

## FORM 10-Q (Quarterly Report)

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## **FORM 10-O**

(Mark One) ☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended: September 30, 2015 OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to Commission file number: 001-35731 InspireMD, Inc. (Exact name of registrant as specified in its charter) 26-2123838 Delaware (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification No.) 321 Columbus Avenue Boston, MA 02116 (Address of principal executive offices) (Zip Code) (857) 453-6553 (Registrant's telephone number, including area code) Indicate by check mark whether registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ⊠ No □ Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\ oxtimes$  No  $\ \Box$ Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Large accelerated filer □ Accelerated filer ⊠ Non-accelerated filer □ Smaller reporting company □ (Do not check if a smaller reporting company) Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes \, \to \, \text{No} \, \text{\Bigs} The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of November 9, 2015: 7,785,268.

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## PART I - FINANCIAL INFORMATION

## **Item 1. Financial Statements**

## INSPIREMD, INC.

# INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) September 30, 2015

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The amounts are stated in U.S. dollars

## INSPIREMD, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited) (U.S. dollars in thousands)

	-	September 30, 2015		eember 31, 2014
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	6,509	\$	6,300
Accounts receivable:				
Trade, net		664		635
Other		199		359
Prepaid expenses		108		150
Inventory		1,081		1,924
Total current assets		8,561		9,368
NON-CURRENT ASSETS:				
Property, plant and equipment, net		516		622
Deferred issuance costs		102		153
Funds in respect of employees rights upon retirement		466		498
Long-term prepaid expenses		20		66
Royalties buyout		96		752
Total non-current assets		1,200		2,091
Total assets	\$	9,761	\$	11,459

## INSPIREMD, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited) (U.S. dollars in thousands)

	September 30, 2015	December 31, 2014
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 834	\$ 909
Other	2,403	3,576
Advanced payment from customers	170	179
Current maturity of loan	4,123	3,809
Total current liabilities	7,530	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	658	687
Long-term loan	2,147	5,086
Total long-term liabilities	2,805	5,773
COMMITMENTS AND CONTINGENT LIABILITIES		
(Note 11)		
Total liabilities	10,335	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value \$0.0001 per share; 125,000,000 shares authorized; 7,632,752 and 4,136,889 shares		
issued and outstanding at September 30, 2015 and December 31, 2014, respectively	7	4
Additional paid-in capital	119,561	104,620
Accumulated deficit	(120,142)	(107,411)
Total capital deficiency	(574)	(2,787)
Total liabilities net of capital deficiency	\$ 9,761	\$ 11,459

## INSPIREMD, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three months ended September 30,				Nine months ended			
					Septem	30,		
		2015		2014		2015		2014
REVENUES	\$	632	\$	273	\$	1,794	\$	1,948
COST OF REVENUES		543		349		1,954		1,558
GROSS PROFIT (LOSS)		89		(76)	'	(160)		390
OPERATING EXPENSES:								
Research and development		781		2,460		2,880		7,485
Selling and marketing		588		1,806		2,600		5,030
General and administrative		1,713		2,139		5,270		7,126
Restructuring and impairment expenses		418				964		
Total operating expenses		3,500		6,405		11,714		19,641
LOSS FROM OPERATIONS		(3,411)		(6,481)		(11,874)		(19,251)
FINANCIAL EXPENSES, net:								
Interest expense		246		361		822		1,072
Other financial expenses (income)		(18)		(48)		34		(21)
Total financial expenses		228		313		856		1,051
LOSS BEFORE INCOME TAXES		(3,639)		(6,794)		(12,730)		(20,302)
TAX EXPENSES (INCOME)		2		(19)		1		3
NET LOSS	\$	(3,641)	\$	(6,775)	\$	(12,731)		(20,305)
NET LOSS PER SHARE - basic and diluted	\$	(0.48)	\$	(1.96)	\$	(1.89)	\$	(5.93)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON								
STOCK USED IN COMPUTING NET LOSS PER SHARE - basic								
and diluted		7,630,985		3,458,152		6,753,011		3,425,162

## INSPIREMD, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(U.S. dollars in thousands)

	Nine months ended September 30,		
	2015 20		
CASH FLOWS FROM OPERATING ACTIVITIES:			,
Net loss	\$	(12,731) \$	(20,305)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization		195	181
Impairment of royalties buyout		576	
Loss from sale of property, plant and equipment		3	
Change in liability for employees right upon retirement		(29)	109
Financial expenses		191	279
Share-based compensation expenses		2,600	3,151
Loss on amounts funded in respect of employee rights upon retirement, net		11	15
Changes in operating asset and liability items:			
Decrease in prepaid expenses		88	37
Decrease (increase) in trade receivables		(29)	1,458
Decrease (increase) in other receivables		160	(157)
Decrease (increase) in inventory		843	(89)
Decrease in trade payables		(75)	(75)
Increase (decrease) in other payables and advance payment from customers		(1,182)	1,124
Net cash used in operating activities		(9,379)	(14,272)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment		(12)	(105)
Decrease in restricted cash			93
Amounts funded in respect of employee rights upon retirement, net		21	(55)
Net cash provided by (used in) investing activities		9	(67)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Taxes withheld in respect of share issuance		(88)	(115)
Proceeds from issuance of shares and warrants, net of \$1,315 and \$46 issuance costs, respectively		12,432	2,229
Repayment of long-term loan		(2,739)	(290)
Net cash provided by financing activities	<u></u>	9,605	1,824
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS		(26)	(42)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		209	(12,557)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD		6,300	17,535
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	\$	6,509 \$	4,978
	φ	0,505	4,770

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

#### NOTE 1 - DESCRIPTION OF BUSINESS

#### a. General

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. The Company's coronary products combining MicroNet and a bare-metal stent (MGuard Prime™ EPS) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). In October 2014, the Company launched a limited market release of its carotid embolic prevention system (CGuard™ EPS), which combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease, using an over-the-wire delivery system. In January 2015, the Company received CE mark approval for the rapid exchange delivery system and fully launched CGuard in countries in Europe. The Company markets its products through distributors in international markets, mainly in Europe and Latin America.

#### b. Liquidity

The Company has an accumulated deficit as of September 30, 2015, as well as net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations beyond the first half of 2016. Therefore, there is substantial doubt about the Company's ability to continue as a going concern .

Management's plans include the continued commercialization of their products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

During the first quarter of 2015, the board of directors approved to curtail developing and promoting our bare metal stent platform and implementing another cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses primarily to those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.).

## **NOTE 2 - BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2014, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 12, 2015. The balance sheet for December 31, 2014 was derived from the Company's audited financial statements for the twelve months ended December 31, 2014. The results of operations for the nine months ended September 30, 2015 are not necessarily indicative of results that could be expected for the entire fiscal year.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

#### NOTE 3 – RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In April, 2015, the Financial Accounting Standards Board ("FASB") issued guidance related to the presentation of Debt Issuance Costs. The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

On July 22, 2015, the FASB issued Accounting Standards Update 2015-11, Simplifying the Measurement of Inventory, which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out (LIFO) and the retail inventory method (RIM) are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

## **NOTE 4 - EQUITY:**

a. During the nine months ended September 30, 2015, the Company granted stock options to employees and directors to purchase a total of 214,520 shares of the Company's common stock. The options have exercise prices ranging from \$1.7 to \$8.3 per share, which were the fair market value of the Company's common stock on the date of each respective grant. Of the 214,520 options described above, 107,744 options are fully vested as of their grant date. The remaining options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0%; expected term of 5-6.5 years; expected volatility of 62.68%-71.12%; and risk-free interest rate of 1.41%-1.71%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$0.66 million.

b. During the nine months ended September 30, 2015, the Company granted a total of 132,353 restricted shares of the Company's common stock to employees, of which 43,300 restricted shares are subject to a one-year vesting period, 9,250 restricted shares are fully vested as of their grant date and are subject to a 6 month lock up period, 32,914 restricted shares are subject to a six-month vesting period and 46,889 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately \$0.96 million.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## (UNAUDITED)

- c. On March 9, 2015, the Company sold 3,436,968 shares of its common stock and warrants to purchase 3,436,968 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants, which are classified as equity, have a term of exercise of 5 years from the date of issuance and an exercise price of \$5.50. This offering resulted in net proceeds to the Company of approximately \$12.4 million after deducting placement agent fees and other offering expenses.
- d. On September 9, 2015, the stockholders approved the amendment of its Long Term Incentive Plan which was adopted by our board of directors on July 16, 2015 to increase the total number of shares of common stock issuable under such plan by 470,000 shares.
- e. On September 9, 2015, the stockholders approved the authorization of the board of directors, in its discretion, to amend the Amended and Restated Certificate of Incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio of one-for-ten and to reduce the number of authorized shares of our common stock from 125 million shares to 50 million shares.
- f. On September 30, 2015, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a one-for-ten reverse stock split of its common stock, par value \$0.0001 per share (the "Reverse Stock Split"), effective as of October 1, 2015, which decreased the number of issued and outstanding shares of common stock and restricted shares of common stock from 78 million shares to 7.8 million shares. The Company's authorized common stock was decreased from 125 million shares to 50 million shares. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

## NOTE 5- NET LOSS PER SHARE:

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, and restricted stocks as the effect is anti-dilutive.

The total number of shares of common stock related to outstanding options, warrants and restricted stock excluded from the calculations of diluted loss per share were 5,010,580 and 1,048,402 for the nine and three month periods ended September 30, 2015 and 2014, respectively.

## **NOTE 6 - FAIR VALUE MEASURMENT:**

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. If measured at fair value in the financial statements, these financial instruments would be classified as Level 3 in the fair value hierarchy. As of September 30, 2015, the carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments. The fair value of the loan received on October 23, 2013 (the "Loan") approximated its carrying amount since it bears interest at rates that approximate current market rates.

As of September 30, 2015 and December 31, 2014, allowance for doubtful accounts was \$349,000 and 337,000, respectively.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

## **NOTE 7 - INVENTORY:**

	September 30 2015		December 31, 2014	
	(\$ ir	(\$ in thousands)		
Finished goods	\$	275 \$	1,273	
Work in process		529	326	
Raw materials and supplies		277	325	
	\$ 1,	081 \$	1,924	

## NOTE 8- IMPAIRMENT OF ROYALTIES BUYOUT

During the nine month period ended September 30, 2015 the Company recorded expenses related to the impairment of our royalties buyout asset amounting to \$576,000 due to anticipated lower sales of MGuard Prime in the future resulting from industry preferences for drug eluting stents. The expense is recorded under "Restructuring and impairment expenses" in the consolidated statements of operations.

## NOTE 9 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	Sep	September 30, Decen 2015 20	
		ousands)	
Employees and employee institutions	\$	494	\$ 1,022
Accrued vacation and recreation pay		352	410
Accrued clinical trial expenses		589	1,016
Accrued expenses		863	993
Provision for sales commissions		96	120
Taxes payable		9	15
	\$	2,403	\$ 3,576

## **NOTE 10 - RELATED PARTIES:**

- a. During the nine month period ended September 30, 2015, the Company's chief executive officer was granted options to purchase 30,777 shares of common stock at an exercise price of \$7.2 per share, as well as 51,759 shares of restricted stock. Of the 51,759 shares of restricted stock, 31,250 were in lieu of salary as part of his amendment for his base salary to be paid 50% in cash payments with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock. See Note 4.
- b. During the nine month period ended September 30, 2015, directors of the Company were granted options to purchase an aggregate of 138,542 shares of common stock at exercise prices ranging from \$1.7-\$7.8, of which, 107,744 were in lieu of cash compensation that was owed to them for their services as directors for the third and fourth quarters of 2014 and the first through third quarter of 2015. See Note 4a.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## (UNAUDITED)

c. On June 29, 2015, the Company amended the employment agreement with the Company's CEO in order to, among other things, (i) modify the term of employment to end on June 30, 2016 unless earlier terminated by either party; and (ii) provide that, until the Company raises an aggregate of \$5 million from investors, the CEO will receive (A) with respect to his employment in 2015, 50% of his base salary in cash payments, with the remaining 50% having been paid to the CEO on January 26, 2015, through the issuance of 31,250 shares of restricted common stock of the Company valued at \$7.20 per share, representing the fair market value of the Company's common stock as of the market close on January 26, 2015, which will be subsequently adjusted based upon the volume-weighted average price of the Company's common stock during the calendar year ended December 31, 2015 (or during the period from January 2, 2015 through his termination date if his employment is terminated upon his death or disability, by the CEO for good reason, or by the Company without cause prior to December 31, 2015) to represent the equivalent of 50% of the CEO's base salary in 2015, and (B) with respect to his employment in 2016, 50% of his base salary from January 1, 2016 through June 30, 2016 to be paid in shares of restricted common stock of the Company valued at the fair market value of the Company's common stock as of the market close on January 2, 2016. The amendment also amends those certain provisions in the Employment Agreement related to payments on termination of employment.

With respect to the adjustment of the 31,250 shares of restricted common stock mentioned above, the Company determined, based on the provisions of ASC 718, that following the employee amendment, the related restricted stock compensation was classified from equity to a liability in the consolidated balance sheets and measured at fair value in the amount of \$83,000 and will subsequently be measured at fair value at each reporting period. As of September 30, 2015, the fair value of the liability is \$87,000.

## NOTE 11 - COMMITMENT AND CONTINGENT LIABILITIES:

## a. Litigation

- 1) In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company's former CEO and President for a declaratory and enforcement order that it is entitled to options to purchase 8,364 shares of the Company's common stock at an exercise price of \$7.60 per share. In December 2014 the court accepted a motion to dismiss the former CEO and president from the lawsuit. On May 27, 2015 the Company and the assignee of options accepted a settlement agreement pursuant to which the claim was removed and the plaintiff waived his entire claim against the Company, in consideration of the Company's consent to allow him to exercise 5,855 options of the Company's shares of common stock.
- 2) In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of \$193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of \$250,000 in the financial statements for the quarter ended December 31, 2012. In March 2015, the interest rate made by the Court of Appeal in Argentina was increased retroactively, which resulted in the provision increasing to \$340,000. The related expense for the increase of \$90,000 was recorded to "General and administrative" within the Consolidated Statements of Operations. As of the date of approval the financial statements, the Company reached a verbal agreement with the plaintiff in the amount of \$80,000 plus \$16,000 for legal fees. The Company's management, after considering the views of its legal counsel, believes that it is highly probable that the district court will accept the settlement as described above, which resulted in the provision decreasing to \$100,000. The related decrease in provision amounting to \$240,000 was recorded to "General and administrative" within the Consolidated Statements of Operations.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## (UNAUDITED)

3) The Company received written communication from a distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action. After considering the views of its legal counsel as well as other factors, the Company's management believes that a loss from any related future proceedings would range from a minimal amount up to 1,075,000 Euros and is reasonably possible.

## b. Liens and pledges

The Company's obligations under the Loan (as defined in Note 6) were secured by Israeli security agreements and deposit account control agreements on all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd.

## **NOTE 12 - ENTITY WIDE DISCLOSURE:**

The Company operates in one operating segment.

Disaggregated financial data is provided below as follows:

- (1) Revenues by geographic area and
- (2) Revenues from principal customers.

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues by geographic areas:

	Three mo Septen	nths end aber 30,			Nine months ended September 30,		
	 2015		2014	2015 2		2014	
	(\$ in thousands)						
Germany	\$ 195	\$	72		491		164
Italy	186				302		83
Brazil	57				207		
Spain	48		5		119		206
Middle East	23		39		90		664
Malaysia			41				119
Argentina			40		54		40
Other	123		76		531		672
Total	\$ 632	\$	273	\$	1,794	\$	1,948

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

The following is a summary of revenues by principal customers:

	Three months September		Nine months ended September 30,		
	2015	2014	2015	2014	
Customer A	31%		11%		
Customer B	21%		9%	4%	
Customer C	8%	2%	7%	11%	
Customer D	4%	14%	5%	4%	
Customer E		17%	14%	6%	
Customer F		15%		6%	
Customer G		14%	3%	2%	
Customer H				31%	

All tangible long-lived assets are located in Israel.

## INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

September 30, 2015

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-O.

Unless the context requires otherwise, references in this Form 10-Q to the "Company," "InspireMD," "we," "our" and "us" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries.

## **Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- market acceptance of our existing and new products;
- negative clinical trial results or lengthy product delays in key markets;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- our dependence on single suppliers for certain product components and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- our limited manufacturing capabilities and reliance on subcontractors for assistance;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;

- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions;
- 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;
- 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;
- · the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- loss or retirement of key executives and research scientists.

For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the twelve month period ended December 31, 2014, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

## Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet<sup>TM</sup> stent platform technology for the treatment of complex coronary and vascular disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet<sup>TM</sup>, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. Our initial MGuard<sup>TM</sup> coronary products (MGuard<sup>TM</sup> and MGuard<sup>TM</sup> Prime Embolic Protection Stent ("MGuard<sup>TM</sup> Prime EPS")) are marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

In October 2014, we launched a limited market release of our second product, CGuard<sup>TM</sup> carotid embolic prevention system ("CGuard<sup>TM</sup> EPS") in certain European countries. CGuard<sup>TM</sup> EPS combines MicroNet<sup>TM</sup> and a self-expandable nitinol stent in a single device to treat carotid artery disease. In January 2015, we received CE mark approval for a rapid exchange delivery version of CGuard<sup>TM</sup> EPS and fully launched CGuard<sup>TM</sup> EPS in Europe.

We are also developing a pipeline of other products and additional applications by leveraging our MicroNet<sup>TM</sup> technology, including evaluating partnership proposals to advance our next generation coronary stent program with an existing drug eluting stent supplier, and new products to improve peripheral and neurovascular procedures.

Presently, none of our products may be sold or marketed in the U.S.

## **Recent Events**

On September 30, 2015, we amended our certificate of incorporation in order to (i) effectuate a one-for-ten reverse stock split of our outstanding shares of common stock and (ii) reduce the number of authorized shares of our common stock from 125,000,000 to 50,000,000. All share and related option and warrant information presented in the following discussion and analysis of our financial condition and results of operations and the accompanying consolidated interim financial statements have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

During the first quarter of 2015, we decided to curtail developing and promoting our bare metal stent platform and implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) continuing to limit the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard<sup>TM</sup> EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which was previously our focus.

## **Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2014. There have not been any material changes to such critical accounting policies since December 31, 2014.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ("\$" or "dollar"). Accordingly, our reporting currency is the dollar.

#### Contingencies

Our subsidiaries are involved in legal proceedings that arise from time to time in the ordinary course of business. We record accruals for these types of contingencies to the extent that we conclude the occurrence of such contingencies is probable and that the related liabilities are estimable. When accruing these costs, we recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. Legal costs are expensed as incurred.

#### **Results of Operations**

Three months ended September 30, 2015 compared to the three months ended September 30, 2014

Revenues. For the three months ended September 30, 2015, revenue increased by \$0.3 million, or 131.1%, to \$0.6 million from \$0.3 million during the same period in 2014. This increase was predominantly driven by \$0.3 million of sales of our new carotid product, CGuard<sup>TM</sup> EPS, which we launched in October 2014. The sales of CGuard<sup>TM</sup> EPS during the three months ended September 30, 2015 were predominantly driven by initial sales to our new strategic distribution partner, Penumbra, Inc. Sales of MGuard<sup>TM</sup> Prime EPS, our coronary product remained relatively flat at \$0.3 million, of which, the sales volume increased by \$78,000, or 28.5% in the three months ended September 30, 2015, as compared to the same period in 2014. This increase in sales volume of MGuard<sup>TM</sup> Prime EPS was partially offset by a decrease of \$29,000, or 10.8%, of price decreases to distributors as well as the effects of the weakening of the Euro against the U.S dollar.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$0.4 million in revenue from our distributors in Europe, partially offset by a decrease of \$0.1 million in revenue from our distributors in the rest of the world.

Gross Profit (Loss). For the three months ended September 30, 2015, we had a gross profit (revenue less cost of revenues) of \$0.1 million, as compared to a gross loss of \$0.1 million during the same period in 2014, representing an improvement of 217.1% or \$0.2 million. This improvement in gross profit was attributable to an increase in revenues of \$0.3 million (see above for explanation) and a decrease of write-offs of inventory of MGuard™ Prime EPS of \$0.1 million. These improvements in gross profit, however, were partially offset by an increase in labor and material costs of \$0.3 million attributable to higher revenues. Gross margin (gross profits as a percentage of revenue) increased from (27.8)% in the three months ended September 30, 2014 to 14.1% in the same period in 2015.

Research and Development Expenses. For the three months ended September 30, 2015, research and development expenses decreased by 68.3%, or \$1.7 million, to \$0.8 million from \$2.5 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of \$0.9 million in clinical trial expenses associated with our MASTER II trial, for which enrollment was suspended in October 2014, a decrease of \$0.3 million in clinical trial and development costs associated with CGuard<sup>TM</sup> EPS, which were predominantly related to our CARENET trial, for which enrollment was completed in 2014, and a decrease of \$0.3 million in miscellaneous expenses. The decreases in compensation and miscellaneous expenditures primarily resulted from our cost reduction/focused spending plan. Research and development expenses as a percentage of revenue decreased to 123.6% for the three months ended September 30, 2015, from 901.1% in the same period in 2014.

Selling and Marketing Expenses. For the three months ended September 30, 2015, selling and marketing expenses decreased by 67.4%, or \$1.2 million, to \$0.6 million, from \$1.8 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of \$0.9 million in compensation expenses, as we reduced our sales force in connection with a realignment of our commercial strategy to focus on using third party distributors for our products, a decrease of \$0.1 million in travel expenses associated with the decreased size of our sales force and a decrease of \$0.2 million in expenditures related to our participation in the Transcatheter Cardiovascular Therapeutics (TCT) conference in San Francisco, California, as part of our cost reduction/focused spending plan. Selling and marketing expenses as a percentage of revenue decreased to 93.0% in the three months ended September 30, 2015 from 661.5% in the same period in 2014.

General and Administrative Expenses. For the three months ended September 30, 2015, general and administrative expenses decreased by 19.9%, or \$0.4 million, to \$1.7 million, from \$2.1 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of \$0.6 million in compensation expenses due to lower salaries as part of our cost reduction/focused spending plan and the lower value of ESOP grants made to our management and directors, partially offset by an increase in consulting expenses of \$0.2 million. General and administrative expenses as a percentage of revenue decreased to 271.0% in the three months ended September 30, 2015 from 783.5% in the same period in 2014.

Restructuring and impairment expenses. For the three months ended September 30, 2015, we incurred \$0.4 million of restructuring and impairment expenses, made up of \$260,000 of expenses related to the impairment of an MGuard™ Prime EPS royalty buyout option due to anticipated lower sales in the future due to the shift in industry preferences away from bare metal stents in favor of drug eluting stents, \$0.1 million associated with our early exit from a portion of our lease in our Boston offices and \$57,000 of cash payouts given to terminated employees in connection with our restructuring (as mentioned above). Restructuring and impairment expenses as a percentage of revenue was 66.1% for the three months ended September 30, 2015.

Financial Expenses . For the three months ended September 30, 2015, financial expenses decreased by 27.2% or \$0.1 million, to \$0.2 million, from \$0.3 million during the same period in 2014. The decrease in financial expenses resulted from a decrease of \$0.1 of interest expenses due to the reduction in principal of our outstanding indebtedness. Financial expenses as a percentage of revenue decreased to 36.1% in the three months ended September 30, 2015, from 114.7% in the same period in 2014.

Tax Expenses (Income). For the three months ended September 30, 2015 there was no material change in tax expenses (income) compared to the same period in 2014.

Net Loss. Our net loss decreased by \$3.2 million, or 46.3%, to \$3.6 million for the three months ended September 30, 2015 from \$6.8 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of \$2.9 million in operating expenses primarily associated with lower research and development and sales and marketing expenses related to our cost reduction/focused spending plan, an increase of \$0.2 million in gross profit (see above for explanation) and a decrease of \$0.1 million in financial expenses (see above for explanation).

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Revenues. For the nine months ended September 30, 2015, revenue decreased by \$0.1 million, or 7.9%, to \$1.8 million from \$1.9 million during the same period in 2014. This decrease was predominantly driven by a decrease in sales of MGuard<sup>TM</sup> Prime EPS of \$0.7 million, or 35.5% from \$1.9 million in the nine months ended September 30, 2014 to \$1.2 million in the same period in 2015. This decrease in sales of MGuard<sup>TM</sup> Prime EPS was predominantly driven by a decrease in sales volume of \$0.5 million, or 22.9% due to the trend of doctors increasingly using drug eluting stents rather than bare metal stents in STEMI patients, which impacted current sales. Price decreases to our distributors drove the remaining decrease of \$0.2 million, or 12.6% of MGuard<sup>TM</sup> Prime EPS, due to lower average sales prices received from distributor sales rather than direct sales to hospitals, as well as the effects of the weakening of the Euro against the U.S dollar. These decreases, however, were partially offset by \$0.5 million of sales of our new product CGuard<sup>TM</sup> EPS, which was launched in October 2014. The sales of CGuard<sup>TM</sup> EPS during the nine months ended September 30, 2015 included initial sales to our new strategic distribution partner, Penumbra, Inc. which commenced during the third quarter.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of \$0.6 million in revenue from our distributors in the Middle East, partially offset by an increase of \$0.4 million in revenue from our distributors in Europe and \$0.1 million in revenue from our distributors in Latin America.

Gross Profit (Loss). For the nine months ended September 30, 2015, we had a gross loss (revenue less cost of revenues) of \$0.2 million, as compared to a gross profit of \$0.4 million during the same period in 2014, representing a decrease of 141.0%, or \$0.6 million. This decrease in gross profit was attributable to an increase in labor and material costs of \$0.4 million attributable to higher material and labor costs for CGuard™ EPS, an increase of write-offs of inventory of \$0.3 million, of which, \$0.2 million related to the write-offs of MGuard™ Prime EPS units due to expected lower sales in the future resulting from industry preferences for drug eluting stents (as mentioned above), and our transition to a third party distributor commercial strategy, as well as \$0.1 million in write-offs of CGuard™ EPS resulting from us transitioning to an RX delivery system from an over the wire platform, as well as an increase of \$0.2 million related to underutilization of our manufacturing resources and a decrease in revenues of \$0.1 million (see above for explanation). These increases, however, were partially offset by a decrease of \$0.4 million in costs associated with the VFA (as mentioned above). Gross margin (gross profits as a percentage of revenue) decreased from 20.0% in the nine months ended September 30, 2014 to (8.9)% in the same period in 2015. The decrease in gross margin of 28.9% was driven mainly by write-offs of inventory (see above for explanation), the change in product mix, including CGuard™ EPS, which has higher material and labor costs than MGuard™ Prime EPS, and a lower average sales price of MGuard™ Prime EPS due to the new commercial strategy built on using third party distributors.

Research and Development Expenses. For the nine months ended September 30, 2015, research and development expenses decreased by 61.5%, or \$4.6 million, to \$2.9 million from \$7.5 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of \$3.0 million in clinical trial expenses associated with our MASTER II trial, a decrease of \$0.7 million in clinical trial and development costs associated with CGuard<sup>TM</sup> EPS, which were predominantly related to our CARENET trial, a decrease of \$0.5 million in salaries, a decrease of \$0.3 million of expenses related to our stent retention program, which we concluded in 2014 and a decrease of \$0.4 million in miscellaneous expenses. The decreases in salaries and miscellaneous expenditures resulted from our cost reduction/focused spending plan. These decreases were partially offset by an increase of \$0.3 million in share based compensation expenses primarily related to the hiring of our chief operating officer. Research and development expenses as a percentage of revenue decreased to 160.5% for the nine months ended September 30, 2015, from 384.2% in the same period in 2014.

Selling and Marketing Expenses. For the nine months ended September 30, 2015, selling and marketing expenses decreased by 48.3%, or \$2.4 million, to \$2.6 million, from \$5.0 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of \$1.4 million in salaries and \$0.2 million in share based compensation expenses due to our transition away from direct sales in favor of using third party distributors, a decrease of \$0.3 million in travel expenses associated with the decreased size of our sales force, a decrease of \$0.3 million in expenditures related to the Euro PCR Congress in Paris, France, incurred in the same period in 2014, and a decrease of \$0.2 million in expenditures related to our participation in the Transcatheter Cardiovascular Therapeutics (TCT) conference in San Francisco, California. The decrease in spending at the above-mentioned two conferences was a result of our cost reduction/focused spending plan. Selling and marketing expenses as a percentage of revenue decreased to 144.9% in the nine months ended September 30, 2015 from 258.2% in the same period in 2014.

General and Administrative Expenses. For the nine months ended September 30, 2015, general and administrative expenses decreased by 26.0%, or \$1.8 million, to \$5.3 million, from \$7.1 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of \$1.8 million in compensation due to lower salaries as part of our cost reduction/focused spending plan and the lower value of ESOP grants made to our management and directors and a decrease of \$0.1 million in travel expenditures. These decreases were partially offset by an increase in miscellaneous expenses of \$0.1 million. General and administrative expenses as a percentage of revenue increased to 293.8% in the nine months ended September 30, 2015 from 365.8% in the same period in 2014.

Restructuring and impairment expenses. For the nine months ended September 30, 2015, we incurred \$1.0 million of restructuring and impairment expenses made up of \$0.6 million of expenses related to the impairment of an MGuard<sup>TM</sup> Prime EPS royalty buyout option due to anticipated lower sales in the future due to the shift in industry preferences away from bare metal stents in favor of drug eluting stents (as discussed above), \$0.2 million of cash payouts and \$0.1 million of restricted shares given to terminated employees in connection with our restructuring (as mentioned above) and \$0.1 million associated with our early exit from a portion of our lease in our Boston offices. Restructuring and impairment expenses as a percentage of revenue was 53.7% for the nine months ended September 30, 2015.

Financial Expenses . For the nine months ended September 30, 2015, financial expenses decreased by 18.6%, or \$0.2 million, to \$0.9 million from \$1.1 million during the same period in 2014. The decrease in financial expenses resulted from a decrease of \$0.2 of interest expenses due to the reduction in principal of our outstanding indebtedness. Financial expenses as a percentage of revenue decreased to 47.7% in the nine months ended September 30, 2015, from 54.0% in the same period in 2014.

Tax Expenses (Income). For the nine months ended September 30, 2015 there was no material change in tax expenses (income) compared to the same period in 2014.

Net Loss . Our net loss decreased by \$7.6 million, or 37.3%, to \$12.7 million for the nine months ended September 30, 2015 from \$20.3 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of \$7.9 million in operating expenses primarily associated with lower research and development expenses, due to our cost reduction/focused spending plan (see above for explanation), and a decrease of \$0.2 million in financial expenses, partially offset by a decrease of \$0.6 million in gross profit (see above for explanation).

## **Liquidity and Capital Resources**

We had an accumulated deficit as of September 30, 2015, as well as net losses and negative operating cash flows in recent years. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard<sup>TM</sup>) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we do not have sufficient resources to fund operations beyond the first half of 2016. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include the continued commercialization of our products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products and raising capital, we may need to reduce activities, curtail or cease operations.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

General. At September 30, 2015, we had cash and cash equivalents of \$6.5 million, as compared to \$6.3 million as of December 31, 2014. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was \$9.4 million for the nine months ended September 30, 2015 and \$14.3 million for the same period in 2014. The principal reason for the usage of cash in our operating activities for the nine months ended September 30, 2015 was a net loss of \$12.7 million, as well as an increase in working capital of \$0.2 million, offset by \$2.6 million in non-cash share based compensation that was largely paid to our directors and chief executive officer, \$0.6 million of non-cash expenses related to the impairment of our royalty buyout option (discussed above), \$0.2 million of non-cash financial expenses and \$0.2 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the nine months ended September 30, 2014 was a net loss of \$20.3 million, offset by \$3.2 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, a decrease in working capital of \$2.3 million, \$0.3 million of non-cash financial expense and \$0.2 million of depreciation and amortization expenses.

Cash provided by our investing activities was \$9,000 during the nine months ended September 30, 2015, compared to \$67,000 of cash used by our investing activities during the same period in 2014.

Cash provided by financing activities for the nine months ended September 30, 2015 was \$9.6 million, compared to \$1.8 million during the same period in 2014. The principal source of the cash provided by financing activities during the nine months ended September 30, 2015 was the issuance of shares and warrants for approximately \$12.4 million of proceeds, offset by loan repayments of \$2.7 million and \$0.1 million of payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by some of our employees. The principal source of the cash provided by financing activities during the nine months ended September 30, 2014 relates to funds received from the issuance of shares for approximately \$2.2 million of proceeds, offset by loan repayments of \$0.3 million.

As of September 30, 2015, our current assets exceeded our current liabilities by a multiple of 1.1. Current assets decreased by \$0.8 million during the period and current liabilities decreased by \$0.9 million during the period. As a result, our working capital surplus increased by \$0.1 million to \$1.0 million at September 30, 2015.

## **Off Balance Sheet Arrangements**

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **Recent Accounting Pronouncements**

In April, 2015, the Financial Accounting Standards Board ("FASB") issued guidance related to the presentation of Debt Issuance Costs, The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

On July 22, 2015, the FASB issued Accounting Standards Update 2015-11, Simplifying the Measurement of Inventory, which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out (LIFO) and the retail inventory method (RIM) are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

## **Factors That May Affect Future Operations**

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products. For a discussion of these and other risks that relate to our business, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the twelve month period ended December 31, 2014, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

## **Contractual Obligations and Commitments**

During the nine months ended September 30, 2015, there were no material changes to our contractual obligations and commitments.

## Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our market risk profile as of September 30, 2015 has not significantly changed since December 31, 2014. Our market risk profile as of December 31, 2014 is disclosed in our Annual Report on Form 10-K.

#### **Item 4. Controls and Procedures**

#### Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

As of September 30, 2015, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of September 30, 2015.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II - OTHER INFORMATION**

## Item 1. Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not aware of any material legal proceedings to which we or any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation or any such proceedings known to be contemplated by governmental authorities.

We are not aware of any material proceedings in which any of our directors, officers or affiliates or any registered or beneficial stockholder of more than 5% of our common stock, or any associate of any of the foregoing, is a party adverse to or has a material interest adverse to, us or any of our subsidiaries.

## Item 1A. Risk Factors

During the fiscal quarter ended September 30, 2015, there were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014, except for the following:

## **Risks Related to Our Business**

Our financial statements for the nine months ended September 30, 2015 contain an explanatory paragraph in the footnotes that expresses substantial doubt as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities and have significant future commitments, substantial doubt exists regarding our ability to continue as a going concern. Such doubts regarding our ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

## Risks Related to Our Organization and Our Common Stock

Our common stock could be delisted from the NYSE MKT if we fail to regain compliance with the NYSE MKT's continued listing standards on the schedule required by the NYSE MKT.

On January 20, 2015, we received a notice indicating that we do not meet certain of the NYSE MKT's continued listing standards as set forth in Part 10 of the NYSE MKT Company Guide ("Company Guide"). Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than \$6 million as of September 30, 2014 and had net losses in our five most recent fiscal years. In addition, the NYSE MKT indicated that we were not in compliance with Section 1003(a)(iv) of the Company Guide because we had sustained losses that are substantial in relation to our overall operations or our then-existing financial resources, or our financial condition had become impaired such that it appeared questionable, in the opinion of the NYSE MKT, as to whether we would be able to continue operations and/or meet our obligations as they matured. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide.

In order to maintain our listing on the Exchange, we submitted a plan of compliance to the NYSE MKT on February 19, 2015 addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016 and Section 1003(a)(iv) of the Company Guide by June 1, 2015. On March 9, 2015, we closed a public offering of our common stock and warrants that resulted in net proceeds of approximately \$12.4 million after deducting placement agent fees and other estimated offering expenses. In light of this, the NYSE MKT determined that we have resolved the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide. In addition, the NYSE MKT has accepted our plan to gain compliance with the Section 1003(a)(iii) of the Company Guide by July 20, 2016.

If we do not regain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE MKT will initiate delisting proceedings. The market price and liquidity of our common stock could be adversely affected by the commencement of such proceedings. If those proceedings resulted in delisting of our common stock and resulting cessation of trading of the stock on the NYSE MKT, we believe that the market price and liquidity of our common stock would be adversely affected.

## **Item 5. Other Information**

Not applicable

## Item 6. Exhibits

See Index to Exhibits.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSPIREMD, INC.

Date: November 9, 2015 By: /s/ Alan Milinazzo

Name: Alan Milinazzo

Title: President and Chief Executive Officer

Date: November 9, 2015 By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer, Secretary and Treasurer

## EXHIBIT INDEX

Exhibit No.	Description
3.1*	Amended and Restated Certificate of Incorporation, as amended through September 30, 2015
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.1*^	Distribution Agreement, dated August 5, 2015, by and between Penumbra, Inc. and InspireMD, Inc.
10.2+	First Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 9, 2015).
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

<sup>\*</sup> Filed herewith.

<sup>^</sup> Certain portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission under a confidential treatment request pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>+</sup> Management contract or compensatory plan or arrangement.

## AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

**OF** 

## InspireMD, INC.

## (as amended through September 30, 2015)

FIRST: The name of the corporation is InspireMD, Inc. (hereinafter referred to as the "Corporation").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware, postal code 19801. The name of the registered agent of the Corporation at that address is The Corporation Trust Company.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the DGCL.

<u>FOURTH:</u> A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is Fifty Five Million (55,000,000), consisting of Fifty Million (50,000,000) shares of Common Stock, par value \$0.0001 per share (the "<u>Common Stock</u>") and Five Million (5,000,000) shares of Preferred Stock, par value \$0.0001 per share (the "<u>Preferred Stock</u>").

- B. Effective as of 12:00 a.m., New York time, on October 1, 2015 (the "Effective Time") each share of the Corporation's common stock, \$0.0001 par value per share (the "Old Common Stock"), either issued or outstanding or held by the Corporation as treasury stock, immediately prior to the Effective Time, will be automatically reclassified as and converted (without any further act) into 1/10 of a fully paid and nonassessable share of common stock, \$0.0001 par value per share, of the Corporation (the "New Common Stock") without increasing or decreasing the amount of stated capital or paid-in surplus of the Corporation (the "Reverse Stock Split"), provided that no fractional shares shall be issued to any registered holder of Old Common Stock immediately prior to the Effective Time, and that instead of issuing such fractional shares to such holders, such fractional shares shall be rounded up to the next even number of shares of Common Stock issued as a result of this Reverse Stock Split at no cost to the stockholder. Any stock certificate that, immediately prior to the Effective Time, represented shares of the Old Common Stock will, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent the number of shares of the New Common Stock as equals the product obtained by multiplying the number of shares of Old Common Stock represented by such certificate immediately prior to the Effective Time by 1/10.
- C. The board of directors is authorized, subject to any limitations prescribed by law, to provide for the issuance of shares of Preferred Stock in series, and by filing a certificate pursuant to the applicable law of the State of Delaware (such certificate being hereinafter referred to as a "Preferred Stock Designation"), to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights of the shares of each such series and any qualifications, limitations or restrictions thereof. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, without a vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any Preferred Stock Designation.

D. Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; <i>provided</i> , <i>however</i> , that, except as otherwise required by law, holders of Common Stock shall not be
entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any Preferred Stock Designation relating to any
series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Amended and Restated
Certificate of Incorporation (including any Preferred Stock Designation relating to any series of Preferred Stock).
FIFTH: The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation, and for
definition, limitation and regulation of the powers of the Corporation and of its directors and stockholders:

further

- The business and affairs of the Corporation shall be managed by or under the direction of the board of directors. In addition to the powers and authority expressly conferred upon them by statute or by this Amended and Restated Certificate of Incorporation or the by-laws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.
  - B. The directors of the Corporation need not be elected by written ballot unless the by-laws so provide.
- C. Special meetings of stockholders of the Corporation may be called only by the board of directors acting pursuant to a resolution adopted by a majority of the Whole Board. For purposes of this Amended and Restated Certificate of Incorporation, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.
- SIXTH: A. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the number of directors shall be fixed from time to time exclusively by the board of directors pursuant to a resolution adopted by a majority of the Whole Board. The directors, other than those who may be elected by the holders of any series of Preferred Stock under specified circumstances, shall be divided into three classes, with the term of office of the first class to expire at the Corporation's 2012 annual meeting of stockholders, the term of office of the second class to expire at the Corporation's 2013 annual meeting of stockholders and the term of office of the third class to expire at the Corporation's 2014 annual meeting of stockholders, with each director to hold office until his or her successor shall have been duly elected and qualified. At each annual meeting of stockholders, commencing with the 2012 annual meeting, directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election, with each director to hold office until his or her successor shall have been duly elected and qualified.
  - B. Subject to the rights of the holders of any series of Preferred Stock then outstanding, newly created directorships resulting from any increase in the authorized number of directors or any vacancies in the board of directors resulting from death, resignation, disqualification, removal from office or other cause shall, unless otherwise required by law or by resolution of the board of directors, be filled only by a majority vote of the directors then in office, though less than a quorum (and not by stockholders), and directors so chosen shall serve for a term expiring at the annual meeting of stockholders at which the term of office of the class to which they have been chosen expires or until such director's successor shall have been duly elected and qualified. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

- C. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the by-laws of the Corporation.
- D. Subject to the rights of the holders of any series of Preferred Stock then outstanding, any director, or the entire board of directors, may be removed from office at any time, but only for Cause and only by the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of capital stock of the Corporation then entitled to vote at an election of directors, voting together as a single class. "Cause" shall mean removal because of a director's (i) final, nonappealable conviction of a felony involving moral turpitude, (ii) breach of fiduciary duty, gross negligence or willful misconduct with respect to the Corporation or any of its subsidiaries, or (ii) willful violation of any written policy of the Corporation or any of its subsidiaries.

SEVENTH: The board of directors is expressly empowered to adopt, amend or repeal by-laws of the Corporation. Any adoption, amendment or repeal of the by-laws of the Corporation by the board of directors shall require the approval of a majority of the Whole Board. The stockholders shall also have power to adopt, amend or repeal the by-laws of the Corporation; *provided, however*, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Amended and Restated Certificate of Incorporation, the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to adopt, amend or repeal any provision of the by-laws of the Corporation.

EIGHTH: A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Any repeal or modification of the foregoing paragraph shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification.

NINTH: The Corporation reserves the right to amend or repeal any provision contained in this Amended and Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that, notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any vote of the holders of any class or series of the stock of this corporation required by law or by this Amended and Restated Certificate of Incorporation, and subject to Section D of Article FOURTH, the affirmative vote of the holders of at least a majority of the voting power of all of the then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of Directors, voting together as a single class, shall be required to amend or repeal this Article NINTH, Section C of Article FIFTH, Article SIXTH, Article SEVENTH, or Article EIGHTH.

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*".

## DISTRIBUTION AGREEMENT

## **BETWEEN**

## PENUMBRA, INC.

and

## INSPIREMD, LTD.

This Distribution Agreement ("Agreement") is entered into and made effective as of August 5, 2015 (the "Effective Date"), by and between Penumbra, Inc., a corporation organized under the laws of the state of Delaware, with offices at 1351 Harbor Bay Parkway, Alameda, California, 94502 ("Penumbra") and InspireMD, LTD., a corporation organized under the laws of the state of Israel, ("InspireMD"). References in this Agreement to Penumbra shall include its Affiliates who issue purchase orders for Products under this Agreement.

Whereas, InspireMD is a medical device company focusing on the development and commercialization of its proprietary MicroNet stent platform technology for the treatment of complex coronary and vascular disease; and InspireMD desires to engage a marketing and distribution associate in the Distribution Territory (as defined below), on the terms and conditions below; and

Whereas, Penumbra and its Affiliates desire to be InspireMD's exclusive marketing and distribution associate for the Products (as defined below) in the Distribution Territory, on the terms and conditions below; and,

WHEREAS, the relationship between Penumbra and InspireMD is that of buyer and seller, respectively;

Now Therefore, in consideration of the mutual covenants and conditions herein contained, and intending to be legally bound hereby, the parties mutually agree as follows:

- 1. **D** EFINITIONS. The following terms shall have the respective meanings indicated:
  - 1.1 "Acquisition Transaction" means a merger or consolidation of a party with or into any other entity, including a reverse triangular merger involving such party, a sale of all or substantially all of the assets or business of such party, or a similar transaction, or a sale of the business unit to which this Agreement relates, or sale of at least a majority of the outstanding voting stock or other ownership interests of such party.

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*\*".

- 1.2 "Affiliate" of a person means any person that controls, is controlled by, or is under common control with that person.
- 1.3 "Approvals" means all required permits, licenses, and other approvals necessary to import, market and/or sell the Products in the Distribution Territory.
- 1.4 "Business Day" means a day on which banks in the United States are open for business, and with respect to an Affiliate, means a day on which banks in the Affiliate's country are open for business.
- 1.5 "Distribution Territory." means the countries listed on **Exhibit A** as in effect from time to time.
- 1.6 "FCPA" means the United States Foreign Corrupt Practices Act of 1977.
- 1.7 "Government" means any national, federal, state, provincial, municipal, local, or any other government, including any department, agency, instrumentality, company, corporation, or other entity owned or controlled by any Government;
- 1.8 "Government Entity" means (i) any Government; (ii) any political party; (iii) any public international organization (i.e., United Nations, World Bank, etc.); and (iv) any company or business entity that is wholly or partially owned, sponsored or controlled by or affiliated with a Government, including companies and entities with commercial functions in which a Government owns a minority interest as long as the Government has the power to direct or control the operations of the entity, and expressly includes Government owned or operated hospitals and clinics.
- 1.9 "Government Official" means any (i) official, employee, or representative of any enterprise owned, funded or operated by a Government, including any official, employee or representative of a hospital or other health facility owned, funded or operated by a Government; (ii) political party, or any official, employee, or representative of any political party; (iii) candidate for political office; (iv) official, employee, or representative of any international organization. For the avoidance of doubt, a physician employed by a Government owned, funded or operated hospital is a "Government Official" within the meaning of this Agreement.

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- 1.10 "Marks" means trade names, trademarks and service marks, logos, indicia or source of goods, and any application or registration for any of the foregoing, owned or in-licensed by InspireMD at any time, that are applicable to the Products.
- 1.11 "<u>Minimum Target</u>" means a minimum purchase target (but not requirement) for Products agreed to by InspireMD and Penumbra prior to the start of a Target Period.
- 1.12 "Payment" means any monetary payment, loan, donation, gift, in-kind service, or any other thing of value.
- 1.13 "Products" means the carotid products listed on Exhibit B of this Agreement from time to time. The Products will also include updates, improvements, and replacements of such carotid Products or any components thereof released by InspireMD during the term of this Agreement. "Product" means one of the Products.
- 1.14 "Proprietary Information" means any confidential or proprietary information provided to one party by the other, orally or in written or electronic form, including but not limited to technical information concerning Products, customer lists, sales figures, cost or pricing information and marketing materials.
- 1.15 "<u>Target Period</u>" means the following: the first target period shall commence on the Target Period Start Date and end on the next following December 31. Each Target Period thereafter shall commence on January 1 and end on the next following December 31.
- 1.16 "<u>Target Period Start Date</u>" means a date to be agreed upon by InspireMD and Penumbra, which is expected to be the first day of the calendar month beginning at least thirty (30) days after receipt of all Approvals to sell the first Product in the Distribution Territory have been obtained.

## 2. APPOINTMENT, PRODUCTS AND SCOPE.

2.1 InspireMD hereby appoints Penumbra, on an exclusive basis, as its authorized distributor of the Products for sale to purchasers in the Distribution Territory.

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- 2.2 From time to time, InspireMD may propose to add additional countries to the Distribution Territory by notice to Penumbra. Penumbra shall have thirty (30) days from receipt of such notice to decide whether it elects to include each such proposed country in the Distribution Territory. Penumbra shall advise InspireMD of its election within such thirty (30) day period, and if it fails to do so Penumbra shall be deemed to have elected not to add such proposed country to the Distribution Territory. When countries are added or deleted from the Distribution Territory, Exhibit A shall be amended to reflect the addition or deletion.
- 2.3 Penumbra shall not sell any products manufactured by InspireMD that are not included in the Products. From time to time InspireMD may propose to add new products to the Products by notice to Penumbra. Penumbra shall have forty five (45) days to object in writing to the inclusion of such new products as Products. If Penumbra objects in writing to the inclusion of such products, they shall be excluded from the Products. If Penumbra agrees to add such products or does not object to the addition of such products, the new Products shall be listed on Exhibit B. The parties agree to delete Products from time to time during the term of this Agreement, and if they do they shall amend Exhibit B as necessary to reflect such deletions. In the event Penumbra objects to including a product on, or desires to remove a Product from, Exhibit B, InspireMD may appoint another distributor on an exclusive or non-exclusive basis (in InspireMD's discretion) in the Distribution Territory for any and all such products, or may sell such products directly or through agents.
- Penumbra shall not engage in any advertising or promotional activities relating to the Products directed primarily to customers outside the Distribution Territory. Penumbra shall not solicit orders from any prospective purchaser located outside the Distribution Territory. To the extent permitted by applicable law, Penumbra shall refer any customer that is outside of the Distribution Territory to InspireMD or one of its other distributors for orders and order fulfillment. InspireMD shall not sell or supply Products to any end user in the Distribution Territory or to any person (other than Penumbra) who InspireMD has reason to believe intends to resell such Products in the Distribution Territory without agreement of Penumbra; provided that InspireMD will not be required to stop a third party from reselling Products in the Distribution Territory so long as InspireMD did not have reason to believe, at the time of granting authorization to the reseller to resell Products outside of the Distribution Territory (if any such authorization is granted), that such party would resell Products in the Distribution Territory, other than Penumbra's approved sub-distributors.

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2.5 Penumbra may from time to time use sub-distributors, agents or other third parties proposed to sell Products in the Distribution Territory. Penumbra may use or appoint sub-distributors, agents or other third parties for any purpose related to its business with InspireMD or the Products in its sole discretion without InspireMD's prior approval. Penumbra shall be responsible for compliance with all terms and conditions of this Agreement by all of its sub-distributors and shall be liable to InspireMD under this Agreement for any action, inaction, breach, negligence or misconduct of any sub-distributor to the same extent as if Penumbra or its representatives were responsible for such action, inaction, breach, negligence or misconduct. Penumbra shall comply with all laws and regulations of any Government that are applicable to Penumbra's relationship or agreement with any sub-distributor.

#### 3. REGULATORY APPROVAL IN DISTRIBUTION TERRITORY.

3.1 InspireMD will use all commercially reasonable efforts to obtain all Approvals for the Products in the Distribution Territory, and will attempt to obtain reimbursement authorization for all such Products. Recognizing that it will take time to obtain the Approvals and reimbursement authorization in each country in the Distribution Territory, InspireMD and Penumbra will consult and develop a strategy to prioritize obtaining Approvals and reimbursement authorization for each such country. All Approvals shall be obtained in InspireMD's name. Penumbra shall not sell any Product in the Distribution Territory in a transaction that requires one or more Approvals until InspireMD advises Penumbra that all required Approvals have been obtained. If Products may be sold in transactions that do not require Approvals, Penumbra may sell Products in those transactions after confirming with InspireMD in writing that no Approval is required. Penumbra shall not apply for or obtain any Approvals for the Products in Penumbra's name or in the name of any other party without InspireMD's prior written approval. Specifically, InspireMD will use commercially reasonable efforts to perform the following actions in a timely manner:

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- (a) cause its regulatory department to prepare all necessary applications for all Approvals;
- (b) submit all such applications, including supporting data and materials;
- (c) respond promptly to all inquiries and requests for information from the relevant governmental authorities; and
- (d) keep Penumbra informed of the status of all applications for, and promptly after they are obtained provide Penumbra copies of all, Approvals.
- 3.2 InspireMD will perform the actions and obligations set forth in Section 3.1 using its own employees or advisors of its choosing. Penumbra will co-operate with InspireMD and any such advisors and will consult with InspireMD or its advisors on strategies for obtaining Approvals.
- 3.3 InspireMD will pay all filing and registration fees paid to regulatory agencies in connection with the actions described in Section 3.1, and will bear all other costs of obtaining the Approvals for commercialization and reimbursement.
- 3.4 If InspireMD is required to perform any clinical study in order to obtain Approvals, InspireMD will consult with Penumbra on the design and execution of each such clinical study. InspireMD shall bear the costs for each such clinical study, and InspireMD shall have the right to approve in its sole discretion the design of the clinical study and shall have the right to supervise and oversee the clinical study. In lieu of conducting any such study, InspireMD may elect to withdraw the application for Approvals of the Product in question from the jurisdiction requiring the clinical study and such Product will automatically be deleted from Exhibit B as to such portion of the Distribution Territory.

## 4. CONTINUING REGULATORY AND REPORTING REQUIREMENTS.

After all Approvals have been obtained with respect to a Product, InspireMD will use commercially reasonable efforts to keep Penumbra informed in a timely manner regarding ongoing regulatory requirements in the Distribution Territory with respect to that Product, including without limitation those relating to labeling and packaging, product enhancements and modifications and recalls. InspireMD will use commercially reasonable efforts to observe and satisfy all such requirements in a timely manner. InspireMD will pay all filing and registration fees paid to regulatory agencies in connection with the actions described in this Section 4.1. InspireMD, at its expense, will provide Penumbra with all information, data, materials and Product samples necessary or useful to observe and satisfy such requirements. InspireMD shall be responsible for any necessary or required translations of such information, data and materials. InspireMD shall develop and/or approve (in writing and prior to use) of all labeling, packaging, use of product samples and other activities that may impact any Approval or right to sell products in the Distribution Territory.

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- 4.2 Penumbra will gather and report to InspireMD complaints and adverse event reports within the Distribution Territory relating to the Products within the following timeframes:
  - (a) Within twenty four (24) hours after Penumbra's first receipt of any complaint or information suggesting that any Product was associated with the death or serious injury of a patient in the Distribution Territory; and
  - (b) Within forty eight (48) hours after Penumbra's first receipt of any other complaint or adverse information relating to any Product in the Distribution Territory.
- 4.3 InspireMD will file with appropriate agencies any and all notices of adverse events required to be filed in the Distribution Territory with respect to the Products. Upon request, Penumbra shall assist InspireMD with such filings. Penumbra shall inform InspireMD of the types of adverse events that occur outside the Distribution Territory that may be reportable to appropriate authorities in the Distribution Territory, and InspireMD will use commercially reasonable efforts to keep Penumbra informed of any such adverse events. InspireMD will determine whether any such adverse event is reportable, and any required report shall be prepared by InspireMD with Penumbra's assistance.

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## 5. SUPPLY TERMS: PRICES AND PAYMENT.

- 5.1 Purchase Orders. The parties mutually agree that Penumbra, or any of its Affiliates, may issue purchase orders under this Agreement. Penumbra further agrees that, within sixty (60) days after receipt of all necessary Approvals with respect to a Product in a Distribution Territory, Penumbra, or one of its Affiliates, will place its initial stocking order for that Product and as to such initial stocking order, will pay for one-half of the purchase price of the ordered Products upon placing such order and the remainder of the purchase price thirty (30) days after receipt of the Products and InspireMD's invoice for such Products. If Penumbra's initial stocking order is not for a sufficient quantity of Products (in InspireMD's reasonable discretion) to sufficiently commercialize the Products in the Distribution Territory, InspireMD may reduce the Distribution Territory granted by this Agreement upon 60 days' notice to Penumbra. The purchase orders will be in writing, and will contain the following information: the company name and contact person for Penumbra or the Affiliate placing the purchase order, as applicable, the description and number of units of each Product ordered, the price of each Product, delivery date, and delivery location. InspireMD will use commercially reasonable efforts to ship Products on the date requested in a purchase order, but shall not be in breach of this Agreement in the event that that date is not met. If InspireMD determines that it will not be able to ship Products by the date requested in a purchase order, InspireMD shall promptly notify Penumbra, or the Penumbra Affiliate issuing the purchase order, in writing of such delay. Penumbra and its Affiliates will use commercially reasonable efforts to place orders for Products in an even and regular fashion (e.g., monthly or quarterly) so as to allow for efficient production and warehousing by InspireMD. No purchase order or other purchasing documentation shall contain any term or condition that is different from or in addition to the terms of this Agreement; any such different or additional term shall be null and void and InspireMD expressly rejects any purchase order or other documentation that contains any terms different from or in addition to the terms and conditions set forth in this Agreement.
- 5.2 **Delivery and Risk of Loss**. Unless Penumbra requests otherwise, InspireMD will ship all Products ordered pursuant to a purchase order within the time period specified in Section 5.1. All Products shall be packed for shipment and storage in accordance with InspireMD's standard commercial practices. Penumbra shall inform InspireMD of documentation that must accompany each shipment before the Product is shipped and InspireMD will use commercially reasonable efforts to provide or facilitate the provision of such documentation.

For the first four orders placed by Penumbra, InspireMD will, at its expense, select a carrier and ship the ordered Products to Penumbra. Title to the Products will pass upon InspireMD delivering the Products to the carrier that InspireMD selects, and Penumbra shall bear the risk of loss during shipment (including by obtaining insurance, at its election, to cover any losses which may occur during shipment).

THE COMPANY HAS REQUESTED AN ORDER FROM THE SECURITIES AND EXCHANGE COMMISSION (THE "COMMISSION") PURSUANT TO RULE 24b-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, GRANTING CONFIDENTIAL TREATMENT TO SELECTED PORTIONS. ACCORDINGLY, THE CONFIDENTIAL PORTIONS HAVE BEEN OMITTED FROM THIS EXHIBIT, AND HAVE BEEN FILED SEPARATELY WITH THE COMMISSION. OMITTED PORTIONS ARE INDICATED IN THIS EXHIBIT WITH "\*\*\*\*\*".

For all subsequent orders placed by Penumbra, Penumbra will, at its expense, designate a carrier (that should be accessible to and reasonably acceptable to InspireMD) and bear the risk of loss during shipment (including by obtaining insurance, at its election, to cover any losses which may occur during shipment). Title to and risk of loss of the Products will pass to Penumbra upon InspireMD's delivery of the Products to Penumbra's designated carrier.

- Inspection. Penumbra will inspect all Products promptly upon receipt thereof for proper sterilized packaging, to the extent determinable by reasonable inspection upon delivery. Any Products not rejected for nonconformance for reasons that would have been obvious on reasonable inspection by Penumbra within thirty (30) days of receipt will be deemed accepted. InspireMD will replace defective Products with obvious nonconformance returned by Penumbra within a reasonable amount of time and will replace defective products whose nonconformance is not obvious during the inspection period within a reasonable time after discovery of the nonconformance. InspireMD's liability in either event shall be limited to such replacement, which shall be Penumbra's sole remedy. InspireMD shall pay the cost of shipping non-conforming Products to InspireMD and shall pay the cost of shipping repaired or replacement Products to Penumbra.
- Pricing. The initial transfer prices to be paid by Penumbra for Products shall be agreed to and set forth on Exhibit A. Further, the transfer price will be reduced by an additional \$\*\*\*\*\* per unit for inventory with less than 9 month shelf life and additional adjustments to transfer pricing may be negotiated for specific markets or strategic accounts based on mutually agreeable terms or volume commitments.
- 5.5 **Sample and Demonstration Products.** InspireMD will provide Penumbra with a reasonable number of field sales samples (25 units) of Products for demonstration purposes, for the initial commercial launch. Samples required beyond the initial launch will be available for Penumbra at mfg. cost but paid for by Penumbra.
- 6. **Payments.** All amounts due and payable with respect to Products sold by InspireMD pursuant to this Agreement shall be paid in full within thirty (30) days from the date of invoice. All such amounts shall be paid in US dollars by wire transfer, to the bank account designated on **Exhibit C** or to such other bank or account as InspireMD may from time to time designate in writing. Whenever any amount hereunder is due on a day that is not a Business Day, such amount shall be paid on the next Business Day. Any and all risks of loss or damage to Product(s) shall be borne by Penumbra from the time such Product(s) are delivered to Penumbra's representative or its own facilities in any place worldwide. Penumbra's obligation to pay for all Product(s) ordered and all charges which it has incurred in connection with the execution of this Agreement shall survive termination or expiration of this Agreement.

- 7. **Taxes.** All taxes applicable to the import, distribution or sale of Products in the Distribution Territory will be paid by Penumbra, with the exception of income or other taxes levied on InspireMD and measured by InspireMD's gross or net income.
- 8. **Business Records.** Penumbra shall keep complete and accurate records of its business with InspireMD and its interactions with regulatory authorities and customers, including without limitation Government Officials, related to the Products. Such records shall be sufficiently detailed so that InspireMD and its auditors can understand the significant aspects of all transactions including all parties involved and how they were compensated. All information submitted by Penumbra to InspireMD shall be complete, truthful and accurate. Penumbra will not prepare, approve or execute any contract or other document or make any record related to the Products or this Agreement that it knows or has reason to know is false, inaccurate or misleading.
- 9. **Record of Implantables.** Penumbra shall maintain records of shipments of implantable Products sold in the Distribution Territory. Such records shall include the production lot, serial numbers and the name and address of every purchaser or consignee.
  - 9.1 Penumbra will comply with the quality agreement in Exhibit D.
- 10. Forecasts, Targets and Minimums.
  - 10.1 **Forecasts.** At least thirty (30) days before the start of each Target Period, Penumbra and InspireMD shall agree on a Minimum Target for the Target Period.
  - 10.2 **Targets.** During the Initial Target Period, Penumbra shall use commercially reasonable efforts to purchase from InspireMD Products with an aggregate purchase price equal to the Minimum Targets for the Target Periods. The Minimum Targets are set forth on Exhibit A.
    - (a) For all Target Periods subsequent to the initial Target Period, at least thirty (30) days before commencement of such Target Period, InspireMD and Penumbra will endeavor to agree to any changes to Minimum Targets for such Target Period.

- (b) The Minimum Targets shall be determined in good faith by mutual agreement of InspireMD and Penumbra. The parties intend that such all Minimum Targets will be realistic, taking into account the sales actually attained in the immediately preceding Target Period, market conditions then prevailing and other relevant factors.
- (c) If more than one Product has received all required Approvals to be sold in the Distribution Territory, the Minimum Target shall be provided for all Products approved as a total, not for a specific approved Product, unless InspireMD and Penumbra agree otherwise.
- (d) In case of failure to attain the Minimum Target, both parties shall in good faith consult regarding the reasons for such shortfall.

#### 11. ADDITIONAL OBLIGATIONS OF PENUMBRA.

- 11.1 **Training and Product Support.** Throughout the term of this Agreement, Penumbra will use all commercially reasonable efforts to promote the sale of the Products in the Distribution Territory. Specifically, Penumbra shall:
  - (a) provide training and education to physicians, nurses, laboratory technicians and its sales force, as well as to all sub-distributors, to adequately support the Products, including without limitation training on the approved indications for use of all Products and training to ensure that Products are not sold or recommended for uses other that those indicated for the Products;
  - (b) order and maintain, at its own expense, a sufficient inventory of the Products as well as a sufficient non-operative inventory (sample, demo) to fulfill Penumbra's forecasted demand for the Products in the Distribution Territory;
  - (c) maintain an adequate number of experienced and trained sales personnel, who need not be exclusively dedicated to the sale of the Products.

- (d) in cooperation with InspireMD, translate into appropriate languages any promotional materials, user and technical manuals, or advertising and marketing information supplied at the discretion of InspireMD that Penumbra determines may be useful in the marketing of Products in the Distribution Territory; provided that all such materials shall be subject to InspireMD's prior written approval as provided in Section 7.2 below. InspireMD shall retain the copyright to all translations, as well as the materials from which they were translated; InspireMD hereby grants Penumbra a non-exclusive right to use all such materials during the term of this Agreement in connection with its activities pursuant to this Agreement; Penumbra's right to use such material shall expire on termination of this Agreement;
- (e) participate in appropriate trade shows;
- (f) make sales calls on physicians;
- (g) train Penumbra's personnel with respect to procedures for handling and storing Products, keep accurate records of such training, and make such records available to InspireMD on its request; and
- (h) promptly effect any field corrective actions or recalls in accordance with InspireMD's instructions and in conformance with any and all applicable regulatory requirements.
- 11.2 Translations. Penumbra will prepare or arrange for (including arranging for translations) and affix any labeling, instructions or other documents required by regulatory authorities in the Distribution Territory or required by the conditions of the Approvals. Penumbra shall not translate any documents, including without limitation any written, printed or graphic matter on any Product or Product container or wrapper, or accompanying any Product, or materials submitted in connection with the Approvals or any post-Approval required submissions by Penumbra unless such translation is performed by a qualified supplier or by qualified internal resources. Penumbra shall review all translations with native-speaking individuals to ensure their completeness and accuracy. In the case of translations submitted to regulatory agencies, Penumbra shall maintain documentation of the translated material's accuracy to the English language version and compliance with local regulations in accordance with Penumbra's internal procedures or any procedures established by InspireMD. Penumbra shall provide such matter and materials together with an English translation to InspireMD for InspireMD's review and approval at least thirty (30) days prior to publication. InspireMD shall own the copyright on all translated materials and documents if and to the extent it owns the copyright on the English language version of the materials and documents from which the translation was made.

- 11.4 Sales Reports. Penumbra will provide Inspire periodic reports on the number of Products sold on a quarterly basis.
- 12. InspireMD's Obligations. In order to facilitate Penumbra's performance of its obligations under this Agreement, InspireMD at its own expense shall:
  - 12.1 provide Penumbra with such marketing and technical assistance and promotional materials, as InspireMD may in its reasonable discretion consider necessary to assist with the promotion of the Products;
  - 12.2 provide training to Penumbra's personnel in connection with the marketing, sale, installation, maintenance, handling and support of the Products;
  - 12.3 use commercially reasonable efforts to provide to Penumbra reasonable notification of any improvements to or replacements for Products, and use commercially reasonable efforts to continue to supply the original Products until such time as such improvements or replacements receive all required Approvals. InspireMD shall provide all information and additional components necessary to permit Penumbra to modify its inventory in the event InspireMD announces a revised version of any Product, or any component thereof, at the sole discretion of and under the direction of InspireMD;
  - 12.4 provide such access and availability to its support personnel to assist Penumbra's support personnel in providing support services;
  - 12.5 maintain Approvals and comply with applicable law in connection with the distribution of Products in the Distribution Territory; and
  - 12.6 use commercially reasonable efforts to promptly notify Penumbra in writing immediately upon learning of any adverse event or experience related to any Product that is reportable to regulatory authorities.

# 13. PATENTS; TRADEMARKS.

- 13.1 InspireMD shall prosecute and maintain all patents, trademarks, copyrights and trade names relating to the Products. InspireMD shall decide, in its sole discretion, whether to apply for or maintain patents, trademarks, copyrights and trade names for Products distributed, marketed or sold in the Distribution Territory. Penumbra acknowledges that InspireMD is the owner of the exclusive right, title and interest in and to the patents, copyrights, trademarks and trade names relating to the Products, including, without limitation, all Marks. Penumbra shall not apply for, acquire, adopt, use or register any patents, copyrights, trademarks, trade names or other intellectual property of any kind relating to the Products in the Distribution Territory during the term of this Agreement or after termination hereof except as permitted by this Agreement.
- During the term of this Agreement, InspireMD hereby grants Penumbra a non-exclusive, non-transferrable, revocable, fully-paid license to use the name "InspireMD" and a non-exclusive, non-transferrable, revocable, fully-paid license to use other Marks in the Distribution Territory solely for display or advertising purposes in connection with selling and distributing the Products in accordance with this Agreement. These licenses are personal to Penumbra, are not sublicensable, and expire automatically upon the expiration or earlier termination of this Agreement, except as expressly stated in this Agreement. Penumbra acknowledges that InspireMD is the owner of the exclusive right, title and interest in and to the Marks and all goodwill associated therewith or with the Products. Penumbra has no permission to and will not adopt, use or register as trademark, trade name, business name, or corporate name or part thereof, whether during the term of this Agreement or after its termination, any word or symbol confusingly similar to any of the Marks or InspireMD.
- 13.3 In order to comply with InspireMD's quality control standards, Penumbra shall use the Marks in compliance with the laws of the Distribution Territory, shall not modify any of the Marks and shall not use any Marks in connection with goods other than Products, except with the prior written consent of InspireMD.

- InspireMD shall, at its expense, indemnify, defend and hold Penumbra, its subsidiaries and affiliates harmless against all costs and liabilities incurred in connection with any claim, action, suit, or proceeding maintaining that any patent, trademark or other intellectual property rights of any third-party are infringed or violated by the import, distribution or sale of Products in the Distribution Territory, as provided in this Agreement. Penumbra agrees to give InspireMD prompt notice of any such claim, action, suit or proceeding of which Penumbra becomes aware and InspireMD shall have absolute control of any defense in such matter, including the right to settle such claim, action, suit or proceeding, provided that InspireMD will not enter into any settlement that requires Penumbra to pay cost or damages, admit liability or fault or results in any permanent injunction or consent order without Penumbra's prior written consent. InspireMD shall keep Penumbra regularly informed regarding such action, including providing Penumbra with copies of legal filings pertaining thereto. InspireMD will also have the sole and exclusive right to enforce its Marks and other intellectual property rights against any person in the event of any infringement, misappropriation, violation, of ownership claim relating thereto. Penumbra will promptly notify InspireMD in writing if it becomes aware of any such infringement, misappropriation, violation, or ownership claim of InspireMD's intellectual property rights with sufficient particularity for InspireMD to bring suit to enjoin such person regarding the same.
- 13.5 If use, distribution or sale of any Product in the Distribution Territory is enjoined, prohibited or prevented, in each case after a final, non-appealable appellate court decision against InspireMD based upon the product infringing any third-party rights, then InspireMD shall, at its option and expense in its sole discretion:
  - (a) procure a license for Penumbra to continue selling the Products; or
  - (b) replace or modify the Products to render them non-infringing; or
  - (c) repurchase the Products purchased but not yet sold by Penumbra and refund to Penumbra the price it paid for the Products provided that the Products are in original package, are not damaged and their expiration date has not passed.

#### 14. WARRANTY; INDEMNIFICATION.

- 14.1 InspireMD warrants, for a period of three (3) years from the date a Product is received by Penumbra's customer, that the Product will:
  - (a) meet all specifications;
  - **(b)** be free from defects in design, manufacture, materials, and workmanship;
  - (c) be of merchantable quality and fit for the purpose for which they are intended; and

- (d) comply with all applicable laws in effect in the place of manufacture and those laws in the Distribution Territory related to Product approval, anti-corruption and anti-bribery.
- 14.2 INSPIREMD'S SOLE OBLIGATION UNDER THE FOREGOING WARRANTY SHALL BE, AT INSPIREMD'S SOLE ELECTION, TO EITHER REPLACE THE RELEVANT PRODUCT OR REFUND PENUMBRA'S PURCHASE PRICE FOR THE PRODUCT.
- InspireMD shall, at its expense, indemnify, defend and hold Penumbra, its subsidiaries and affiliates harmless against all costs and liabilities incurred in connection with any third-party claim, action, suit, or proceeding alleging bodily injury (including death) or damage to personal property to the extent such claim arises out of or relates to any breach of a warranty made by InspireMD regarding the Products or any negligent or reckless act or omission or willful misconduct by InspireMD or any of its employees or agents. Penumbra agrees to give InspireMD prompt notice of any such claim, action, suit or proceeding of which Penumbra becomes aware and InspireMD shall have absolute control of any defense in such matter. InspireMD shall keep Penumbra regularly informed regarding such action, including providing Penumbra with copies of legal filings pertaining thereto.
- Penumbra shall, at its expense, indemnify, defend and hold InspireMD, its affiliates and each of their respective shareholders, members, managers, officers, directors, owners, agents and representatives (the "InspireMD Indemnitees") harmless against all costs and liabilities incurred in connection with any claim, action, suit, or proceeding arising out of: (a) Penumbra's relationship with any sub-distributor, whether related to the appointment thereof, the termination of any sub-distributor or any other matter; (b) any negligence, recklessness or willful misconduct by Penumbra or any of its employees, agents, sub-distributors or third parties, including, without limitation, any violation of any law by any such party; or (c) any improper use, negligent repair or alteration of a Product by Penumbra. InspireMD agrees to give Penumbra prompt notice of any such claim, action, suit or proceeding of which InspireMD becomes aware and Penumbra shall have absolute control of any defense in such matter. Penumbra shall keep InspireMD regularly informed regarding such action, including providing InspireMD with copies of legal filings pertaining thereto.

#### 15. Compliance Matters.

- 15.1 Compliance with Anti-Bribery Law. Penumbra shall take no action, directly or indirectly, that would constitute a violation of the FCPA as amended from time to time, any other applicable anti-bribery laws or regulations. Specifically, neither Penumbra nor any of its officers, directors, employees, representatives, agents, shareholders, owners or Affiliates, nor any other party acting on its or their behalf, will directly or indirectly, in order to obtain or retain any contract, business opportunity or other similar benefit, make, offer, authorize, or promise to make any Payment (i) to or for the use or benefit of any Government Official; (ii) to any other person where Penumbra knows or has reason to know or suspect that any part of such Payment will be directly or indirectly given or paid by such other person, or will reimburse such other person, for any Payment previously made or given to any Government Official when such Payment could not be made directly in accordance with this Section 11.1; or (iii) to any person where such Payment violates the applicable laws, decrees or regulations of any Government.
- No Government Official Employees . Penumbra represents and warrants that unless disclosed to InspireMD in a separate written statement, neither Penumbra nor any of its officers, directors, employees, agents, shareholders or owners or sub-distributors is a Government Official nor has any of them been in the last five (5) years. If at any time during the term of this Agreement, Penumbra and/or any such person is named, appointed, or otherwise becomes a Government Official, Penumbra will notify InspireMD in writing within seven (7) Business Days. Penumbra further represents that no such person is a Specially Designated National (as included in the list published by the US Office of Foreign Assets Control (OFAC)) or otherwise someone that InspireMD would be prohibited from doing business with directly.
- 15.3 **No Anti-bribery Offenses** . Penumbra represents and warrants that neither it nor any Affiliate has been convicted of, pleaded guilty, or charged with any offense involving fraud, corruption or bribery in any jurisdiction or country.
- 15.4 **Fully Qualified and Authorized**. Penumbra represents and warrants that it is fully qualified to assist InspireMD and is authorized to act in the capacity contemplated by this Agreement in accordance with all applicable laws. Further, Penumbra has complied with and shall continue to comply with any applicable registration and licensing requirements and laws and regulations.

- 15.5 **Immediate Disclosure by Penumbra** . Penumbra agrees to immediately inform InspireMD if a possible violation by Penumbra or any of its sub-distributors of the FCPA, other applicable anti-bribery law, has occurred. Further, if any Government Official or any relative of such Government Official solicits, asks for, or attempts to extort, any money or thing of value from Penumbra, Penumbra shall refuse such solicitation, request or extortionate demand, and immediately report the event to InspireMD.
- 15.6 **Compliance Training for Penumbra**. Penumbra warrants that it fully understands these provisions relating to its business conduct and will ensure that it and all of its officers, directors, employees, sub-distributors and agents fully understand and comply with these provisions. Penumbra agrees to make its employees available from time to time, following a reasonable notice period, for compliance training as directed by InspireMD.

#### 16. TERMINATION.

- 16.1 This Agreement shall expire on December 31, 2018.
- 16.2 Notwithstanding anything to the contrary set forth in this Agreement, either Party may terminate this Agreement, without cause and without liability other than for amounts accrued prior to the effective date of such termination, by providing 60 days' notice of termination to the other Party.
- 16.3 Upon the occurrence of a material breach or default of this Agreement by either party, this Agreement may be terminated by the non-breaching party by giving thirty (30) days notice of termination to the breaching party, unless the breaching party cures such material breach or default within the time stated in the notice or, using commercially reasonable efforts, commences a cure of any material breach or default which cannot be fully cured within such thirty (30) day period and thereafter diligently pursues such cure.

- InspireMD may terminate this Agreement immediately by notice to Penumbra if it reasonably believes that Penumbra or any of its officers, directors, employees, representatives, agents, shareholders, owners or Affiliates, or any other party acting on its or their behalf, has engaged in conduct that may constitute a violation of the FCPA, or any other anti-bribery law applicable to Penumbra. If InspireMD reasonably believes that such a violation has occurred or may be occurring, InspireMD may at its election suspend business with Penumbra or prohibit Penumbra from engaging in any business related to providing Products to Government Entities; such suspension or prohibition shall be effective on notice by InspireMD to Penumbra until InspireMD has investigated and confirmed to its sole satisfaction that no such violation has occurred.
- 16.5 Either party shall have the right to terminate this Agreement immediately without notice on the bankruptcy, insolvency, dissolution, assignment for the benefit of creditors, appointment of a trustee or receiver with respect to the assets of, liquidation of or similar event with respect to the other party.
- 16.6 Termination or expiration of this Agreement shall relieve InspireMD of any obligation to fill any and all purchase orders received by InspireMD prior to the date of termination or expiration.
- 16.7 Should Penumbra or any Affiliate of Penumbra at any time during the term of this Agreement distribute or offer for sale products that, in InspireMD's reasonable judgment, compete with any of the Products, InspireMD shall have the option, on not less than thirty (30) days' notice to Penumbra, to (i) terminate this Agreement or (ii) make Penumbra's appointment non-exclusive in the Distribution Territory with respect to such Products.
- 16.8 Notwithstanding anything else in this Agreement to the contrary, the parties agree that Sections 9.3, 10, 12.8, 13, 18 and 19 shall survive the termination or expiration of this Agreement, as the case may be, to the extent required thereby for the full observation and performance by any or all of the parties hereto.
- 16.9 Upon expiration or other termination of this Agreement:
  - (a) Penumbra shall pay to InspireMD all undisputed amounts that are owed and payable by Penumbra to InspireMD under this Agreement less any such amounts payable on the grounds of a dispute arising out of this Agreement against any claim or damages sought by Penumbra;
  - (b) Each party shall return to the other all of the Proprietary Information of the other party in the possession or under the control of the receiving party, together with a statement signed by an authorized representative of the party to the effect that all Proprietary Information has been returned to the party; and

- (c) Penumbra shall cease using any of the Marks and shall return to InspireMD all materials supplied to Penumbra by InspireMD that contain any of the Marks, provided that Penumbra may continue to use the Marks for the period specified in Section 17 to the extent necessary to sell off its remaining inventory of products.
- **DISPOSITION OF INVENTORY.** Within thirty (30) days after termination or expiration of this Agreement, Penumbra shall sell off its remaining inventory of Products; *provided however*, that Penumbra shall comply with all terms and conditions of this Agreement applicable to such sales and the terms and conditions of this Agreement applicable to such sales shall survive for as long as Penumbra is engaging in any such sales.
- 18. **Modification.** No modification or change may be made in this Agreement except by written instrument duly signed by a duly authorized representative of Penumbra and by a duly authorized representative of InspireMD.
- 19. **Assignment.** This Agreement and the rights and obligations hereunder may not be assigned, delegated or transferred by either party without the prior written consent of the other party. Notwithstanding the foregoing, participation of either party in an Acquisition Transaction pursuant to which the owners of a majority of the outstanding voting stock or other ownership interests or assets of such party immediately prior to the consummation of the Acquisition Transaction do not own at least a majority of the outstanding voting stock or other ownership interests or assets of such party immediately after the consummation of the Acquisition Transaction shall not constitute an assignment within the meaning of this Section. This Agreement shall bind and inure to the benefit of all successors and permitted assigns of each party.
- 20. **Notice.** 
  - 20.1 All notices given under this Agreement shall be in writing and shall be addressed to the parties at their respective addresses set forth below:

IF TO INSPIREMD: General Counsel InspireMD, Inc. 321 Columbus Avenue, 3rd Floor

321 Columbus Avenue, 3rd Floo Boston, MA 02116

Email:

IF TO PENUMBRA:
General Counsel
Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

USA Email: legal@penumbrainc.com

- 20.2 Either party may change its address or its e-mail address for purposes of this Agreement by giving the other party notice of its new address or e-mail address. Any such notice if given or made by registered or recorded delivery international air mail letter shall be deemed to have been received on the earlier of the date actually received and the date fifteen (15) calendar days after the same was posted, if given or made by e-mail transmission shall be deemed to have been received at the next such succeeding Business Day at the recipient's location, and if given by internationally recognized international package delivery service shall be deemed to have been received at the time of delivery.
- WAIVER. None of the conditions or provisions of this Agreement shall be deemed to have been waived by any act or knowledge on the part of either party, except by an instrument in writing signed by a duly authorized officer or representative of the parties. Further, the waiver by either party of any right hereunder or the failure to enforce at any time any of the provisions of this Agreement, or any rights with respect thereto, shall not be deemed to be a waiver of those same rights in the future or of any other rights hereunder or any breach or failure of performance of the other party.

#### 22. RESOLUTION OF DISPUTES.

22.1 In the event of any dispute, controversy or claim arising out of or relating to this Agreement, including its interpretation, performance or termination, or to a breach hereof, the parties agree to commence a good faith discussion toward the resolution of such issues. If, after sixty (60) days, the parties are unable to reach a resolution or if one party notifies the other in writing after at least thirty (30) days of negotiating that it believes in good faith that negotiating for the remainder of such sixty (60) day period will not result in a resolution of the dispute, such issues shall be finally resolved by arbitration, under the rules of the JAMS/Endispute. The arbitration shall be conducted by one arbitrator mutually selected by the parties.

- 22.2 The arbitration, including the rendering of the award, shall take place in New York, New York in the United States. The decision of the arbitrator shall be binding upon the parties hereto, and the expense of the arbitration (including without limitation the award of attorneys' fees to the prevailing party) shall be paid as the arbitrator determines. The decision of the arbitrator shall be executory, and judgment thereon may be entered by any court of competent jurisdiction.
- 22.3 This Agreement and any arbitration or legal proceeding related to it shall be governed by the laws of the State of New York, USA, without regard to its conflict of laws rules.

#### 23. CONFIDENTIALITY; PUBLICITY.

- Neither party shall use or disclose the other's Proprietary Information except disclosure only to those of its agents and employees to whom it is necessary in order properly to carry out their duties as limited by the terms and conditions hereof and only if such agents or employees are bound by conditions of confidentiality substantially similar to those imposed on the parties herein. During the term of this Agreement and for a period of five (5) years after termination or expiration of this Agreement, each party shall hold the Proprietary Information of the other party in strict confidence and shall not use or disclose such Proprietary Information for any purpose other than performing the terms of this Agreement. Each party shall return documents, computer disks and other media containing the other's Proprietary Information as soon as practicable, and in any event within ten (10) days, after the termination or expiration of this Agreement or on demand by the party furnishing the information. All such Proprietary Information shall remain the exclusive property of the disclosing party during the term of this Agreement and thereafter.
- Notwithstanding anything contained in this Agreement to the contrary, neither party shall have the above obligations with respect to Proprietary Information if it:
  - (a) was in the public domain at the time of disclosure without breach of this Agreement;
  - (b) was known to or contained in the records of the receiving party from a source other than the disclosing party at the time of disclosure and can be so demonstrated;

- (c) becomes known to the receiving party from a source other than disclosing party without breach of this Agreement and can be so demonstrated; or
- (d) was disclosed pursuant to court order or as otherwise compelled by law; *provided however*, the other party is notified of such proposed disclosure as soon as is reasonably possible and the disclosure is limited to the maximum extent reasonably possible.
- 23.3 The parties shall consult with each other before issuing any press release or otherwise making any public statements with respect to this Agreement. Except as may be required by law or court order, neither party shall issue a press release or make any public statement without the prior consent of the other party, which consent shall not be unreasonably withheld or delayed.
- 24. **Entire Agreement.** This Agreement supersedes and cancels any previous agreements or understandings, whether oral, written or implied, heretofore in effect and sets forth the entire agreement between InspireMD and Penumbra with respect to the subject matter hereof.
- 25. **INDEPENDENT CONTRACTOR.** Nothing herein contained shall be deemed to create an agency, joint venture, franchisor-franchisee, employer-employee or partnership relationship between the parties hereto. The parties are independent contractors. InspireMD will not provide significant assistant to or control Penumbra's method of business or operation of its business. It is understood and agreed that neither party is, by reason of this Agreement or anything herein contained, constituted or appointed the agent or represen **t** ative of the other for any purpose. Each party acknowledges that this Agreement creates an arm's length commercial relationship that cannot and will not be transformed into a fiduciary or other special relationship by course of dealing, by any special indulgences or benefits that InspireMD bestows upon Penumbra or by inference from a party's conduct. Any contrary final determination by any board, tribunal or court of competent jurisdiction requires the amendment of this Agreement in any way necessary to establish an independent contractor relationship.

Penumbra acknowledges that Penumbra and its subdistributors shall purchase Products from InspireMD at bona fide wholesale prices. Penumbra shall not pay any fee or other amount to InspireMD, whether to obtain the rights set forth in this Agreement or for any other reason. Penumbra is not obligated by this Agreement to make any initial or ongoing purchase of inventory of Products. Penumbra acknowledges that InspireMD is not requiring the purchase or lease of any real or personal property as a condition of obtaining this Agreement.

As an independent contractor, Penumbra has the right to operate its business as it chooses, including hiring, terminating, scheduling and disciplining of Penumbra's own employees, and bears all risks and costs of operating such business. Penumbra has no authority to retain any person on behalf of InspireMD. It is expressly understood that Penumbra has no claim, or right under any circumstances, to any benefits or other compensation currently or at any time paid InspireMD to its employees. No fiduciary relationship exists between the parties.

Penumbra is solely responsible for: (a) all matters relating to payment of its employees, contractors or agents, including compliance with hiring, supervision, termination, discipline, workers' compensation, unemployment, disability insurance, Social Security, withholding and all other applicable laws and regulations governing such matters; and (b) Penumbra's own acts and omissions, and those of its employees, contractors and agents.

Penumbra confirms and acknowledges that no person representing InspireMD made any oral, visual or written claim, presentation or representation to Penumbra that suggested that Penumbra might obtain any actual, projected or forecasted level of sales, income or profits.

26. NO AGENCY. Penumbra acknowledges and agrees that InspireMD would not consider entering into this Agreement with Penumbra were it contemplated by either of the Parties that any laws, rules or regulations in the Distribution Territory that apply to commercial agency relationships, sales representative relationships, franchises, or distributorships would apply to the relationship created by this Agreement to the extent that such laws may grant Penumbra goodwill indemnity or other consideration upon the expiration or termination of this Agreement or to the extent that such laws may otherwise afford rights to Penumbra which extend beyond those expressly granted by InspireMD in this Agreement (collectively, "Agency Laws"). Accordingly, Penumbra agrees that this Agreement requires Penumbra to: (a) unconditionally waive any rights that each of them might have under any Agency Laws and any other law of similar import; (b) unconditionally and forever release InspireMD from any liability under the Agency Laws and any other law of similar import, including but not limited to any obligation to pay Penumbra any compensation under any Agency Laws upon the expiration or termination of this Agreement, or any obligation to provide Penumbra with additional territory or exclusive rights of any sort beyond those provided in this Agreement, (c) represent, warrant and covenant that Penumbra will not seek to file or register as an agent under any Agency Laws or bring or attempt to bring any cause of action, suit, proceeding, claim, demand, investigation or inquiry (whether a formal proceeding or otherwise) under any Agency Laws or laws of similar import in any court, arbitration proceeding or before any other tribunal; and (d) acknowledge and agree that any attempt to register or bring any cause of action, suit, proceeding, claim, demand, investigation or inquiry (whether a formal proceeding or otherwise) under any of Agency Laws or laws of similar import will be an event of default under this Agreement permitting InspireMD to terminate this Agreement immediately upon notice to Penumbra.

**EXCUSABLE DELAY/ADVERSE CHANGE OF LAW.** If there occurs any adoption, promulgation, modification or reinterpretation, by any governmental authority in the Distribution Territory or governmental authority in the US having jurisdiction over the Parties, of any law, regulation, policy, order, circular or similar directive which action materially and adversely affects InspireMD's or Penumbra's ability to enjoy the economic benefits of this Agreement or to enforce its rights under this Agreement (" **Adverse Change of Law**"), the Parties agree to use their best efforts to cooperate with each other to amend this Agreement either to bring it into conformity with the requirements of the Adverse Change of Law or to seek an alternative way to comply with the Adverse Change of Law. If, in InspireMD's or Penumbra's, as the case may be, sole judgment, this Agreement cannot be modified to comply with an Adverse Change of Law without undermining material elements of the relationship, InspireMD or Penumbra may, at its option, without liability for such action or any further obligation to the other party, terminate this Agreement and the rights granted hereby upon 15 days' prior notice to the other party. From the time that InspireMD provides notice of such termination of this Agreement to Penumbra, InspireMD will have no obligation to accept any order for Products from Penumbra.

#### 28. Force Majeure.

Except for payments due under this Agreement, neither party shall be liable in damages, or shall be subject to termination of this Agreement by the other party, for any delay or default in performing any obligation hereunder if that delay or default is due to any cause beyond the reasonable control and without fault or negligence of that party; *provided that* in order to excuse its delay or default hereunder, a party shall use commercially reasonable efforts to notify the other of the occurrence or the cause within five (5) days of the occurrence or cause, specifying the nature and particulars thereof and the expected duration thereof; and *provided*, *further*, that within fifteen (15) days after the termination of such occurrence or cause, such party shall give notice to the other party specifying the date of termination thereof. All obligations of both parties shall return to being in full force and effect upon the termination of such occurrence or cause.

- In the event that any delay or default in performing any obligation hereunder, as described in section 22.1, extends for ninety (90) days beyond the termination of the occurrence or cause then the parties shall meet to determine how to resolve such delay or default.
- 28.3 If, after meeting for an additional thirty (30) days, the parties are unable to agree on how to resolve the delay or default then the party not invoking *force majeure*, as provided above, shall have the right to terminate the Agreement upon thirty (30) days notice.
- 28.4 For the purposes of this Section, a "cause beyond the reasonable control" of a party shall include, without limiting the generality of the phrase, any act of God, act of any government or other authority or statutory undertaking, act of terrorism, industrial dispute, fire, explosion, accident, power failure, flood, riot or war (declared or undeclared).
- 29. Severability. If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that this Agreement shall continue in force and effect except for the part declared invalid or unenforceable by order of such court. The parties shall consult and use commercially reasonable efforts to agree upon a valid and enforceable provision as a reasonable substitute for such invalid or unenforceable provision in light of the intent of this Agreement.
- 30. COUNTERPARTS. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 31. Use of Affiliates. Each party acknowledges that the other party may use Affiliates to perform obligations under this Agreement.
- 32. FILINGS. Penumbra agrees that it shall not file any copy of this Agreement or memorandum of this Agreement with any Government without InspireMD's prior written consent. Penumbra shall not have any right to obtain or maintain any government approval, registration or recordation of this Agreement unless deemed necessary by InspireMD, including, but not limited to, in relation to any Agency Laws. Penumbra shall bear the expense, either directly or through reimbursement to InspireMD, of obtaining approval of, and/or registering or recording this Agreement and any amendment with appropriate governmental authorities and accrediting bodies in the Distribution Territory.

33. **PENUMBRA REPRESENTATION.** Penumbra represents and warrants to InspireMD that it and all of its employees and or agents are fully authorized and able to enter into this Distribution Agreement and that Penumbra and that the actions contemplated under this Distribution Agreement by Penumbra and its employees or agents do not violate any existing agreement, employment contract, law, or other understanding.

In WITNESS WHEREOF, the parties hereto have signed this Agreement.

INSPIREMD, INC. PENUMBRA, INC.

By: /s/ Alan Milinazzo By: /s/ JamesPray

Name: Alan Milinazzo Name: James Pray

Title: Chief Executive Officer Title: President

# Exhibit A - Distribution Territory/Pricing/Minimum Target

Austria Full Penumbra coverage

Benelux Transition Plan

France Full Penumbra coverage

Germany Transition Plan

Nordic

Sweden Full Penumbra Coverage

Denmark Full Penumbra Coverage

Norway Full Penumbra Coverage

Finland Full Penumbra Coverage

**Baltics** 

Latvia Non Exclusive arrangement.

Estonia Full Penumbra Coverage

Lithuania Full Penumbra Coverage

Poland Transition Plan

Portugal Full Penumbra Coverage

Switzerland Full Penumbra Coverage

UK/Ireland Full Penumbra Coverage

CGUARD TRANSFER PRICING: Initial transfer pricing will be \$\*\*\*\* per unit through 12/31/15. After \*\*\*\*\*, transfer pricing will be \*\*\*\*\*.

# **Minimum Target (In Units/Quarter):**

	Q3 2015	Q4 2015	<b>Total 2015</b>	Q1 2016	Q2 2016	Q3 2016	Q4 2016	<b>Total 2016</b>
<b>CGuard Units</b>	****	****	****	****	****	****	****	****

# EXHIBIT B-PRODUCTS

Name of the Item	Type	Article Number	Range
CGuard Carotid	Carotid	MCSddll	
Embolic Prevention Stent System	Embolic Prevention Stent System		
		Explanation:	dd: 06 – 10 mm
		dd= diameter of stent (mm)	ll: 20 to 60 mm
		ll= length of stent (mm)	
		CRXddll	
		Explanation:	dd: 06 – 10 mm
		dd= diameter of stent (mm)	ll: 20 to 60 mm
		ll= length of stent (mm)	
		30	
· · · · · · · · · · · · · · · · · · ·		<u> </u>	

# Exhibit C- Wiring

	<u>Instructions</u>
Bank Name:	****
Account Number:	****
Routing/Transit for ACH Debits & Credits:	****
TRANSACTIONS)	
Routing/Transit for Wires:	****
SWIFT:	****
Bank Address:	****
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### Exhibit D - Quality Agreement

- 1. Products. The Inspire Products that are the subject matter of this Agreement are listed in Exhibit B which is an integral part of this Agreement.
- 2. Quality Penumbra or any sub-distributor rendered by Penumbra shall be responsible for the implementation and maintenance of a Quality System that fulfills the requirements of MDD 93/42/EEC, including, *inter alia* recalls, notification to local authorities and document maintenance.
- 3. Post-Marketing Surveillance Program. Penumbra shall maintain a Post-Marketing Surveillance Program (the "PMSP"). Inspire and Penumbra shall cooperate with each other in order to facilitate the efficient use of the PMSP. Said PMSP shall include, among others, immediate notification to both Inspire and Penumbra in the event that a serious defect is discovered in a product which has already been released.
- 4. <u>Documentation</u>. Penumbra shall maintain and keep all written and electronic records required by any laws or regulations relating to the distribution of the Inspire Products for 15 years at least. Further, Penumbra shall submit all documentation requested by the authorities or notified bodies for inspection or for any other purpose, as instructed by Inspire from time to time.
- 5. <u>Traceability of products</u>. In order to ensure compliance with laws and regulations relating to the traceability of the products, Penumbra undertakes to take all appropriate measures to ensure:
  - backward traceability to Inspire (and where applicable, to the Authorized Representative (name and address of the Authorized Representative printed on Product packaging); and
  - reasonable product traceability to users to minimize the risks in case of recall; and
  - language requirements according to national legislation; and
  - compliance with any other responsibilities, liabilities, and obligations as set forth in Council Directive 93/42/EEC for manufacturers and any other laws, statutes, directives and regulations promulgated by any governmental body that may apply to the manufacturing and distribution of products.

# 6. General Requirements:

- 6.1. Penumbra is aware of the rules and regulations relating to modifications to the manufacturing process or to the product which are relevant for safety and for the CE documentation are those which could possible affect the essential requirements as defined in ISO 13485 especially in respect to the established risk management in accordance with EN ISO 14971:2012 and undertakes to comply with said regulations.
- 6.2. Inspire shall inform Penumbra of the results of quality audits relevant the registration of the products, should such result require an amendment to the certificate.
- 7. <u>Customer Complaints and Recalls</u>. If Penumbra discovers or becomes aware of a serious defect in a product which has already been distributed, Penumbra shall immediately notify Inspire in writing, specifically where notifiable incidents according to MDD ISO 13485 which are to be reported immediately in written form to the safety commissioner for medical products of Inspire.

/s/ Alan Milinazzo	/s/ James Pray	
Inspire MD LTD	Penumbra, Inc.	
By: Alan Milinazzo	By: James Pray	
Title: Chief Executive Officer	Title: President	
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# CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Alan Milinazzo, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

ovember 9, 2015	/s/ Alan Milinazzo
	Alan Milinazzo

Chief Executive Officer

# CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

### I, Craig Shore, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

November 9, 2015	/s/ Craig Shore	
	Craig Shore	
	Chief Financial Officer	

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2015 of InspireMD, Inc. (the "Company"). I, Alan Milinazzo, the Chief Executive Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 9, 2015 By: /s/ Alan Milinazzo

Name: Alan Milinazzo

Title: Chief Executive Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

# CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2015 of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 9, 2015 By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.