C. R. Bard	12%
W. L. Gore	10%
Covidien	9.5%
Cordis	7%

Source: MRG 2013/2014\_ReportLinker

# Target Milestones



Support & Execute on Growth Initiatives

	2015E	2016E	2017E
<b>R&amp;D/Clin/Reg</b>	CARENET I GM FU	NVGuard CE Mark Submission CGuard FDA IDE Submission DES CE Mark Submission *	PVGuard CE Mark Submission
<b>Corporate</b>	Strategic Partnership Penumbra	Strategic Partnership IV Strategic Partnership V	
<b>Operational</b>		Achieve Targeted COGS	
<b>Commercial</b>	CGuard RX Launch	CGuard RX Full Launch with Penumbra MOH Russia MGuard Prime	NVGuard Estimated CE Mark DES Estimated CE Mark

\*Subject to Strategic Partner Support

# Investment Summary

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- 2015 return to revenue growth driven by the full launch of carotid platform through strategic distribution partnership with Penumbra, Inc.
- Operating and financial realignment inline with development and growth initiatives.
- Advancing into highly valued Neuro and Peripheral markets to leverage MicroNet technology into high growth segments.
- Expanding collaboration activities on multiple MicroNet technology applications.



Alan Milinazzo, CEO  
(888) 776-6804  
alanm@inspiremd.com

Craig Shore, CFO  
(888) 776-6804  
craigs@inspiremd.com





**InspireMD Announces Distribution Partnership of its CGuard™ Embolic Prevention System with Penumbra, Inc.**

*Accelerates InspireMD's Access into Key Geographic & Specialty Markets*

*Enables CGuard™ to be Commercialized as Part of a Total Systems Solution*

**BOSTON, MA** – August 5, 2015 – [InspireMD, Inc.](http://InspireMD, Inc.) (NYSE MKT: NSPR) a leader in stent embolic prevention systems (“EPS”) and thrombus management technologies, today announced that it has entered into a partnership with Penumbra, Inc. to distribute its carotid CGuard™ EPS through their direct commercialization team. Penumbra is a leading interventional technology company that develops and markets innovative medical devices to the neurovascular and peripheral vascular communities around the world.

InspireMD has aggressively been pursuing a strategy in treating carotid artery disease and other neurovascular applications for its proprietary MicroNet™ technology. Clinical trials of the CGuard™ system, including the recent CARENET and PARADIGM studies, have continued to support the benefits of the MicroNet™ enhanced CGuard™ system resulting in increased commercial adoption throughout the European market.

Penumbra has a direct and distributor sales organization in all markets where the CGuard™ system is commercially available. Penumbra’s neurovascular product portfolio includes medical devices for ischemic stroke and brain aneurysms, as well as peripheral vascular products that include products for embolization and thrombectomy. Penumbra has approximately 1,000 global employees with direct sales operations in North America, Europe, and Australia. Penumbra sells through distributors in Asia and select other international markets.

Alan Milinazzo, CEO of InspireMD, commented, “We are excited to partner with a leading global organization such as Penumbra. The Penumbra commercial organization is a well-respected, strong and growing team of experienced professionals that will help communicate the benefits of our proprietary CGuard™ EPS to all specialists that manage carotid artery disease.” Milinazzo continued, “We are confident that the Penumbra team will successfully commercialize CGuard™ over the next several months. Penumbra’s customers have already started placing the CGuard™ device and are anxious to discuss additional possible uses of the MicroNet™ technology in the neurovascular space.”

In addition, Jim Pray, President, International of Penumbra, stated, “The Penumbra team is looking forward to offering the CGuard™ to our customers. The CGuard™ carotid system from InspireMD is unique and addresses many limitations of existing carotid stents. The CGuard™ offers an unmatched ability to protect against plaque protrusion and prevent embolic events. The InspireMD team has done a remarkable job getting this breakthrough technology to market and our customers are looking forward to incorporating it into their practices. We are fortunate to be able to partner with InspireMD.”

CGuard™ EPS is CE Mark approved. CGuard™ EPS, however, is not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

**About Penumbra, Inc.**

Penumbra, Inc. ([www.penumbrainc.com](http://www.penumbrainc.com)) is a global interventional therapies company that designs, develops, manufactures and markets innovative medical devices. The company has a broad portfolio of products that address challenging medical conditions and significant clinical need across two major markets, neuro and peripheral vascular. Penumbra has approximately 1,000 employees and sells its products to hospitals primarily through its direct sales organization in the U.S., most of Europe, Canada and Australia, and through distributors in select international markets.

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## **About InspireMD, Inc.**

InspireMD ([www.inspiremd.com](http://www.inspiremd.com)) seeks to utilize its proprietary MGuard™ with MicroNet™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard™), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

## **Forward-looking Statements**

*This press release 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.*

## **Investor Contacts:**

### **InspireMD, Inc.**

Craig Shore  
Chief Financial Officer

Phone:  1-888-776-6804  
Email: [craigs@inspiremd.com](mailto:craigs@inspiremd.com)

### **PCG Advisory**

Vivian Cervantes  
Investor Relations  
Phone: (212) 554-5482

### **Penumbra, Inc**

Penumbra Media Relations:  
Merryman Communications  
Betsy Merryman  
310-560-8176  
[betsy@merrymancommunications.com](mailto:betsy@merrymancommunications.com)

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