

INSPIREMD, INC.

FORM 10-Q (Quarterly Report)

Filed 11/09/20 for the Period Ending 09/30/20

Telephone	(888) 776-6804
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment, Supplies & Distribution
Sector	Healthcare
Fiscal Year	12/31

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

FORM 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, 2020

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)

Delaware

(State or other jurisdiction of
incorporation or organization)

26-2123838

(I.R.S. Employer
Identification No.)

4 Menorat Hamaor St.

Tel Aviv, Israel 6744832

(Address of principal executive offices)
(Zip Code)

(888) 776-6204

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

Yes No

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	NSPR	NYSE American
Warrants, exercisable for one share of Common Stock	NSPR.WS	NYSE American
Series B Warrants, exercisable for one share of Common Stock	NSPR.WSB	NYSE American

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of November 5, 2020: 36,954,755



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INSPIREMD, INC.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER AND NINE MONTHS ENDED SEPTEMBER 30, 2020

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INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(U.S. dollars in thousands)

	September 30	December 31
	2020	2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,882	\$ 5,514
Accounts receivable:		
Trade, net	565	823
Other	332	150
Prepaid expenses	169	87
Inventory	1,388	1,236
TOTAL CURRENT ASSETS	13,336	7,810
NON-CURRENT ASSETS:		
Property, plant and equipment, net	415	547
Operating lease right of use assets	1,215	937
Fund in respect of employee rights upon retirement	643	586
TOTAL NON-CURRENT ASSETS	2,273	2,070
TOTAL ASSETS	\$ 15,609	\$ 9,880

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands other than share and per share data)

	September 30 2020	December 31 2019
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	427	646
Other	2,123	2,449
Contract liability	19	20
TOTAL CURRENT LIABILITIES	2,569	3,115
LONG-TERM LIABILITIES-		
Operating lease liabilities	917	653
Liability for employees rights upon retirement	843	729
TOTAL LONG-TERM LIABILITIES	1,760	1,382
COMMITMENTS AND CONTINGENT LIABILITIES (Note 8)		
TOTAL LIABILITIES	4,329	4,497
EQUITY:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at September 30, 2020 and December 31, 2019; 36,059,128 and 3,916,134 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at September 30, 2020 and December 31, 2019; 17,303 shares issued and outstanding at September 30, 2020 and December 31, 2019.	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at September 30, 2020 and December 31, 2019; 2,343 and 34,370 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	-	-
Additional paid-in capital	175,600	163,015
Accumulated deficit	(164,323)	(157,632)
Total equity	11,280	5,383
Total liabilities and equity	\$ 15,609	\$ 9,880

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

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
REVENUES	\$ 980	\$ 939	\$ 2,327	\$ 2,708
COST OF REVENUES	682	811	1,854	2,211
GROSS PROFIT	298	128	473	497
OPERATING EXPENSES:				
Research and development	546	442	1,513	2,432
Selling and marketing	485	537	1,486	1,791
General and administrative	1,462	1,146	4,136	3,584
Total operating expenses	2,493	2,125	7,135	7,807
LOSS FROM OPERATIONS	(2,195)	(1,997)	(6,662)	(7,310)
FINANCIAL EXPENSES, net:	(38)	(73)	(29)	(173)
NET LOSS	(2,233)	(2,070)	(6,691)	(7,483)
NET LOSS PER SHARE - basic and diluted	\$ (0.06)	\$ (1.26)	\$ (0.38)	\$ (5.79)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	34,884,285	1,648,302	17,460,184	1,293,321

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

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(Unaudited)

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

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2019	768,615	*	17,303	*	61,423	*	\$ 156,355	\$ (147,592)	\$ 8,763
Net loss								(7,483)	(7,483)
Issuance of common shares, warrants, pre-funded warrants and exercise of pre-funded warrants, net of \$1,177 issuance costs	2,588,828	*					6,331		6,331
Conversion of Series C Convertible Preferred Stock to common shares	29,728	*			(24,554)	*			*
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 837 shares	69,744	*					285		285
BALANCE AT September 30, 2019	<u>3,456,915</u>	<u>*</u>	<u>17,303</u>	<u>*</u>	<u>36,869</u>	<u>*</u>	<u>\$ 162,971</u>	<u>\$ (155,075)</u>	<u>\$ 7,896</u>

* Represents an amount less than \$1 thousand

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

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT July 1, 2019	1,397,133	*	17,303	*	38,806	*	\$ 158,579	\$ (153,005)	\$ 5,574
Net loss								(2,070)	(2,070)
Issuance of common shares, warrants, pre-funded warrants and exercise of pre-funded warrants, net of \$710 issuance costs	2,057,444	*					4,285		4,285
Conversion of Series C Convertible Preferred Stock to common shares	2,480	*			(1,937)	*			*
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 142 shares	(142)	*					107		107
BALANCE AT September 30, 2019	<u>3,456,915</u>	<u>*</u>	<u>17,303</u>	<u>*</u>	<u>36,869</u>	<u>*</u>	<u>\$ 162,971</u>	<u>\$ (155,075)</u>	<u>\$ 7,896</u>

* Represents an amount less than \$1 thousand

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2020	3,916,134	*	17,303	*	34,370	*	\$ 163,015	\$ (157,632)	\$ 5,383
Net loss								(6,691)	(6,691)
Exercise of pre-funded warrants	14,856,400	2					16		18
Settlement of restricted stock units in shares of common stock	165,000	*							*
Issuance of common shares, including at the market offering net of \$945 issuance costs	11,562,202	1					10,808		10,809
Exercise of Warrants F	2,866,600	*					1,418		1,418
Exercise of Unit Purchase Option	253,587	*					82		82
Conversion of Series C Convertible Preferred Stock to common shares	372,173	*			(32,027)	*			*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 41,484 shares	2,067,032	*					261		261
BALANCE AT September 30, 2020	36,059,128	3	17,303	*	2,343	*	\$ 175,600	\$ (164,323)	\$ 11,280

* Represents an amount less than \$1 thousand

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT July 1, 2020	33,358,994	3	17,303	*	2,343	*	\$ 175,301	\$ (162,090)	\$ 13,214
Net loss								(2,233)	(2,233)
Issuance of common shares at the market offering, net of \$110 issuance costs	593,102	*					158		158
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 1,484 shares	2,107,032	*					141		141
BALANCE AT September 30, 2020	36,059,128	3	17,303	*	2,343	*	\$ 175,600	\$ (164,323)	\$ 11,280

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	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (6,691)	\$ (7,483)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	122	114
Loss from sale of property, plant and equipment	14	-
Change in liability for employees rights upon retirement	114	99
Financial income and interest paid	(4)	(1)
Change in right of use asset and leasing liability	(19)	76
Share-based compensation expenses	261	285
Changes in operating asset and liability items:		
Increase in prepaid expenses	(82)	(74)
Decrease (Increase) in trade receivables	258	(80)
Increase in other receivables	(160)	(82)
Increase in inventory	(152)	(149)
Decrease in trade payables	(219)	(242)
Decrease in other payables and contract liability	(323)	(705)
Net cash used in operating activities	<u>(6,881)</u>	<u>(8,242)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(26)	(231)
Amounts (withdrawn) in respect of employee rights upon retirement, net	(57)	(87)
Net cash used in investing activities	<u>(83)</u>	<u>(318)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of \$945 and \$467 issuance costs, respectively	12,327	6,331
Net cash provided by financing activities	<u>12,327</u>	<u>6,331</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	<u>5</u>	<u>(1)</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>5,368</u>	<u>(2,230)</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	<u>5,514</u>	<u>9,384</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	<u>\$ 10,882</u>	<u>\$ 7,154</u>
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING ACTIVITIES:		
Sale of Fixed Asset (non-cash)	22	

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

INSPIREMD, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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.

b. Liquidity

The Company has an accumulated deficit as of September 30, 2020, 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 has sufficient resources to fund operations through the third quarter of 2021. 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. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations.

c. COVID-19 Pandemic

During the nine months ended September 30, 2020, in an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. As of the beginning of the second quarter of 2020, we began to experience a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. To the best of our knowledge, most European countries in which we operate are reinstating elective procedures, but we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures in light of recent increases in COVID-19 cases in the territories we sell into. We anticipate that the continuation of the pandemic and related restrictions and safety measures would likely result in a continued decline in sales of our products for the upcoming periods.

In response to the significant market volatility and uncertainties relating to COVID-19, the fees and salaries of the Company's board of directors, management and most of its employees were reduced in order to alleviate corporate operating expenses. Following the closing of an underwritten public offering in June 2020, which provided \$10.7 million of net proceeds to the Company, the Company reinstated the fees and salaries of its board of directors, management and employees. As a result of the reduction of those fees and salaries during the second quarter of 2020, the Company's operating expenses were reduced by approximately \$235,000 in the second quarter of 2020.

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, 2019, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 10, 2020. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - EQUITY:

- a. During the nine months ended September 30, 2020, the Company issued a total of 270,000 shares of its common stock in connection with the exercise of 270,000 Pre-Funded Warrants issued in September 2019. As of September 30, 2020, there are no outstanding Pre-Funded Warrants issued in September 2019.
- b. On June 5, 2020, the Company closed an underwritten public offering of (i) 7,635,800 units ("Units"), with each Unit being comprised of one share of the Company's common stock, par value \$0.0001 per share, and one Series F warrant (a "Series F Warrant") to purchase one share of common stock, and (ii) 14,586,400 pre-funded units (the "Pre-Funded Units"), with each Pre-Funded Unit being comprised of one pre-funded warrant (a "Pre-Funded Warrant") to purchase one share of common stock and one Series F Warrant. In connection with this public offering, the underwriter exercised its over-allotment option in full and purchased an additional 3,333,300 shares of common stock and 3,333,300 Series F Warrants. The offering price to the public was \$0.45 per Unit and \$0.449 per Pre-Funded Unit. The net proceeds to the Company from the offering and the exercise of the underwriter's over-allotment option were approximately \$10.7 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series F Warrants and the Pre-Funded Warrants sold in the offering.

The Series F Warrants included in the Common Units and the Pre-Funded Units are immediately exercisable at a price of \$0.495 per share of common stock, subject to adjustment in certain circumstances, and expire June 2, 2025. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series F Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately. During the nine months ended September 30, 2020, 2,866,600 Series F Warrants were converted into 2,866,600 shares of common stock. The net proceeds to the Company from exercise of the Series F Warrants were approximately \$1.4 million.

During the nine months ended September 30, 2020, the Company issued a total of 14,586,400 shares of common stock in connection with the exercise of all outstanding Pre-Funded Warrants issued in June 2020.

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 \$0.45 per share, effective as of the date of the underwriting agreement entered for the June 2020 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 1,665,414 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 2, 2020.
- An aggregate of 283,285 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 26,558 shares of Series C Preferred Stock outstanding as of June 2, 2020.

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. The Company has also concluded that the series F warrants are classified as equity, since the warrants meet all criteria for equity classification.

- c. During the nine months ended September 30, 2020, 32,027 shares of Series C Convertible Preferred Stock were converted into 372,173 shares of common stock.
- d. During June 2020, the placement agent from the July 2016 Offering exercised its unit purchase option to purchase 1,976 units and received 1,976 shares of Series B Convertible Preferred Stock and 5 Series A warrants to purchase common stock. The placement agent subsequently converted its Series B Convertible Preferred Stock and received an aggregate of 253,587 shares of common stock. The Company received \$81,510 from the placement agent for the exercise of the unit purchase option. As of September 30, 2020, there are no unit purchase options issued in July 2016.
- e. During the three months ended September 30, 2020, the Company sold 593,102 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with MLV & Co. LLC. These sales resulted in net proceeds to the Company of approximately \$158 thousand.
- f. On August 31, 2020 the Company granted to employees and directors options to purchase a total of 1,094,594 shares of the Company's common stock. The options have an exercise prices of \$0.39 per share, which was the fair market value of the Company's common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 127.71%-136.66%; and risk-free interest rate of 0.32%-0.42%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$382 thousand.

- g. On August 31, 2020, the Company granted 2,108,516 restricted shares of the Company's common stock to employees and directors. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately \$822 thousand.

- h. On August 31, 2020, the Company granted 1,175,287 restricted share units of the Company's common stock to the chief executive officer. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately \$458 thousand

- i. As of September 30, 2020, the number of preferred shares and the amount each class is convertible into is below:

	Number of Preferred Stock	Number of underlying Common stock
Series B Convertible Preferred Stock	17,303	2,220,552*
Series C Convertible Preferred Stock	2,343	33,322
Total		2,253,874

* Including the shares of common stock the holders of Series B Convertible Preferred Stock are 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.

As of September 30, 2020, the Company has outstanding warrants to purchase an aggregate of 26,705,502 shares of common stock as follows:

	Number of underlying Common stock	Weighted average exercise price
Series A Warrants	1,107	\$ 8,750.00
Series B Warrants	2,448	\$ 3,500.00
Series D Warrants	766,698	\$ 15.00
Series E Warrants	2,972,221	\$ 1.80
Series F Warrants	22,688,900	\$ 0.50
Underwriter Warrants	274,029	\$ 0.50
Other warrants	99	\$ 21,993.00
Total Warrants	26,705,502	\$ 1.82

As of September 30, 2020, the Company had 155,000,000 authorized shares of capital stock, par value \$0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock.

In January 2020, the Company granted its new chief executive officer and president 182,381 restricted stock units and stock options to purchase 60,794 shares of common stock at \$1.10 per share. The restricted stock units and options are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the restricted stock units was approximately \$0.2 million.

NOTE 4- NET LOSS PER SHARE:

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

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 31,378,762 for the nine and three month period ended September 30, 2020.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Preferred Stock excluded from the calculations of diluted loss per share were 5,001,451 for the nine and three month period ended September 30, 2019.

NOTE 5 - FAIR VALUE MEASUREMENT:

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 September 30, 2020, and December 31, 2019, allowance for doubtful accounts was \$0.

NOTE 6 - INVENTORY:

	September 30, 2020	December 31, 2019
	(\$ in thousands)	
Finished goods	\$ 306	\$ 173
Work in process	290	81
Raw materials and supplies	792	982
	<u>\$ 1,388</u>	<u>\$ 1,236</u>

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	September 30, 2020	December 31, 2019
	(\$ in thousands)	
Employees and employee institutions	720	1,238
Accrued vacation and recreation pay	237	188
Accrued expenses	761	604
Current Operating lease liabilities	357	362
Other	49	57
	<u>\$ 2,124</u>	<u>\$ 2,449</u>

NOTE 8 - COMMITMENTS AND CONTINGENT LIABILITIES:**a. Lease Agreements**

- 1) The Company's Israeli subsidiary has a lease agreement for a facility in Israel, which expires on December 31, 2020 with an option to extend the agreement for two additional years until December 31, 2022 under the terms stipulated in the agreement (the Option Period). The Company's Israeli subsidiary entered into an amendment to the lease agreement to exercise the option to extend the agreement by two years until December 31, 2022 and to add an additional option for two additional years until December 31, 2024 under the terms stipulated in the agreement.

The amendment to the lease agreement and the new Option Period was taken in consideration when calculating the operating lease right of use assets and liabilities since it is reasonably certain that the Company will exercise the option.

- 2) The Company leases its motor vehicles under operating lease agreements.

b. Litigation:

- i. In July 2019, a former distributor filed a suit seeking damages from the Company's subsidiary for pre-paid goods subject to the voluntary field action (from April 2014) amounting to €1,830,000 (which is approximately \$2.0 million), or alternatively €1,024,000 (which is approximately \$1.2 million). 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 €1,830,000.

- ii. On July 28, 2020, we entered into a settlement agreement and release with the prior underwriter, under which it provided us a final, unconditional release from any further obligations arising out of or related to the engagement agreements, underwriting agreements and placement agency agreements which we had been party to with it and with respect to any services which it had provided to us. We, in turn, provided the prior underwriter a final, unconditional release from any further obligations arising out of or related to the prior agreements and services.

As consideration for the final release provided to us, we paid to the prior underwriter \$400,000 in cash and reduced, to \$0.495, the exercise price per share of warrants to purchase 274,029 shares of our common stock that had been issued by us to the prior underwriter in various offerings that took place between March 2018 and September 2019. That reduced exercise price represents the exercise price for the Series F Warrants that we issued in our June 2020 public offering. The warrants that were repriced had existing exercise prices per share ranging from \$187.50 to \$2.25 and a weighted average exercise price per share of \$7.32. All other terms of those warrants will remain unchanged. The related increase in expenses of \$400,000 was recorded to "General and Administrative expense" within the Consolidated Statements of Operations

- iii. In July 2020, a former senior employee of InspireMD GmbH filed a statement of claim at the Munich Labor Court, seeking confirmation of the court that the notice of termination is not effective. 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.

NOTE 9 - 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,	
	2020	2019	2020	2019
	(\$ in thousands)			
Germany	\$ 292	\$ 189	\$ 551	\$ 513
Italy	185	211	433	550
Poland	63	90	184	277
Russia	-	100	116	129

Other	<u>440</u>	<u>349</u>	<u>1,043</u>	<u>1,239</u>
	<u>\$ 980</u>	<u>\$ 939</u>	<u>\$ 2,327</u>	<u>\$ 2,708</u>

By product:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
	(\$ in thousands)			
CGuard	\$ 833	\$ 852	\$ 2,075	\$ 2,344
MGuard	147	87	252	364
	<u>\$ 980</u>	<u>\$ 939</u>	<u>\$ 2,327</u>	<u>\$ 2,708</u>

By principal customers:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Customer A	27%	17%	22%	16%
Customer B	10%	11%	8%	12%
Customer C	9%	12%	11%	8%
Customer D	6%	10%	8%	10%
Customer E	-	11%	5%	5%

All tangible long lived assets are located in Israel.

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,” “plans,” “believes,” “estimates,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may 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 maintain compliance with NYSE American listing standards;
- the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy;
- 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.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. 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 was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. In September, 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020, and we are seeking strategic partners for a potential launch of CGuard EPS in Japan and China.

On September 8, 2020, we received approval from the U.S. Food and Drug Administration (“FDA”) of our Investigation Device Exemption (“IDE”), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, CARENET-III, for prevention of stroke in patients in the United States.

Additionally, we intend to continue to invest in current and future potential product and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery system. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are exploring adding a procedural protection device to our portfolio. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever, for potential product enhancements and manufacturing enhancements. In addition, such additional financings may be costly or difficult to complete. Even if we receive sufficient proceeds from future financings, there is no assurance that we will be able to timely apply for CE mark approval following our receipt of such proceeds. We believe these improvements may allow us to reduce our cost of goods and increase penetration in our existing geographies and better position us for entry into new markets.

We consider the addressable market for our CGuard EPS to be individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, $\geq 70\%$ occlusion) for whom 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*).

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, however, 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.

Recent Developments

Sixth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan

Effective as of August 31, 2020, our stockholders approved the Sixth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (the “Plan”) and, accordingly, increased the number of shares of common stock, par value \$0.0001 per share (the “Common Stock”) available for issuance pursuant to awards under such Plan by 6,500,000 shares, to a total of 7,178,395 shares of Common Stock.

Regained Compliance with New York Stock Exchange

On August 7, 2019, we received a notification from the NYSE American that we did 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 September 30, 2019, and net losses in our five most recent fiscal years ended December 31, 2018. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 11, 2019, the NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020.

On August 7, 2020, following our submission to the NYSE American of our plan for regaining compliance, the NYSE American approved such plan and, accordingly and as of such date, we are compliant with all of the NYSE American LLC continued listing standards set forth in Part 10 of the NYSE American Company Guide. In particular, we regained compliance with the continued listing requirement under NYSE American Company Guide Section 1003(a)(iii). The return to compliance was achieved as a result of our recently-consummated public offering, in which we raised approximately \$10.7 million of net proceeds from the sale of units and pre-funded units.

FDA Approval of IDE

On September 8, 2020, we received approval from the FDA of our IDE, thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, CARENET-III, for prevention of stroke in patients in the United States.

ATM Offering

On July 28, 2020, we entered into a Sales Agreement (the “Sales Agreement”) with A.G.P./Alliance Global Partners, as sales agent (“A.G.P.”), pursuant to which we may offer and sell, from time to time, at our option, through or to A.G.P., up to an aggregate of approximately \$9,300,000 of shares of Common Stock. Any shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to the Company’s Registration Statement on Form S-3 (File No. 333-223130), filed with the Securities and Exchange Commission (the “SEC”) on February 21, 2018 and the prospectus supplement thereto filed with the SEC on July 28, 2020, by methods deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by us, by any other method permitted by law. On September 1, 2020, we delivered written notice to A.G.P., in accordance with Section 4 of the Sales Agreement, that we are suspending offers and sales of our Common Stock under our at-the-market offering pursuant to the Sales Agreement.

Public Offerings

On June 5, 2020, we closed an underwritten public offering of (i) 7,635,800 units (“Units”), with each Unit being comprised of one share of the Company’s common stock, par value \$0.0001 per share, and one Series F warrant (a “Series F Warrant”) to purchase one share of common stock, and (ii) 14,586,400 pre-funded units (the “Pre-Funded Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant (a “Pre-Funded Warrant”) to purchase one share of common stock and one Series F Warrant. In connection with this public offering, the underwriter exercised the option practically in full, for 3,333,300 shares of common stock and 3,333,300 Series F Warrants. The offering price to the public was \$0.45 per Unit and \$0.449 per Pre-Funded Unit. The net proceeds to the Company from the offering and the exercise of the underwriter’s over-allotment option were approximately \$10.7 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series F Warrants and the Pre-Funded Warrants sold in the offering.

Registration Clearance for CGuard™ MicroNet® in Brazil

On July 23, 2020, we announced that we obtained registration from the Brazilian registration authority, Agência Nacional de Vigilância Sanitária (ANVISA), for our CGuard MicroNet covered stent, clearing it for sale and distribution in Brazil.

New Trial Results for CGuard EPS

On June 10, 2020, we reported the publication of the results of our PARADIGM trial in the *EuroIntervention* journal. In that trial, 101 unselected consecutive real-life patients were treated with our CGuard MicroNET covered stent for carotid stenosis and were monitored for postprocedural neurologic events for a period of 12 months. The results displayed sustained protection against any such neurologic events. At 30 days, only one adverse event occurred (a minor transient stroke with no other strokes, myocardial infarctions, or deaths). Furthermore, those study results showed that no strokes occurred between 30 days and twelve months.

On June 25, 2020, we reported the results from an investigator-initiated SIBERIA randomized clinical trial of our CGuard EPS, which evaluated 30-day silent brain infarcts associated with the use of the Acculink™ conventional open-cell nitinol stent vs. our CGuard Micronet-covered stent. Those results displayed that CGuard had a statistically significant (greater than three-fold) reduction in the procedure-generated mean cerebral lesion volume relative to Acculink. At 30 days, there were zero new cerebral lessons in the CGuard arm, compared to six in the Acculink arm, also statistically significant.

On September 3, 2020 we reported the award for Best ESC Congress Poster for the presentation of updated data from the large, long-term PARADIGM-EXTEND study of the CGuard™ Embolic Prevention System (EPS), as part of the European Society of Cardiology 2020 Carotid Update e-presentation at the European Society of Cardiology (ESC) Congress 2020. PARADIGM/EXTEND is an investigator-driven on-going study performed with CGuard Carotid stent for primary and secondary stroke prevention in a large, consecutive all-comers population, with 5 years (60 months) follow-up. The results for 480 patients of the expected total of 550 that completed the 30-day follow-up were presented were no peri-procedural major strokes or death. The total death/stroke /myocardial incidence at 30 days was 1.04% (5/480) due to two minor strokes, one myocardial infarction and two stent-unrelated deaths. In the study, 354/480 patients completed the 12-month follow-up with only 1 patient experiencing in-stent restenosis, 0.28% (1/354). At the 12-month follow-up there were no other device-related adverse clinical events. Finally, 46/480 patients completed the 60-month follow-up period with one more case of in-stent restenosis and no additional cases of device-related stroke.

COVID-19 Developments

In an effort to contain and mitigate the spread of COVID-19, which the World Health Organization, or WHO, declared to be a pandemic on March 12, 2020, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. As of the beginning of the second quarter of 2020, we began to experience a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. To our knowledge, most European countries in which we operate are slowly reinstating elective procedures, but we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures in light of recent increases in COVID-19 cases in the territories we sell into. We anticipate that the continuation of the pandemic and related restrictions and safety measures would likely result in a continued decline in sales of our products for the upcoming periods. For more discussion on our risks related to COVID-19, please see risk factors included under “Item 1A. Risk Factors” herein.

In response to significant market volatility and uncertainties relating to COVID-19, the fees and salaries of our board of directors (the “Board”), management and most of our employees were reduced in order to alleviate corporate operating expenses.

Effective April 1, 2020, the Board approved a 50% decrease in the annual cash compensation for non-employee directors from an aggregate amount of \$154,000 to \$77,000.

On April 21, 2020, Marvin Slosman, our President, Chief Executive Officer and Director, signed a waiver reducing his monthly base salary from \$33,333 to \$16,666 for the period beginning April 1, 2020 and ending on such date as Mr. Slosman was to determine, and Craig Shore, our Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer, signed a waiver reducing his monthly base salary from NIS 80,125 to NIS 40,063 for the period beginning April 1, 2020 and ending on such date as Mr. Shore was to determine.

Effective April 1, 2020, we reduced the annual salaries of most of our employees by 20% to 30% until further notice.

Based on a determination made by each of Mr. Slosman and Mr. Shore on June 10, 2020, following the closing of our underwritten public offering in June 2020, as described above, each of Mr. Slosman's and Mr. Shore's monthly base salaries were reinstated to \$33,333 and NIS 80,125, respectively, effective as of June 1, 2020. Each of the salaries for the remaining officers, directors and employees was similarly reinstated by no later than June 30, 2020.

As a result of the reduction of those fees and salaries during the second quarter of 2020, our operating expenses were reduced by approximately \$235,000 in the second quarter of 2020.

Release from Former Underwriter

The terms of our engagement of the underwriter for our September 2019 financing contained a purported 12 month right of first refusal in favor of such underwriter with respect to future financings. Due to, among other things, difficulties in the relationship with that prior underwriter and our need to raise additional funds to finance our ongoing operations, we engaged A.G.P. in May 2020 as underwriter for our June 2020 public offering, and again in July 2020 for an At-the-market offering (ATM).

On July 28, 2020, we entered into a settlement agreement and release with that prior underwriter, under which it provided us a final, unconditional release from any further obligations arising out of or related to the engagement agreements, underwriting agreements and placement agency agreements which we had been party to with it and with respect to any services which it had provided to us. We, in turn, provided the prior underwriter a final, unconditional release from any further obligations arising out of or related to the prior agreements and services.

As consideration for the final release provided to us, we paid to the prior underwriter \$400,000 in cash and reduced, to \$0.495, the exercise price per share of warrants to purchase 274,029 shares of our common stock that had been issued by us to the prior underwriter in various offerings that took place between March 2018 and September 2019. That reduced exercise price represents the exercise price for the Series F Warrants that we issued in our June 2020 public offering. The warrants that were repriced had existing exercise prices per share ranging from \$187.50 to \$2.25 and a weighted average exercise price per share of \$7.32. All other terms of those warrants remained unchanged. The related increase in expenses of \$400,000 was recorded to "General and Administrative expense" within the Consolidated Statements of Operations

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, 2019. There have not been any material changes to such critical accounting policies since December 31, 2019.

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, 2020 compared to the three months ended September 30, 2019

Revenues. For the three months ended September 30, 2020, revenue increased by \$41,000, or 4.4%, to \$980,000, from \$939,000 during the three months ended September 30, 2019. This increase was predominantly driven by a 69.0% increase in sales volume of MGuard EPS from \$87,000 during the three months ended September 30, 2019, to \$147,000 during the three months ended September 30, 2020. This increase was mainly due to the timing of shipments to one of the distributors for a tender recently won. This increase was offset, in part, by a 2.2% decrease in sales volume of CGuard Prime EPS from \$852,000 during the three months ended September 30, 2019, to \$833,000 during the three months ended September 30, 2020, largely driven by procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, only beginning to return to normal levels towards the end of the quarter as hospitals began to re-shift resources to non COVID-19 patients.

With respect to geographical regions, the increase in revenue was primarily attributable to: a \$70,000 increase in revenue from sales made in Latin America (driven by a \$40,000 increase of CGuard EPS sales and \$30,000 increase of MGuard Prime EPS sales), an increase of \$41,000 in revenue from sales made in Europe (primarily driven by a \$39,000 increase of MGuard Prime EPS sales for the reasons discussed in the paragraph above), offset by a decrease of \$62,000 in revenue from sales made in Asia and Middle East (primarily driven by a \$53,000 decrease of CGuard EPS sales for the reasons discussed in the paragraph above).

Gross Profit (Loss). For the three months ended September 30, 2020, gross profit (revenue less cost of revenues) increased by 132.8%, or \$170,000, to \$298,000, from \$128,000 during the three months ended September 30, 2019. This increase in gross profit resulted from a \$94,000 increase in revenues (as described above), less the related material and labor costs, a \$56,000 decrease in write-offs, which were driven by a component supply issue during the three months ended September 30, 2019 and which did not reoccur during the three months ended September 30, 2020 and a decrease of \$20,000 in miscellaneous expenses during the three months ended September 30, 2020. Gross margin (gross profits as a percentage of revenue) increased to 30.4% during the three months ended September 30, 2020 from 13.6% during the three months ended September 30, 2019, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended September 30, 2020, research and development expenses increased by 23.5%, or \$104,000, to \$546,000, from \$442,000 during the three months ended September 30, 2019. This increase resulted primarily from an increase of \$112,000 in development expenses related to CGuard EPS enhancements, offset by a decrease of \$8,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended September 30, 2020, selling and marketing expenses decreased by 9.7%, or \$52,000, to \$485,000, from \$537,000 during the three months ended September 30, 2019. This decrease resulted primarily from a decrease in travel expenses of \$97,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19, offset, in part, by an increase of \$45,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended September 30, 2020, general and administrative expenses increased by 27.6%, or \$316,000, to \$1,462,000, from \$1,146,000 during the three months ended September 30, 2019. This increase resulted primarily from an increase in Directors' and Officers' Liability Insurance expenses of \$92,000, partially due to recent economic effects on the insurance industry caused by the COVID-19 pandemic, an increase in compensation expenses of \$77,000, an increase in regulatory expenses of \$71,000 required due to new regulatory standards, and an increase in shareholder related expenses of \$60,000 mainly due to the timing of our annual shareholders meeting (which occurred in 2020, but not in 2019, during the third quarter of the fiscal year) and an increase of \$91,000 in miscellaneous expenses. These increases were partially offset by a decrease in travel expenses of \$75,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19 during the three months ended September 30, 2020

Financial Expenses. For the three months ended September 30, 2020, financial expenses decreased by 47.9%, or \$35,000, to \$38,000, from \$73,000 during the three months ended September 30, 2019. The decrease in financial expense primarily resulted from a decrease of \$37,000 in financial expenses related to changes in exchange rates, offset, in part, by an increase of \$2,000 in miscellaneous expenses.

Tax Expenses. For the three months ended September 30, 2020, there was no material change in our tax expenses as compared to the three months ended September 30, 2019.

Net Loss. Our net loss increased by \$163,000, or 7.9%, to \$2,233,000, for the three months ended September 30, 2020, from \$2,070,000 during the three months ended September 30, 2019. The increase in net loss resulted primarily from an increase of \$368,000 in operating expenses offset, in part, by an increase of \$170,000 in gross profit.

Nine months ended September 30, 2020 compared to the nine months ended September 30, 2019

Revenues. For the nine months ended September 30, 2020, revenue decreased by \$381,000, or 14.1%, to \$2,327,000, from \$2,708,000 during the nine months ended September 30, 2019. This decrease was predominantly driven by a 11.5% decrease in sales volume of CGuard EPS from \$2,344,000 during the nine months ended September 30, 2019, to \$2,075,000 during the nine months ended September 30, 2020, mainly due to the postponement of procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, as hospitals shifted resources to patients affected by COVID-19. In addition, there was a 30.8% decrease in sales volume of MGuard Prime EPS from \$364,000 during the nine months ended September 30, 2019, to \$252,000 during the nine months ended September 30, 2020, mainly due to the impact of COVID-19, as mentioned above.

With respect to regions, the decrease in revenue was primarily attributable to: a \$173,000 decrease in revenue from sales made in Europe (driven by a \$107,000 decrease of CGuard EPS sales and \$66,000 decrease of MGuard Prime EPS sales due to the COVID-19-related factor identified in the paragraph above), a decrease of \$128,000 in revenue of CGuard from sales made in Asia and Middle East due to the same COVID-19-related factor, as well as a decrease of \$48,000 in revenue from sales made in Latin America (primarily driven by a \$43,000 decrease of MGuard Prime EPS sales due to the same COVID-19-related factor).

Gross Profit. For the nine months ended September 30, 2020, gross profit (revenue less cost of revenues) decreased by 4.8%, or \$24,000, to \$473,000, compared to a \$497,000 for the same period in 2019. This decrease in gross profit resulted from a \$119,000 decrease in revenues (as mentioned above), less the related material and labor costs. This decrease was partially offset by a decrease of \$69,000 in expenses related to upgrades made to our production facilities during the nine months ended September 30, 2019, which did not reoccur during the nine months ended September 30, 2020 and a decrease of \$26,000 in miscellaneous expenses during the nine months ended September 30, 2020. Gross margin (gross profits as a percentage of revenue) increased to 20.3% during the nine months ended September 30, 2020 from 18.4% during the nine months ended September 30, 2019, driven by the reasons mentioned above.

Research and Development Expenses. For the nine months ended September 30, 2020, research and development expenses decreased by 37.8%, or \$919,000, to \$1,513,000, from \$2,432,000 during the nine months ended September 30, 2019. This decrease resulted primarily from: a decrease of \$708,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, of which an approval from the FDA was received on September 8, 2020, a decrease of \$354,000 due to settlement expenses that were paid to a former service provider pursuant to a settlement agreement during the nine months ended September 30, 2019, which did not reoccur during the nine months ended September 30, 2020, and a decrease of \$150,000 in quality assurance and regulatory expenses related to the development of various projects during the nine months ended September 30, 2019, which were significantly reduced during the nine months ended September 30, 2020. These decreases were partially offset by an increase of \$280,000 in development expenses related to CGuard EPS enhancements and an increase of \$13,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the nine months ended September 30, 2020, selling and marketing expenses decreased by 17.0%, or \$305,000, to \$1,486,000, from \$1,791,000 during the nine months ended September 30, 2019. This decrease resulted primarily from: a decrease in travel expenses of \$195,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19 during the nine months ended September 30, 2020, a decrease of \$91,000 in promotional expenses, primarily related to having already built our social media infrastructure in 2019, and a decrease of \$19,000 in miscellaneous expenses.

General and Administrative Expenses. For the nine months ended September 30, 2020, general and administrative expenses increased by 15.4%, or \$552,000, to \$4,136,000, from \$3,584,000 during the nine months ended September 30, 2019. This increase resulted primarily from an increase of \$400,000 due to expenses for the settlement agreement with the underwriter of our prior offerings paid during the nine months ended September 30, 2020, an increase in our Directors' and Officers' Liability Insurance expenses of \$115,000 partially due to recent economic effects on the insurance industry caused by the COVID-19 pandemic, an increase in regulatory expenses of \$130,000 required for new regulatory standards and an increase of \$18,000 in miscellaneous expenses, offset, in part, by a decrease in travel expenses of \$111,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19 during the nine months ended September 30, 2020.

Financial Expenses. For the nine months ended September 30, 2020, financial expenses decreased by 83.2%, or \$144,000, to \$29,000, from \$173,000 during the nine months ended September 30, 2019. The decrease in financial expenses primarily resulted from a decrease of \$154,000 in financial expenses related to changes in exchange rates, offset, in part, by an increase of \$10,000 in miscellaneous expenses.

Tax Expenses (Income). For the nine months ended September 30, 2020, there was no material change in our tax expenses as compared to the nine months ended September 30, 2019.

Net Loss. Our net loss decreased by \$792,000, or 10.6%, to \$6,691,000, for the nine months ended September 30, 2020, from \$7,483,000 during the nine months ended September 30, 2019. The decrease in net loss resulted primarily from a decrease of \$672,000 in operating expenses and a decrease of \$144,000 in financial expenses, offset, in part, by a decrease of \$24,000 in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of September 30, 2020, of approximately \$164 million, as well as a net loss of \$6,691,000 and negative operating cash flows for the nine months ended September 30, 2020. 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 third quarter of 2021. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include 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. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

On June 5, 2020, we closed an underwritten public offering of (i) 7,635,800 Units, with each Unit being comprised of one share of the Company's common stock, par value \$0.0001 per share, and one Series F Warrant to purchase one share of common stock, and (ii) 14,586,400 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 F Warrant. In connection with this public offering, the underwriter exercised the option practically in full, for 3,333,300 shares of common stock and 3,333,300 Series F Warrants. The offering price to the public was \$0.45 per Unit and \$0.449 per Pre-Funded Unit. The net proceeds to the Company from the offering and the exercise of the underwriter's over-allotment option were approximately \$10.7 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series F Warrants and the Pre-Funded Warrants sold in the offering.

During the quarter ended September 30, 2020, we sold 593,102 shares of our Common Stock pursuant to the ATM facility, which sales resulted in \$268,000 and \$158,000 of gross and net proceeds, respectively, for our company. We paid \$9,000 in commissions to A.G.P. in respect of those sales, as required under the Sales Agreement.

Anti-Dilution Provisions

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 9, 2020, 17,303 shares of Series B Preferred Stock and 2,343 shares of Series C Preferred Stock were outstanding.

Nine months ended September 30, 2020 compared to the nine months ended September 30, 2019

General. At September 30, 2020, we had cash and cash equivalents of \$10,882,000, as compared to \$5,514,000 as of December 31, 2019. 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 costs, capital expenditures and general working capital.

For the nine months ended September 30, 2020, net cash used in our operating activities decreased by \$1,361,000 to \$6,881,000, from \$8,242,000 during the same period in 2019. The primary reason for the decrease in cash used in our operating activities was a decrease of \$1,595,000 in payments for third party related expenses and for professional services (primarily due to a decrease in production related payments and a decrease in payments related to IDE application process), offset, in part, by an increase of \$223,000 in compensation costs paid during the nine months ended September 30, 2020, from \$4,378,000 in the nine months ended September 30, 2019 to \$4,601,000 during the same period in 2020 and a decrease of \$11,000 in payments received from customers, to \$2,599,000 during the nine months ended September 30, 2020, from \$2,610,000 during the same period in 2019.

Cash used in our investing activities was \$83,000 during the nine months ended September 30, 2020 compared to \$318,000 during the nine months ended September 30, 2019. The primary reasons for the decrease in cash used by our investing activities were: a decrease of \$205,000 in payments made for purchase of property, plant and equipment to \$26,000 during the nine months ended September 30, 2020, from \$231,000 during the same period in 2019, and a decrease of \$30,000 in cash deposited to employee funds, to \$57,000 during the nine months ended September 30, 2020, from \$87,000 during the same period in 2019.

Cash provided by financing activities for the nine months September 30, 2020 was \$12,327,000, compared to \$6,331,000 during the same period in 2019. The principal sources of the cash provided by financing activities during the nine months ended September 30, 2020 were our June 2020 public offering of common stock, pre-funded warrants and warrants, the subsequent exercise of the pre-funded warrants sold in the offering, as well as exercise of warrants F and Unit Purchase Options as well as proceeds from an At-the-market offering that resulted in approximately \$12,327,000 of aggregate net proceeds. The principal source of the cash provided by financing activities during the nine months ended September 30, 2019, was the funds received from our September 2019 public offering of common stock, pre-funded warrants and warrants, as well as the subsequent exercise of the pre-funded warrants sold in the offering, that resulted in approximately \$4,285,000 of aggregate net proceeds, and funds received from our April 2018 public offering of common stock that resulted in approximately \$2,046,000 of aggregate net proceeds.

As of September 30, 2020, our current assets exceeded our current liabilities by a multiple of 5.2. Current assets increased by \$5,526,000 during the period and current liabilities decreased by \$546,000 during the period. As a result, our working capital increased by \$6,072,000 to \$10,767,000 as of September 30, 2020.

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.

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 impact of the COVID-19 pandemic, 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, 2019, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

The ultimate impact of the COVID-19 pandemic on the Company’s operations remains undetermined and will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, including the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that regulators, or the board or management of the Company, may determine are needed.

Contractual Obligations and Commitments

During the three months ended September 30, 2020, 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, 2020, 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, 2020.

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, 2020, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not aware of any material changes from the information set forth in “Item 3. Legal Proceedings” in the Form 10-K filed with the SEC on March 10, 2020 and available at the following link:

https://www.sec.gov/Archives/edgar/data/1433607/000149315220003630/form10-k.htm#r_003

Item 1A. Risk Factors

Except as set forth below, there have been no material changes from the information set forth in “Item 1A. Risk Factors” in the Form 10-K filed with the SEC on March 10, 2020.

The COVID-19 pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.

In an effort to contain and mitigate the spread of COVID-19, which the World Health Organization, or WHO, declared to be a pandemic on March 12, 2020, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. Procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, have mostly been postponed as hospitals shift resources to patients affected by COVID-19, and we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures in light of recent increases in COVID-19 cases in the territories we sell into. At this point, the extent to which COVID-19 may impact our business cannot be estimated; however, we anticipate that the continuation of the pandemic and related restrictions and safety measures would likely result in a continued decline in sales of our products for the upcoming periods.

Certain component parts of our delivery system are sourced from countries that have been impacted by COVID-19, and the continued pandemic and spreading of COVID-19 may adversely impact our suppliers and in turn our manufacture of CGuard EPS. Although the manufacturing of our products in Israel has not been materially impacted by COVID-19 as of November 2020, we cannot guarantee that we will continue to manufacture at full capacity in the event that pandemic persists and further restrictions are imposed.

Following the consummation of our June 2020 offering, we believe that we have sufficient resources to fund operations through the third quarter of 2021. Given the continuing cash needs for our development and commercialization of CGuard EPS (and in particular if we receive regulatory approval in the U.S.), our management continues to pursue additional financing opportunities so that we can continue to fund our operations beyond that time. However, the COVID-19 pandemic may limit our access to credit and capital. Management continues to evaluate a number of financing opportunities, either through the issue of new equity or the entering into of strategic partnership arrangements; however, there is no assurance that our management will be able to obtain such financing on reasonable terms or at all. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

The extent to which COVID-19 will impact our results will depend on future developments, which are highly uncertain and cannot be predicted at this time, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. The COVID-19 pandemic has produced indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID-19 or any other epidemic and/or pandemic harms the global economy generally.

The market prices of our common stock and our publicly traded warrants are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors.

The market prices of our common stock and our Series A Warrants and Series B Warrants have been and are likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- our ability to execute our business plan;
- operating results that fall below expectations;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Moreover, on March 12, 2020, the WHO declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock. These market fluctuations may also significantly affect the market prices of our common stock and our publicly traded warrants.

Item 5. Other Information

Not applicable

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
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	<u>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)</u>
3.4	<u>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)</u>
3.5	<u>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)</u>
3.6	<u>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)</u>
3.7	<u>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)</u>
3.8	<u>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)</u>

- 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 \(incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 5, 2018\)](#)
- 3.16 [Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. \(incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019\)](#)
- 10.1 [Sales Agreement, dated July 28, 2020 \(incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 28, 2020\)](#)
- 10.2+ [Fourth Amendment to Amended and Restated Employment Agreement, dated August 14, 2020, by and between InspireMD, Inc. and Craig Shore \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 18, 2020\)](#)
- 10.3+ [Sixth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 31, 2020\)](#)
- 31.1* [Certification of Chief 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 Chief 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, 2020, 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 9, 2020

By: /s/ Marvin Slosman

Name: Marvin Slosman,

Title: President and Chief Executive Officer

Date: November 9, 2020

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer, Secretary and Treasurer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marvin Slosman, certify that:

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

Date: November 9, 2020

/s/ Marvin Slosman

Marvin Slosman
Chief Executive Officer

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

I, Craig Shore, certify that:

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

Date: November 9, 2020

/s/ Craig Shore

Craig Shore
Chief Financial Officer

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2020 of InspireMD, Inc. (the "Company"). I, Marvin Slosman, the Chief Executive Officer of the Company, certify that, based on my knowledge:

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

Date: November 9, 2020

By: /s/ Marvin Slosman

Name: Marvin Slosman

Title: Chief Executive Officer

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

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the “Form 10-Q”) for the quarter ended September 30, 2020, of InspireMD, Inc. (the “Company”). I, Craig Shore, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:

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

Date: November 9, 2020

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

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