

InspireMD, Inc.  
Form 10-Q  
November 06, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(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, 2018**

**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)



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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of November 5, 2018:  
37,604,035

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**INSPIREMD, INC.**

**INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

September 30, 2018

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**INSPIREMD, INC.**

INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

September 30, 2018

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The amounts are stated in U.S. dollars in thousands

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**INSPIREMD, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)**

(U.S. dollars in thousands)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	11,247	3,710
Accounts receivable:		
Trade, net	710	643
Other	169	207
Prepaid expenses	145	62
Inventory	816	533
<b>TOTAL CURRENT ASSETS</b>	<b>13,087</b>	<b>5,155</b>
<b>NON-CURRENT ASSETS:</b>		
Property, plant and equipment, net	400	476
Funds in respect of employee rights upon retirement	446	476
<b>TOTAL NON-CURRENT ASSETS</b>	<b>846</b>	<b>952</b>
<b>TOTAL ASSETS</b>	<b>13,933</b>	<b>6,107</b>

**INSPIREMD, INC.****CONSOLIDATED BALANCE SHEETS****(Unaudited)**

(U.S. dollars in thousands other than share and per share data)

	September 30, 2018	December 31, 2017
<b>LIABILITIES AND EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accruals:		
Trade	456	328
Other	1,891	2,134
Contract liability	26	20
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,373</b>	<b>2,482</b>
<b>LONG-TERM LIABILITIES-</b>		
Liability for employees rights upon retirement	608	624
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>608</b>	<b>624</b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)</b>		
<b>TOTAL LIABILITIES</b>	<b>2,981</b>	<b>3,106</b>
<b>REDEEMABLE PREFERRED SHARES</b>	<b>-</b>	<b>274</b>
<b>EQUITY:</b>		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at September 30, 2018 and December 31, 2017; 36,694,035 and 1,483,556 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	4	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at September 30, 2018 and December 31, 2017; 17,303 and 27,075 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at September 30, 2018 and December 31, 2017; 61,423 and 741,651 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	-	-
Preferred D shares, par value \$0.0001 per share; 750 shares authorized at September 30, 2018 and December 31, 2017 ; 0 and 750 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively		-
Additional paid-in capital	156,327	143,079
Accumulated deficit	(145,379 )	(140,352 )
<b>Total equity</b>	<b>10,952</b>	<b>2,727</b>
<b>Total liabilities, redeemable preferred shares and equity</b>	<b>13,933</b>	<b>6,107</b>



**The accompanying notes are an integral part of the interim consolidated financial statements.**

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**INSPIREMD, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

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

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30</b>		<b>September 30</b>	
	2018	2017	2018	2017
REVENUES	769	718	2,779	1,927
COST OF REVENUES	571	565	2,011	1,553
GROSS PROFIT	198	153	768	374
OPERATING EXPENSES:				
Research and development	416	288	898	1,041
Selling and marketing	605	671	1,677	1,835
General and administrative	1,156	1,279	3,598	4,281
Total operating expenses	2,177	2,238	6,173	7,157
LOSS FROM OPERATIONS	(1,979	) (2,085	) (5,405	) (6,783
<b>FINANCIAL EXPENSES</b> (Income), net:				
Interest expenses	-	-	-	119
Other financial expenses (income)	32	1	(378	) 36
Total financial expenses (income)	32	1	(378	) 155
LOSS BEFORE TAX EXPENSES	(2,011	) (2,086	) (5,027	) (6,938
TAX EXPENSES	-	-	-	1
NET LOSS	(2,011	) (2,086	) (5,027	) (6,939
<b>NET LOSS PER SHARE</b> - basic and diluted	(0.05	) (6.56	) (0.32	) (30.42
<b>WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE</b> - Basic and diluted	40,764,158	317,896	16,729,052	248,907

**The accompanying notes are an integral part of the interim consolidated financial statements**

**INSPIREMD, INC.****CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY****(Unaudited)****(U.S. dollars in thousands, except share data)**

	Common stock		Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT DECEMBER 31, 2017	1,483,556	*	27,075	*	741,651	*	750	*	\$ 143,079	\$(140,352 )	\$2,727
Net loss										\$(5,027 )	\$(5,027 )
Issuance of common shares, warrants, Pre-funded warrants and exercise of pre-funded warrants, net of \$2,171 issuance costs	33,873,810	4							15,805		15,809
Redemption of Series D Preferred Stock							(750)	*	(750 )		(750 )
Conversion of Series B Preferred Stock to common shares	80,620	*	(9,772 )	*					274		274
Conversion of Series C Preferred Stock to common shares	1,144,726	*			(326,436)	*			936		936
Exercise of Unit Purchase Option	111,442	*							557		557
Accretion of redeemable preferred shares									(438 )		(438 )
<b>Redemption of Series C</b>					(353,792)	*			(3,200 )		(3,200 )

**Preferred Stock**

Share-based compensation related to restricted stock and stock options award, net of forfeitures of 121 shares	(119	)	*						64		64
BALANCE AT											
September 30, 2018	36,694,035	4	17,303	*	61,423	*	-	*	\$ 156,327	\$(145,379 )	\$ 10,952

\* Represents an amount less than \$1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

**INSPIREMD, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)**

(U.S. dollars in thousands)

	Nine months ended September 30,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,027 )	\$ (6,939)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	115	127
Loss from sale of property, plant and equipment	-	13
Change in liability for employees right upon retirement	(16 )	23
Financial expenses	(425 )	(505 )
Share-based compensation expenses	64	612
Changes in operating asset and liability items:		
Increase in prepaid expenses	(83 )	(44 )
Increase in trade receivables	(67 )	(182 )
Decrease (increase) in other receivables	29	(10 )
Increase in inventory	(283 )	(76 )
Increase (decrease) in trade payables	128	(216 )
Increase (decrease) in other payables and contract liability	(238 )	841
Net cash used in operating activities	(5,803 )	(6,356)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment	(30 )	(237 )
Amounts funded (withdrawn) in respect of employee rights upon retirement, net	30	(45 )
Net cash used in investing activities	-	(282 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Taxes withheld in respect of share issuance	-	(10 )
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of \$2,161 and \$776 issuance costs, respectively	16,365	6,072
Redemption of series C and D preferred stock	(3,014 )	
Repayment of long-term loan	-	(2,179)
Net cash provided by financing activities	13,351	3,883
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	(11 )	4
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	7,537	(2,751)
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD</b>	3,710	7,516
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD</b>	\$ 11,247	\$ 4,765
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:</b>		
Classification of Redemption Obligation of Preferred Shares to Mezzanine and Embedded Derivative, see Note 4c	164	-

**The accompanying notes are an integral part of the interim consolidated financial statements.**

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(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 vascular and coronary disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

The Company’s carotid product (CGuard™ EPS) combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease.

The Company’s coronary product combining MicroNet and a bare-metal stent (MGuard Prime™ EPS) is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

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, 2018, as well as a history of 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™ EPS) 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 only has sufficient resources to fund operations through the end of the third quarter of 2019. Therefore, there is substantial doubt about the Company’s ability to continue as a going concern. 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.

Management's plans include the continued commercialization of the Company's 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.

## **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, 2017, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 13, 2018. The results of operations for the nine and three months ended September 30, 2018 are not necessarily indicative of results that could be expected for the entire fiscal year.

### **Revenue from contracts with customers**

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers, and all the related amendments (the "New Revenue Standard") to all contracts using the modified retrospective method. The standard did not have any effect upon its initial application.



**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 2 - BASIS OF PRESENTATION** (continued):

**Revenue recognition prior to the adoption of the New Revenue Standard**

Please refer to Note 1 to the consolidated financial statements and critical accounting policies included in our Annual Report on Form 10-K for the year ended December 31, 2017 for a summary of our significant accounting policies.

**Revenue recognition following the adoption of the New Revenue Standard**

A contract with a customer exists only when: 1) the parties to the contract have approved it and are committed to perform their respective obligations, 2) the Company can identify each party's rights regarding the distinct goods or services to be transferred ("Performance Obligations"), 3) the Company can determine the transaction price for the goods or services to be transferred, 4) the contract has commercial substance and 5) it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for Performance Obligations upon transfer of control to the customer, excluding sales taxes.

Revenue from sales of goods, including sales to distributors, is recognized when the customer obtains control of the product, once the Company has a present right to payment, legal title, and risk and rewards of ownership are obtained by the customer. This occurs when products are shipped.

The Company recognizes the incremental costs of obtaining contracts as an expense since the amortization period of the assets that the Company otherwise would have recognized is one year or less. The costs are recorded under selling and marketing expenses. Disaggregated revenue is disclosed in Note 10.

**NOTE 3 – RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS**

In February 2016, the FASB issued guidance on leases. The guidance requires entities to record lease assets and lease liabilities on the balance sheet and disclose key information about leasing arrangements. In September 2017, the FASB issued additional amendments providing clarification and implementation guidance. The guidance will become effective for interim and annual periods beginning on January 1, 2019. Entities are required to adopt the standard using either a modified retrospective transition approach, which requires application of the new guidance at the beginning of the earliest comparative period, or to initially apply the new leases standard at the adoption date (January 1, 2019) and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

In July 2018, the FASB issued codification improvements, which clarify how to apply certain aspects of the new lease standard. Although the Company has not finalized its process of evaluating the impact of adoption of the ASU on its consolidated financial statements, the Company expects there will be a material increase to assets and liabilities related to the recognition of right of use asset and lease liabilities on the Company's balance sheet for leases currently classified as operating leases in an estimated amount ranging from \$600,000 to \$700,000.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 - EQUITY:**

On February 7, 2018, 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-thirty-five reverse stock split of its common stock, par value \$0.0001 per share, effective as of February 7, 2018. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

On December 1, 2017, as part of a planned recapitalization, the Company sold 750 shares of Series D Convertible Preferred Stock (the "Series D Preferred Stock") to an institutional accredited investor (the "Series D Investor") in a private placement (the "Series D Private Placement") pursuant to a securities purchase agreement (the "Series D Purchase Agreement"), dated November 28, 2017, for aggregate gross proceeds of \$750,000. The stated value of each share of Series D Preferred Stock was \$1,000, and the Series D Preferred Stock was convertible, at the option of the holder, into shares of the Company's common stock (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series D Preferred Stock ("Series D Certificate of Designation")), at the initial conversion price of \$7.00 per share, subject to adjustment as provided in the Series D Certificate of Designation. Pursuant to the Series D Purchase Agreement and the Series D Certificate of Designation, the purchasers of Series D Preferred Stock had the option, subject to certain limitations, to exchange their Series D Preferred Stock into the securities issued in a subsequent offering (the "Series D Exchange Right") or into the securities the Company would sell in an offering of the Company's common stock or common stock equivalents for gross proceeds of at least \$8 million (a "Qualified Offering") upon consummation of a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis. In addition, in accordance with the Series D Purchase Agreement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Convertible Preferred Stock (the "Series B Preferred Stock") would be automatically exchanged into the securities the Company would sell in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis. As a result of the issuance and sale of the Series D Preferred Stock, the conversion price of the outstanding shares of Series B Preferred Stock was reduced to \$7.00 pursuant to the anti-dilution adjustment provisions of the Series B Preferred Stock. There was no change to the conversion price of the outstanding Series C Convertible Preferred Stock ("Series C Preferred Stock") as a result of an amendment made to the terms of the Series C Preferred Stock exempting the issuance of the Series D Preferred Stock from the anti-dilution adjustment provisions of the Series C Preferred Stock.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

On February 21, 2018, the Series D Purchase Agreement was amended (“February 2018 SPA amendment”) to require the Company (i) to use 15% of the proceeds from any subsequent offering of the Company’s securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock, and (ii) upon closing of any subsequent offering that is a Qualified Offering, to exchange all remaining outstanding shares of Series C Preferred Stock held by the Series D Investor for any securities issued in such Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series C Preferred Stock). The February 2018 SPA amendment provided that in the event that the Company fails, or is unable, to issue securities issued in the Qualified Offering to the Series D Investor in exchange for such investor’s remaining Series C Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, the Company would be required to offer to purchase from such investor those shares of Series C Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Preferred Stock. This requirement to purchase from the Series D Investor those shares of Series C Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Preferred Stock in case of a Qualified Offering, and the requirement to use 15% of the proceeds from any subsequent offering of the Company’s securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock are referred to as “Redemption Obligations.”

For accounting purposes, the Company analyzed the classification of the Series C Preferred Stock in light of the Redemption Obligations of the Company regarding such preferred stock held by the Series D Investor, as agreed upon in the February 2018 SPA amendment. Based on ASC 480-10-S99 the Company determined that since the Redemption Obligation may occur upon contingent events, such as subsequent financing transactions not meeting the threshold for a Qualified Offering, that are not solely within the Company’s control, the Series C Preferred Stock is considered as contingently redeemable and should be classified outside of permanent equity, within mezzanine equity.

In addition, the Company analyzed whether the conversion feature embedded in the shares of the Series C Preferred Stock subject to the Redemption Obligation should be bifurcated. As certain shares of the Series C Preferred Stock are contingently redeemable, the host contract was determined to be akin to debt, and the conversion feature not clearly and closely to the debt host given the anti-dilution protection included in the terms of these Series C Preferred Stock. Consequently, an embedded derivative was separated from the host contract and accounted for as a derivative instrument pursuant to Subtopic 815-10.

As of the date of the February 2018 SPA amendment, the Company classified an amount of \$3,200,000 from permanent equity to “Redeemable Preferred Shares” and “Derivative Liability” in an amount of \$2,580,000 and \$620,000, respectively.

The Company values Level 3 derivative liability using an internally developed valuation model, whose inputs include potential equity transactions probability of completing successful fund raising during the relevant period and stock prices.

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

On February 26, 2018, the Company and the Series D Investor entered into a waiver agreement (the “Waiver Agreement”) which provided that (i) the Series D Exchange Right would not be applicable to an offering of up to \$7,000,000 which occurred no later than March 9, 2018, (ii) the Company shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock in such offering, and (iii) instead of using 15% of the proceeds from such offering to redeem shares of Series C Preferred Stock held by the Series D Investor, the Company shall use 15% of the proceeds from such offering to redeem a portion of the outstanding shares of Series D Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On March 1, 2018, the Company closed an underwritten public offering of 1,000,000 shares (the “March 1, 2018 Shares”) of the Company’s common stock. The offering price to the public of the March 1, 2018 Shares was \$3.00 per share. The Company received gross proceeds of \$3.0 million from the offering, before deducting underwriter commissions and discounts and other fees and expenses payable by the Company.

Pursuant to the Series D Purchase Agreement, as amended by February 2018 SPA amendment and the Waiver Agreement, following the closing of the offering on March 1, 2018, the Company used \$450,000 (representing 15% of the gross proceeds from the offering) to purchase from the Series D Investor 450 shares of the Series D Preferred Stock at a per share purchase price equal to the stated value of the Series D Preferred Stock.

In connection with the offering, the Company issued to the underwriter warrants to purchase up to 60,000 shares of common stock, or 6% of the number of shares of common stock sold in the offering (the “March Underwriter Warrants”). The March Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending February 27, 2023, at a price per share equal to \$3.75 (125% of the offering price to the public per share).

As a result of the offering, the respective conversion price for each of the Series B Preferred Stock, the Series C Preferred Stock and the Series D Preferred Stock was reduced to \$3.00 per share, and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock, the Series C Preferred Stock and the Series D Preferred Stock had increased as follows:

an aggregate of 190,333 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of March 1, 2018.

an aggregate of 1,497,427 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 741,651 shares of Series C Preferred Stock outstanding as of March 1, 2018.

an aggregate of 142,857 additional shares of common stock upon conversion of the Series D Preferred Stock, based on 750 shares of Series D Preferred Stock outstanding as of March 1, 2018.

For accounting purposes, the Company analyzed whether the change in the conversion price of the Series D Preferred Stock constitutes an extinguishment for accounting purposes, by comparing the fair value of the Series D Preferred Stock immediately before and after such change in terms. Since the fair value increased substantially, i.e. by more than 10%, the change in terms was accounted for as an extinguishment. As a result, the difference between the fair value of the Series D Preferred Stock immediately after the change in term (the reduction of the conversion price from \$7.00 per share to \$3.00 per share, pursuant to the Series D Purchase Agreement, as amended by February 2018 SPA amendment and the Waiver Agreement) and the carrying amount immediately before such change, in the amount of \$49,000, was added to the basic loss per share attributable to the Company's common stockholders.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

On March 28, 2018, the Company and the Series D Investor entered into the second waiver agreement (the “Second Waiver Agreement”) which provided that (i) the Series D Exchange Right would not be applicable to a subsequent financing consisting solely of shares of common stock, which shall be publicly registered on Form S-3 for gross proceeds to us of up to \$5,000,000, to be consummated by not later than April 3, 2018 (the “Planned April 2018 Offering”), (ii) the Company’s obligation to use 15% of the proceeds from any subsequent offering of our securities **f.** that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor would not be applicable to the Planned April 2018 Offering, (iii) the Company shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock sold in the Planned April 2018 Offering, and (iv) the Company shall use \$300,000 of the proceeds from the Planned April 2018 Offering to redeem outstanding shares of Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock.

On March 28, 2018, the Company entered into an underwriting agreement relating to an underwritten public **g.** offering of 2,857,143 shares of common stock.

On April 2, 2018, the Company closed a public offering of 2,857,143 shares (the “April 2, 2018 Shares”) of the Company’s common stock at the offering price to the public of \$1.75 per share. The Company received gross proceeds of \$5.0 million from the offering, before deducting underwriter discounts and commissions and other fees and expenses payable by the Company.

In connection with the offering, the Company agreed to issue to the underwriter warrants to purchase up to 171,429 shares of common stock, or 6% of the April 2, 2018 Shares sold in the offering (the “April Underwriter Warrants”). The April Underwriter Warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending March 28, 2023, at a price per share equal to \$2.1875 (125% of the offering price to the public per April 2, 2018 Share).

As a result of the issuance and sale of the April 2, 2018 Shares, the conversion price of the outstanding shares of Series D Preferred Stock was reduced to \$1.75 pursuant to the Second Waiver Agreement, and the number of shares of common stock issuable upon conversion of the Series D Preferred Stock increased by an aggregate of 71,429 additional shares of common stock, based on 300 shares of Series D Preferred Stock outstanding as of April 2, 2018.



For accounting purposes, the Company analyzed whether the change in the conversion price of the Series D Preferred Stock constitutes an extinguishment for accounting purposes, by comparing the fair value of the Series D Preferred Stock immediately before and after such change in terms. Since the fair value increased substantially, i.e. by more than 10%, the change in terms was accounted for as an extinguishment. As a result, the difference between the fair value of the Series D Preferred Stock immediately after the change in term (the further reduction of the conversion price from \$3.00 per share to \$1.75 per share, pursuant to the Series D Purchase Agreement, as amended by February 2018 SPA amendment, the Waiver Agreement and the Second Waiver Agreement) and the carrying amount immediately before such change, in the amount of \$32,000, was subtracted from the basic loss per share attributable to the Company's common stockholders.

Pursuant to the Series D Purchase Agreement, as amended by the February 2018 SPA amendment, the Waiver Agreement and the Second Waiver Agreement, following the closing of the offering on April 2, 2018, the Company used \$300,000 of the net proceeds of the offering to purchase from the Series D Investor 46,875 shares of the Series C Preferred Stock at a per share purchase price equal to the stated value of the Series C Preferred Stock.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

Upon execution of the underwriting agreement, the respective conversion price of the outstanding shares of Series B Preferred Stock and Series C Preferred Stock was reduced to \$1.75 pursuant to the anti-dilution adjustment provisions of the Series B Preferred Stock and of the Series C Preferred Stock, and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock had increased as follows:

an aggregate of 237,916 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of March 28, 2018.

an aggregate of 688,297 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 451,695 shares of Series C Preferred Stock outstanding as of March 28, 2018.

On June 28, 2018, the Company and the Series D Investor entered into a letter agreement (the “Letter Agreement”) which further amended the Series D Purchase Agreement to provide that, notwithstanding anything to the contrary in the prior agreements, in the event the Company consummates a Qualified Offering in which the Series D Investor and its affiliates invest at least \$3 million, (i) instead of an automatic exchange of all outstanding shares of Series C Preferred Stock held by the Series D Investor into securities issued in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis, all outstanding shares of Series C Preferred Stock held by the Series D Investor will be redeemed at a per share purchase price equal to the stated value of the Series C Preferred Stock, and (ii) all outstanding shares of Series D Preferred Stock will be redeemed at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On June 29, 2018, the Company entered into an underwriting agreement relating to an underwritten public offering (the “July 2018 Offering”) of (i) 10,851,417 common units (“Common Units”), with each Common Unit being comprised of one share of the Company’s common stock, par value \$0.0001 per share, and one Series D warrant (collectively, the “Series D Warrants”) to purchase one share of common stock and (ii) 22,481,916 pre-funded units (“Pre-Funded Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant (collectively, the “Pre-Funded Warrants”) to purchase one share of common stock and one Series D Warrant, which closed on July 3, 2018. The offering price to the public was \$0.30 per Common Unit and \$0.29 per Pre-Funded Unit. The Company also granted the Underwriter a 30-day option to purchase up to an additional 4,999,999 shares of common stock at a purchase price of \$0.29 per share and/or up to 4,999,999 additional Series D Warrants to purchase 4,999,999 shares of common stock at a purchase price of \$0.01 per Series D Warrant, less the underwriting discounts and commissions of \$0.0203 per share and \$0.0007 per Series D Warrant. The Underwriter exercised its option to purchase an additional 4,999,999 Series D

Warrants to purchase 4,999,999 shares of common stock.

Pursuant to the Letter Agreement, the Company had revised its estimate as of June 30, 2018, of the expected timing of redemption of Series C Preferred stock to the estimated closing date of the July 2018 Offering (July 3, 2018 ). As a result, the total of \$438,000 (accretion of the redeemable preferred shares) was recorded against Additional paid-in capital, and added to basic loss per share attributable to the Company's common stockholders, for the six months ended June 30, 2018, and the nine months ended September 30, 2018.

The Series D Warrants included in the Common Units and the Pre-Funded Units are immediately exercisable at a price of \$0.30 per share of common stock, subject to adjustment in certain circumstances, and expire five years from the date of issuance. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series D Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately.

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

Each Pre-Funded Warrant contained in a Pre-Funded Unit is exercisable for one share of our common stock at an exercise price of \$0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full.

Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company's Series B Convertible Preferred Stock and Series C Preferred Stock, the conversion price of the outstanding shares of the Series B Convertible Preferred Stock and the Series C Preferred Stock was reduced to \$0.30 per share, effective as of the date of the underwriting agreement entered for the July 2018 Offering, and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock had increased as follows:

an aggregate of 2,759,829 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of June 29, 2018.

an aggregate of 6,696,448 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 378,840 shares of Series C Preferred Stock outstanding as of June 29, 2018.

On July 2, 2018, the Company filed with the office of the Secretary of State of the State of Delaware a Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock which removes the provision providing for an automatic exchange of all outstanding shares of Series B Convertible Preferred Stock into securities issued in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis upon a Qualified Offering.

On July 3, 2018, the Company closed the July 2018 Offering. The Company received gross proceeds of \$9.8 million from the offering, before deducting underwriter discounts and commissions and other fees and expenses payable by the Company.

For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the Pre-funded Warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them.

During the three months ended September 30, 2018, the Company issued a total of 19,165,250 shares of its common stock in connection with the exercise of 19,165,250 Pre-Funded Warrants. The Company received <sup>i</sup> aggregate cash proceeds equal to approximately \$192,000 in connection with such exercises. As of September 30, 2018, the outstanding Pre-Funded Warrants are exercisable into 3,316,666 shares of common stock.

Pursuant to the underwriting agreement relating to the July 2018 Offering, the Company, upon closing of the July 2018 Offering, issued to the underwriter warrants to purchase up to 2,000,000 shares of common stock, or 6% of the aggregate number of shares of common stock sold in the July 2018 Offering (including the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants sold in the July 2018 Offering). The underwriter warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending July 3, 2023, at a price per share equal to \$0.375 (125% of the offering price to the public per Common Unit).

Pursuant to the Letter Agreement, on July 3, 2018, upon closing of the July 2018 Offering, which was a Qualified Offering, the Company used \$2,264,269 of the net proceeds of the July 2018 Offering to redeem 306,917 shares of Series C Preferred Stock (convertible into 6,547,563 shares of common stock at the time of the redemption) and 300 shares of Series D Preferred Stock (convertible into 171,429 shares of common stock at the time of the redemption) held by the Series D Investor.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 4 – EQUITY** (continued):

- j.** During the nine-month period ended September 30, 2018, 9,772 shares of Series B Preferred Stock were converted into 80,620 shares of common stock.
- k.** During the nine-month period ended September 30, 2018, 326,436 shares of Series C Preferred Stock were converted into 1,144,726 shares of common stock.

- During January and February 2018, the placement agent from the offering closed in July 2016 exercised its unit purchase option to purchase 13,508 units and received 13,508 shares of Series B Preferred Stock and 1,545 Series
- l.** A warrants to purchase common stock. The placement agent subsequently converted its Series B Preferred Stock and received an aggregate of 111,443 shares of common stock. The Company received an aggregate of \$557,205 from the placement agent for the exercise of the unit purchase option.

- As of September 30, 2018, the outstanding Series B Preferred Stock are convertible into 3,330,828 shares of common stock, including the shares of common stock the holders of Series B Convertible Preferred Stock are
- m.** entitled to receive as cumulative dividends at the rate per share of 15% per annum of the stated value for five years, payable in cash or common stock, at the Company’s discretion, but excluding effect of future conversion price adjustment, if any.

- n.** As of September 30, 2018, the outstanding Series C Preferred Stock are convertible into 1,310,357 shares of common stock.
- o.** As of September 30, 2018, the outstanding Series A Warrants are convertible into 52,165 shares of common stock.
- p.** As of September 30, 2018, the outstanding Series B Warrants are convertible into 122,269 shares of common stock.
- q.** As of September 30, 2018, the outstanding Series D Warrants are convertible into 40,333,332 shares of common stock.
- r.** As of September 30, 2018, the Company has authorized 155,000,000 shares of capital stock, par value \$0.0001 per share, of which 150,000,000 are shares of common stock and 3,328,000 are shares of “blank check” preferred stock.

**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 5- NET LOSS PER SHARE:**

Set forth below is data taken into account in the computation of loss per share:

	<b>3 Months Ended</b>		<b>9 Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
	<b>(\$ in thousands)</b>			
NET LOSS	\$ (2,011 )	\$ (2,086 )	\$ (5,027 )	\$ (6,939 )
Beneficial conversion feature of series C preferred shares	-	-	-	(633 )
Adjustments due to extinguishment and accretion of series D and series C preferred shares		-	(407 )	-
Net loss available to common shareholders	\$ (2,011 )	\$ (2,086 )	\$ (5,434 )	\$ (7,572 )
Weighted average of Common Stock and pre-funded warrants outstanding during the period*	40,764,158	317,896	16,729,052	248,907
Basic and diluted loss per share (dollars)	\$ (0.05 )	\$ (6.56 )	\$ (0.32 )	\$ (30.42 )

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 45,762,531 for the nine and three-month periods ended September 30, 2018.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 292,410 for the nine and three month periods ended September 30, 2017.

\* For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the Pre-funded Warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them. 3,316,666 pre-funded warrants are included in the three and nine-month calculation.





**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 6 - FAIR VALUE MEASUREMENT:**

The following tables summarize the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

	9 Months Ended September 30, 2018 Derivative liability
Balance as of January 1, 2018	\$ -
Classification of Redemption Obligation of preferred shares holder to Mezzanine	620
Conversion of Series C Preferred Stock to common shares	(182 )
Revaluation of embedded derivative- financial income	(438 )
Balance as of September 30, 2018	\$ -

Level 3 liabilities include Derivative Liability related to the Company Series C Preferred Stock, as described in Note 4c. The Company values the Level 3 Derivative Liability using multi-period Binomial model, whose inputs include probability of completing fund raising and the related fund raise amounts, volatility of stock prices, stock prices, term to extinguish the Series C preferred shares held by the Series D investor.

In calculating the fair value of Derivative Liability, the Company used the following assumptions: stock price of \$4.20 for the transaction date, and Volatility of 140.95% -166.60% for the transaction date.

**Fair value of financial instruments**

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.

As of both September 30, 2018, and December 31, 2017, allowance for doubtful accounts was \$72,000.

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**INSPIREMD, INC.****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)**

(Unaudited)

**NOTE 7 - INVENTORY:**

	September 30, 2018	December 31, 2017
	(\$ in thousands)	
Finished goods	\$428	\$ 174
Work in process	41	63
Raw materials and supplies	347	296
	\$816	\$ 533

**NOTE 8 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:**

	September 30, 2018	December 31, 2017
	(\$ in thousands)	
Employees and employee institutions	\$819	\$ 853
Accrued vacation and recreation pay	162	165
Accrued expenses	843	976
Provision for sales commissions	37	109
Other	30	31
	\$1,891	\$ 2,134

**NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES:****Litigation:**

The Company received written communication from a distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action (from April 2014). After considering the views of its legal counsel as well

as other factors, the Company's management believes that there is a reasonably possible likelihood of a loss from any related future proceedings would range from a minimal amount up to 1,075,000 Euros.

On April 26, 2016 the Company received a suit seeking damages from the Company amounting to \$2.2 million in cash and unspecified compensation in equity in connection with certain finders' fees. By Order dated February 23, 2017, the U.S. District Court for the Southern District of New York granted our motion to dismiss the suit in its entirety. On January 23, 2018, the clerk entered judgment dismissing the complaint consistent with the District court's order. The Claimants have not appealed the District Court's judgement, and the time in which to do so has expired. Accordingly, this matter is now closed.

In July 2016, a service provider filed a suit seeking damages from the Company's subsidiary amounting to \$1,967,822. The Company's management, after considering the views of its legal counsel as well as other factors, is of the opinion that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 10 - DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:**

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

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(\$ in thousands)			
Germany	\$178	\$136	\$650	\$371
Italy	119	189	512	423
Russia	9	107	168	216
Other	463	286	1,449	917
	\$769	\$718	\$2,779	\$1,927

By product:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
	(\$ in thousands)			
CGuard	\$604	\$526	\$2,268	\$1,315
MGuard	165	192	511	612
	\$769	\$718	\$2,779	\$1,927

By principal customers:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Customer A	22 %	16 %	22 %	12 %
Customer B	10 %	12 %	10 %	12 %
Customer C	5 %	14 %	8 %	10 %
Customer D	1 %	15 %	6 %	11 %

All tangible long lived assets are located in Israel.

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**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(Unaudited)

**NOTE 11 - SUBSEQUENT EVENTS**

At the annual meeting of stockholders of the Company held on October 24, 2018, the Company's stockholders approved the Fourth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (the "2013 Plan") to increase the number of shares of our common stock available for issuance pursuant to awards under the 2013 Plan by an additional 8,900,000 shares, to a total of 8,919,737 shares of common stock.

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## 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-Q.*

*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," "will," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "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, and substantial doubt regarding our ability to continue as a going concern;

our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;

our ability to regain compliance with NYSE American listing standards;

our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;

our ability to adequately protect our intellectual property;

our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;



the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;

market acceptance of our 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;

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;

inability to carry out research, development and commercialization plans;

loss of a key customer or supplier;

technical problems with our research and products and potential product liability claims;

product malfunctions;

price increases for supplies and components;

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;

adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;

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 in this Quarterly Report on Form 10-Q, 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™ stent platform technology for the treatment of complex vascular and coronary 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, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system (“CGuard EPS”) combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, and, in January 2018, received regulatory approval to commercialize CGuard EPS in India, Vietnam and Ecuador. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS,  $\geq 70\%$  occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately \$1.0 billion in 2017. (source: Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets).

In April 2017, we had a pre-investigational device exemption (“IDE”) submission meeting with the U.S. Food and Drug Administration regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. We intend to further our efforts to obtain an IDE approval for CGuard EPS and to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. We believe these improvements and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

Our MGuard™ Prime™ Embolic Protection System (“MGuard Prime EPS”) is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES™. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES™.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to seal aneurysms in the brain.

Presently, none of our products may be sold or marketed in the United States.

In 2017, we decided to shift our commercial strategy to focus on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Pursuant to our new strategy, we completed our transition away from a single distributor covering 18 European countries to a direct distribution model intended to broaden our sales efforts to key clinical specialties. All territories previously covered by our former European distributor were transferred to local distributors by June 2017. We also have begun to participate in international trade shows and industry conferences in an attempt to gain market exposure and brand recognition.

## Recent Developments

### *Recent Financings and Recapitalization*

On April 2, 2018, we closed an underwritten public offering of 2,857,143 shares of our common stock at a price to the public of \$1.75 per share. Upon closing of the offering, as required by a waiver agreement, dated March 28, 2018, between us and an institutional accredited investor (the “Series D Investor”) who had purchased 750 shares of Series D Convertible Preferred Stock (the “Series D Preferred Stock”) in a private placement that closed on December 1, 2017 (the “Series D Private Placement”) pursuant to a securities purchase agreement, dated November 28, 2017 (the “Series D Purchase Agreement”), we used \$300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Convertible Preferred Stock (the “Series C Preferred Stock”) held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Convertible Preferred Stock (the “Series B Preferred Stock”), our Series C Preferred Stock and our Series D Preferred Stock was reduced to \$1.75 per share.

On June 28, 2018, we and the Series D Investor entered into a letter agreement (the “Letter Agreement”) which further amended the Series D Purchase Agreement to provide that, notwithstanding anything to the contrary in the prior agreements, in the event we consummate an offering of our common stock or common stock equivalents for gross proceeds of at least \$8 million (a “Qualified Offering”) in which the Series D Investor and its affiliates invest at least \$3 million, (i) instead of an automatic exchange of all outstanding shares of Series C Preferred Stock held by the Series D Investor into securities issued in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis, all outstanding shares of Series C Preferred Stock held by the Series D Investor will be redeemed at a per share purchase price equal to the stated value of the Series C Preferred Stock, and (ii) all outstanding shares of Series D Preferred Stock will be redeemed at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On July 3, 2018, we closed an underwritten public offering of (i) 10,851,417 common units (“Common Units”), with each Common Unit being comprised of one share of our common stock, and one Series D warrant (collectively, the “Series D Warrants”) to purchase one share of common stock and (ii) 22,481,916 pre-funded units (“Pre-Funded Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant (collectively, the “Pre-Funded Warrants”) to purchase one share of common stock and one Series D Warrant. We granted the underwriter a 30-day option to purchase up to an additional 4,999,999 shares of common stock at a purchase price of \$0.29 per share and/or up to 4,999,999 additional Series D Warrants to purchase 4,999,999 shares of common stock at a purchase price of \$0.01 per Series D Warrant, less the underwriting discounts and commissions of \$0.0203 per share and \$0.0007 per Series D Warrant. The underwriter exercised its option to purchase an additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common stock. The Series D Warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of \$0.30 per share of common stock. Each Pre-Funded Warrant contained in a Pre-Funded Unit is exercisable for one share of our common stock at an exercise price of \$0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. We received net proceeds from the offering and the exercise of the underwriter’s option to purchase additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common

stock of approximately \$8.7 million, excluding the proceeds, if any, from the exercise of the Series D Warrants and the Pre-Funded Warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that are payable by us. Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company's Series B Convertible Preferred Stock and Series C Preferred Stock, the conversion price of the outstanding shares of the Series B Preferred Stock and the Series C Preferred Stock was reduced to \$0.30 per share, effective as of June 29, 2018.

Pursuant to the Letter Agreement, on July 3, 2018, upon closing of the public offering that was a Qualified Offering, we used \$2,264,269 of the net proceeds of the offering to redeem 306,917 shares of Series C Preferred Stock and 300 shares of Series D Preferred Stock held by the Series D Investor.

Prior to the closing of the public offering, on July 2, 2018, we filed with the office of the Secretary of State of the State of Delaware a Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, which removes the provision providing for an automatic exchange of all outstanding shares of Series B Preferred Stock into securities issued in a Qualified Offering on a \$1.00 per stated value for \$1.00 new subscription amount basis upon a Qualified Offering.

*NYSE American Notification*

On August 17, 2017, we received a notice from NYSE American LLC (“NYSE American”) indicating that we do not meet the continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the “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 June 30, 2017, and net losses in our five most recent fiscal years ended December 31, 2016. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 19, 2017, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by February 17, 2019. We are subject to periodic review by the NYSE American staff during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

On November 22, 2017, we received an additional letter from the NYSE American indicating that we are not in compliance with the stockholders’ equity and net income continued listing standards set forth in Section 1003(a)(ii) of the Company Guide because we reported stockholders’ equity of less than \$4 million as of September 30, 2017. We have until February 17, 2019, to regain compliance with the continued listing requirements.

On January 16, 2018, we received notification from the NYSE American that we are not in compliance with certain NYSE American continued listing standards. The deficiency letter states that our shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 16, 2018. On July 16, 2018, we received notification from the NYSE American that we have resolved the continued listing deficiency with respect to low selling price, described in Section 1003(f)(v) of the company Guide.

*Reverse Stock Split*

Effective as of 5:00 p.m. Eastern Time on February 7, 2018, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-35 reverse stock split of our outstanding shares of common stock. Although we expect that the reverse stock split will result in an increase in the market price of our common stock, the reverse stock split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors. We have adjusted all outstanding restricted stock units, stock options, preferred stock and warrants entitling the holders to purchase shares of our common stock as a result of the reverse stock split, as required by the terms of these securities. In particular, we have reduced the conversion ratio for each security, and increased the exercise price in accordance with the terms of each security based on the reverse stock split ratio (i.e., the number of shares issuable under such



securities has been divided by thirty-five, and the exercise price per share has been multiplied by thirty-five). Also, we reduced the number of shares reserved for issuance under the InspireMD, Inc. 2013 Long-Term Incentive Plan and the 2011 UMBRELLA Option Plan, proportionately based on the reverse stock split ratio. The reverse stock split did not otherwise affect any of the rights currently accruing to holders of our common stock, or options or warrants exercisable for our common stock. All share and related option and warrant information presented in this Annual Report on Form 10-K have been retroactively adjusted to reflect the reduced number of shares outstanding and the increase in share price which resulted from this action.

### **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, 2017. There have not been any material changes to such critical accounting policies since December 31, 2017.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar (“\$” or “dollar”).

## **Contingencies**

We and 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, 2018 compared to the three months ended September 30, 2017*

*Revenues.* For the three months ended September 30, 2018, revenue increased by \$51,000, or 7.1%, to \$769,000, from \$718,000 during the three months ended September 30, 2017. This increase was predominantly driven by a 14.8% increase in sales of CGuard EPS from \$526,000 in the three months ended September 30, 2017, to \$604,000 in the three months ended September 30, 2018, because of our transition from our prior exclusive distribution partner for most of Europe to local distributors and expansion into new geographies such as India, Mexico and Vietnam. The transition to local distributors reflects an effort to broaden our sales from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well. This increase in sales of CGuard EPS was partially offset by a 14.0% decrease in sales of MGuard Prime EPS from \$192,000 in the three months ended September 30, 2017, to \$165,000 in the three months ended September 30, 2018, largely driven by doctors continuously predominantly using drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in ST-Elevation Myocardial Infarction (“STEMI”) patients.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$53,000 in revenue from sales of CGuard EPS made in Asia (for reasons mentioned above).

*Gross Profit.* For the three months ended September 30, 2018, gross profit (revenue less cost of revenues) increased by 29.4%, or 45,000, to \$198,000, compared to \$153,000 during the three months ended September 30, 2017. This increase resulted primarily from an increase of \$61,000 due to the increase in revenues (as mentioned above), less the

related material and labor costs, partially offset by an increase of \$16,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 25.7% in the three months ended September 30, 2018 from 21.3% in the three months ended September 30, 2017, driven mainly by a higher average sales price of MGuard Prime EPS and a reduction in costs of one of the main components of CGuard EPS.

*Research and Development Expenses.* For the three months ended September 30, 2018, research and development expenses increased by 44.4% or \$128,000, to \$416,000, from \$288,000 during the three months ended September 30, 2017. This increase resulted primarily from an increase of \$124,000 in quality assurance and regulatory expenses related to annual routine audit activities which included validation reviews required every two years, and an increase of \$4,000 in miscellaneous expenses.

*Selling and Marketing Expenses.* For the three months ended September 30, 2018, selling and marketing expenses decreased by 9.8%, or \$66,000, to \$605,000, from \$671,000 during the three months ended September 30, 2017. This decrease resulted primarily from a decrease of \$74,000 due to a salary accrual in 2017 and a decrease of \$37,000 in share-based compensation expenses primarily due to the forfeiture of the unvested options caused by the expiration of the employment agreement with our former chief commercial officer, partially offset by an increase of \$34,000 in other salary expenses due primarily to an increase in our headcount to further support the new local distributors in Europe and an increase of \$11,000 in miscellaneous expenses.

*General and Administrative Expenses.* For the three months ended September 30, 2018, general and administrative expenses decreased by 9.6%, or \$123,000, to \$1,156,000, from \$1,279,000 during the three months ended September 30, 2017. This decrease resulted primarily from a decrease of \$86,000 in share-based compensation expenses primarily due to the Company incurring a large expense in the three months ended September 30, 2017, which resulted from an equity grant made to our chief executive officer in 2016, which vested over one year, for which there was no similar expense incurred in the three months ended September 30, 2018 and a decrease of \$67,000 due to a salary accrual in 2017. These decreases in general and administrative expenses were partially offset by an increase of \$30,000 in miscellaneous expenses.

*Financial Expenses (Income).* For the three months ended September 30, 2018, financial expenses (income) increased by \$31,000, to \$32,000, from \$1,000 during the three months ended September 30, 2017. The increase in financial income primarily resulted from an increase of \$31,000 in miscellaneous expenses.

*Tax Expenses.* For the three months ended September 30, 2018, there was no material change in tax expenses (income) compared to the same period in 2017.

*Net Loss.* Our net loss decreased by \$75,000, or 3.6%, to \$2,011,000 for the three months ended September 30, 2018, from \$2,086,000 during the three months ended September 30, 2017. The decrease in net loss resulted primarily from a decrease of \$61,000 in operating expenses and an increase of \$45,000 in gross profit, partially offset by an increase of \$31,000 in financial expenses.

*Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017*

*Revenues.* For the nine months ended September 30, 2018, revenue increased by \$852,000, or 44.2%, to \$2,779,000, from \$1,927,000 during the nine months ended September 30, 2017. This increase was predominantly driven by a 72.5% increase in sales of CGuard EPS from \$1,315,000 in the nine months ended September 30, 2017, to \$2,268,000 in the nine months ended September 30, 2018, as a result of our transition from our prior exclusive distribution partner for most of Europe to local distributors, expansion into new geographies such as India and continued focus on expanding existing markets such as Italy. This increase in sales of CGuard EPS was partially offset by a 16.5% decrease in sales of MGuard Prime EPS from \$612,000 in the nine months ended September 30, 2017, to \$511,000 in the nine months ended September 30, 2018, largely driven by doctors continuously predominantly using drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$754,000 in revenue from sales made in Europe (driven by \$773,000 growth of CGuard EPS for reasons mentioned above), as well as an increase of \$178,000 in revenue from sales made in Asia (driven by \$153,000 growth of CGuard EPS for reasons

mentioned above). These increases in Europe and Asia were partially offset by a decrease of \$82,000 in sales made in Latin America (driven primarily by a decrease of \$91,000 in revenues of MGuard Prime EPS largely driven by doctors increasingly using drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients).

*Gross Profit.* For the nine months ended September 30, 2018, gross profit (revenue less cost of revenues) increased by 105.3%, or \$394,000, to \$768,000, compared to \$374,000 during the same period in 2017. This increase resulted primarily from an increase of \$410,000 due to the increase in revenues (as mentioned above), less the related material and labor costs and a decrease of \$41,000 in expenses related to the underutilization of our manufacturing resources. These increases in gross profit were partially offset by an increase of \$42,000 in write-offs of inventory of MGuard Prime EPS, which primarily resulted from a reversal of write-offs of inventory in the nine months ended September 30, 2017, for which, no such reversal occurred in the same period in 2018 and an increase of \$15,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 27.6% in the nine months ended September 30, 2018 from 19.4% in the nine months ended September 30, 2017, driven mainly by more efficient utilization of our fixed manufacturing resources.

*Research and Development Expenses.* For the nine months ended September 30, 2018, research and development expenses decreased by 13.7%, or \$143,000, to \$898,000, from \$1,041,000 during the nine months ended September 30, 2017. This decrease resulted primarily from a decrease of \$89,000 due to a salary accrual in 2017, a decrease of \$79,000 in development and clinical expenses associated with CGuard EPS, mainly related to pre-IDE efforts in 2017, a decrease of \$34,000 in other salary expenses due to a reduced headcount and a decrease of \$61,000 in miscellaneous expenses. These decreases in expenses were partially offset by an increase of \$120,000 in quality assurance and regulatory expenses related to annual routine audit activities which included validation reviews required every two years.

*Selling and Marketing Expenses.* For the nine months ended September 30, 2018, selling and marketing expenses decreased by 8.6%, or \$158,000, to \$1,677,000, from \$1,835,000 during the nine months ended September 30, 2017. This decrease resulted primarily from a decrease of \$178,000 due to a salary accrual in 2017, a decrease of \$69,000 in share-based compensation expenses primarily due to the forfeiture of the unvested options caused by the expiration of the employment agreement with our former chief commercial officer, a decrease of \$34,000 in consulting expenses and a decrease of \$32,000 in miscellaneous expenses. The decrease in expenses related to consulting and miscellaneous expenditures is primarily due to the Company not incurring in the nine months ended September 30, 2018, the expenditures made during the nine months ended September 30, 2017 to support the newly launched CGuard EPS-related sales and marketing activities in connection with the transition from our prior exclusive distribution partner for most of Europe to local distributors. These decreases in expenses were partially offset by an increase of \$155,000 in other salary expenses due primarily to an increase in our headcount to further support the new local distributors in Europe.

*General and Administrative Expenses.* For the nine months ended September 30, 2018, general and administrative expenses decreased by 16.0%, or \$683,000, to 3,598,000, from 4,281,000 during the nine months ended September 30, 2017. This decrease resulted primarily from a decrease of \$494,000 due to a salary accrual in 2017, a decrease of \$453,000 in share-based compensation expenses primarily due to the Company incurring a large expense in the nine months ended September 30, 2017, which resulted from an equity grant made to our chief executive officer in 2016, which vested over one year, for which there was no similar expense incurred in the nine months ended September 30, 2018, and a decrease of \$6,000 in miscellaneous expenses. These decreases in general and administrative expenses were partially offset by an increase of \$270,000 in legal expenses.

*Financial Expenses (Income).* For the nine months ended September 30, 2018, financial income increased by \$533,000, to \$378,000 of financial income, from \$155,000 of financial expenses during the nine months ended September 30, 2017. The increase in financial income primarily resulted from an increase of \$438,000 in financial income related to the revaluation of the embedded derivative of the Series C Preferred Stock and a decrease in interest expenses of \$119,000 due to the repayment of the remaining balance of our outstanding indebtedness of \$1.2 million on March 21, 2017. These decreases in expenses were partially offset by an increase of \$24,000 in miscellaneous expenses.

*Tax Expenses (Income).* For the nine months ended September 30, 2018, tax expenses decreased by \$1,000 to \$0, from \$1,000 in the nine months ended September 30, 2017

*Net Loss.* Our net loss decreased by \$1,912,000, or 27.6%, to \$5,027,000, for the nine months ended September 30, 2018, from \$6,939,000 during the nine months ended September 30, 2017. The decrease in net loss resulted primarily from a decrease of \$984,000 in operating expenses, an increase of \$533,000 in financial income and an increase of \$394,000 in gross profit.

## **Liquidity and Capital Resources**

We had an accumulated deficit as of September 30, 2018, of \$145 million, as well as a net loss of \$5,027,000 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we only have sufficient resources to fund operations through the end of the third quarter of 2019. 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.

On March 14, 2017, we closed a “best efforts” public offering of 1,069,822 shares of Series C Convertible Preferred Stock (the “Series C Preferred Stock”), Series B warrants to purchase 122,269 shares of common stock and Series C warrants to purchase 122,269 shares of common stock. The Series C Warrants expired on September 14, 2017. The Series B warrants have a term of five years and an exercise price of \$70.00 per share of common stock, subject to adjustment as provided in the Series B warrants. We received gross proceeds of approximately \$6.8 million from the offering, before deducting placement agent fees and offering expenses.

On March 1, 2018, we closed an underwritten public offering of 1,000,000 shares of our common stock at a price to the public of \$3.00 per share. We received gross proceeds of approximately \$3.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, we used \$450,000 of the proceeds from the offering to redeem 450 shares of Series D Preferred Stock. As a result of such offering, the conversion price for each of our Series C Preferred Stock and our Series D Preferred Stock was reduced to \$3.00 per share.

On April 2, 2018, we closed an underwritten public offering of 2,857,143 shares of our common stock at a price to the public of \$1.75 per share. We received gross proceeds of approximately \$5.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, we used \$300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to \$1.75 per share.

On July 3, 2018, we closed an underwritten public offering of (i) 10,851,417 Common Units, with each Common Unit being comprised of one share of our common stock, and one Series D Warrant to purchase one share of common stock, (ii) 22,481,916 Pre-Funded Units (“Pre-Funded Units”), with each Pre-Funded Unit being comprised of one Pre-Funded Warrant to purchase one share of common stock and one Series D Warrant, and (iii) a 4,999,999 additional Series D Warrants to purchase 4,999,999 shares of common stock pursuant to the underwriter’s option. We received net proceeds from the offering and the exercise of the underwriter’s option to purchase additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common stock of approximately \$8.7 million, excluding the proceeds, if any, from the exercise of the Series D Warrants and the Pre-Funded Warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that are payable by us. We used \$2,264,269 of the net proceeds of the offering to redeem 306,917 shares of Series C Preferred Stock and 300 shares of Series D Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price of the outstanding shares of the Series B Preferred Stock and the Series C Preferred Stock was reduced to \$0.30 per share, effective as of June 29, 2018.

Our outstanding shares of Series B Preferred Stock and Series C Preferred Stock contain anti-dilution provisions that may result in the reduction of the conversion price thereof in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of additional shares of common stock issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock as a result of anti-dilution adjustments will dilute the interests of other security holders



and may depress the price of our common stock. Accordingly, we may find it more difficult to raise additional equity capital while any of our Series B Preferred Stock or Series C Preferred Stock is outstanding. As of November 5, 2018, 17,303 shares of Series B Preferred Stock and 61,423 shares of Series C Preferred Stock are outstanding.

During January and February 2018, the placement agent from the public offering that closed in July 2016 exercised its unit purchase option to purchase 13,508 units and received 13,508 shares of Series B Preferred Stock and Series A warrants to purchase 1,545 shares of common stock. The placement agent subsequently converted its Series B Preferred Stock and received an aggregate of 111,442 shares of common stock. We received an aggregate of \$557,205 from the placement agent for the exercise of the unit purchase option.

*Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017*

*General.* At September 30, 2018, we had cash and cash equivalents of \$11,247,000, as compared to \$3,710,000 as of December 31, 2017. 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.

For the nine months ended September 30, 2018, net cash used in our operating activities decreased by \$553,000 to \$5,803,000, from \$6,356,000 in the same period in 2017. The primary reason for the decrease in cash used in our operating activities was an increase of \$939,000 in payments received from customers to \$2,711,000 in the nine months ended September 30, 2018, from \$1,772,000 in the same period in 2017, and a decrease of payments for third party related expenses and for professional services of \$224,000 (primarily due to the end of term charge of \$520,000 paid to Hercules in the nine months ended September 30, 2017, compared to no such payment made in 2018). The decreases in cash used in operating activities was partially offset by an increase of \$610,000 in salary payments from \$3,094,000 in the nine months ended September 30, 2017 to \$3,704,000 in the same period in 2018.

Cash used by our investing activities was \$0 during the nine months ended September 30, 2018 compared to \$282,000 in the nine months ended September 30, 2017 resulting primarily from the purchase of production equipment.

Cash provided by financing activities for the nine months September 30, 2018 was \$13,351,000, compared to \$3,883,000 during the same period in 2017. The principal source of the cash provided by financing activities during the nine months ended September 30, 2018, was the funds received from our July 2018 public offering of common stock, Pre-Funded Warrants and warrants, as well as the subsequent exercise of the Pre-Funded Warrants, that resulted in approximately \$8,866,000 of aggregate net proceeds, funds received from our April 2018 public offering of common stock that resulted in approximately \$4,439,000 of aggregate net proceeds and the funds received from our March 2018 public offering of common stock that resulted in approximately \$3,060,000 of aggregate net proceeds, offset by a redemption of Series C and Series D Preferred Stock from the proceeds of the offering in an aggregate amount of \$3,014,000. The principal source of the cash provided by financing activities during the nine months ended September 30, 2017 was the funds received from our March 2017 public offering of preferred stock and warrants that resulted in approximately \$6,072,000 of aggregate net proceeds, offset by loan repayments of \$2,179,000.

As of September 30, 2018, our current assets exceeded our current liabilities by a multiple of 5.5. Current assets increased by \$7,932,000 during the period and current liabilities decreased by \$109,000 during the period. As a result, our working capital increased by \$8,041,000 to \$10,714,000 at September 30, 2018.

### **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**

See Note 3 – “Recently Issued Accounting Pronouncements” in the accompanied 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 year ended December 31, 2017, 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, 2018, there were no material changes to our contractual obligations and commitments.

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

Not applicable

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

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

As of September 30, 2018, 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, 2018.

#### **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, 2018, 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.

On July 12, 2016, Medpace Inc., a former service provider, filed suit with the Court of Common Pleas, Hamilton County, Ohio, against us asserting that we breached a master services agreement with Medpace Inc. by failing to pay Medpace Inc. certain fees purportedly owed to it in connection with Medpace Inc.'s provision of certain clinical development program services to Inspire Ltd. We have removed the suit to the U.S. District Court for the Southern District of Ohio. Since removal, Medpace Inc. has amended its complaint to name InspireMD Ltd., our wholly owned subsidiary, as the only defendant. Medpace Inc. is seeking \$1,967,822 in damages plus interest, costs, attorneys' fees and expenses against InspireMD Ltd. InspireMD Ltd. filed a motion to dismiss all claims on February 10, 2017. On May 17, 2017, the district court denied InspireMD's motion to dismiss, but ordered Medpace Inc. to file a second amended complaint by June 5, 2017. Medpace Inc. filed a second amended complaint on June 5, 2017, and InspireMD Ltd. again moved to dismiss all claims on June 19, 2017. The district court denied our second motion to dismiss on August 11, 2017. Thereafter, we answered the complaint and asserted several counterclaims. Specifically, we brought counterclaims for fraudulent inducement, negligent misrepresentation, and violation of Ohio's Deceptive Trade Practices Act arising from Medpace's false marketing of its purported abilities to manage the clinical trial, and brings a counterclaim for breach of contract, alleging that Medpace breached the master services agreement by, among other things, failing to assign personnel to the clinical trial who were qualified and professionally capable of performing the services called for by the master services agreement and the related Task Order in accordance with the agreed-upon schedule and budget. We are seeking damages believed to be in excess of \$3 million, as well as punitive damages and attorney's fees. Medpace Inc. has denied our allegations. On February 21, 2018, InspireMD Ltd. filed a motion for summary judgment, seeking to dismiss Medpace's affirmative claims in their entirety, or in the alternative to limit those claims to invoice payments totaling \$468,586. On March 21, 2018, Medpace responded to InspireMD Ltd.'s motion for summary judgment, and also filed two additional motions: (1) a motion under Federal Rule of Civil Procedure 56(d), seeking to deny or delay summary judgment pending completion of additional discovery; and (2) a motion seeking to strike the Declaration of Jonathan Pressment, submitted in support of InspireMD Ltd.'s motion for summary judgment. InspireMD Ltd.'s motion for summary judgment remains pending before the Court. Medpace's motion under Federal Rule of Civil Procedure 56(d) and motion to strike also remain pending before the Court. Pursuant to InspireMD Ltd.'s motion to stay discovery pending the Court's resolution of InspireMD Ltd.'s motion for summary judgment and the completion of Court-ordered mediation, discovery is stayed until the earlier of (1) three days after the entry of an order adjudicating Inspire Ltd.'s motion for summary judgment or (2) August 13, 2018. On August 9, 2018, InspireMD Ltd. filed an unopposed motion to further extend the stay of discovery pending the court's resolution of InspireMD Ltd.'s motion for summary judgment. The court granted this motion on August 9, 2018, and stayed discovery until three days after the entry of an order adjudicating InspireMD Ltd.'s motion for summary judgment. InspireMD Ltd. intends to contest this matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that InspireMD Ltd. will prevail on any claims made against InspireMD Ltd. in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

As of the date of this filing, we are not aware of any other 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 other than other than the foregoing suits filed by Medpace Inc.

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**

Not applicable.

#### **Item 5. Other Information**

Not applicable

#### **Item 6. Exhibits**

#### **EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	<u>Amended and Restated Certificate of Incorporation, as amended through September 30, 2015 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)</u>
3.2	<u>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)</u>
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)

3.4 Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)

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- 3.5 Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.5 to the Quarterly Report on Form 10-Q filed on August 9, 2016)
- 3.6 Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
- 3.7 Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)
- 3.8 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)
- 3.9 Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 4, 2017)
- 3.10 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)
- 3.11 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 22, 2017)
- 3.12 Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)
- 3.13 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 1, 2018)
- 3.14 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 3, 2018)
- 3.15 Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 5, 2018)
- 10.1 Form of Underwriter Warrant, dated April 2, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 3, 2018)
- 10.2 Letter Agreement, dated June 28, 2018 (incorporated by reference to Exhibit 10.67 to the Company's Registration Statement on Form S-1, Amendment No.20, filed with the SEC on September 28, 2018 (File No. 333-225680))
- 10.3 Form of Series D Warrant (incorporated by reference to Exhibit A to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))



10.4 Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))

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- 10.5 Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
- 10.6+ General Release and Severance Agreement, dated September 24, 2018, by and between InspireMD, Inc. and Agustin Gago (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 28, 2018)
- 10.7+ Fourth 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 October 26, 2018)
- 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, 2018, 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

\* Filed herewith.

+ Management contract or compensatory plan or arrangement.

**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 6, 2018 By: */s/ James Barry, Ph.D.*

Name: James Barry, Ph.D

Title: President and Chief Executive Officer

Date: November 6, 2018 By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer, Secretary and Treasurer

