INSPIREMD, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/12/19 for the Period Ending 09/30/19

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)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2019

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	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(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 [X] 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 [X] 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 [ ]	Accelerated filer [ ]
Non-accelerated filer [X]	Smaller reporting company [X]
	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 [X]

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 12, 2019: 3,632,857

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

	September 30 2019	December 31 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,154	$ 9,384
Accounts receivable:		
Trade, net	796	716
Other	186	104
Prepaid expenses	155	81
Inventory	1,283	1,134
TOTAL CURRENT ASSETS	9,574	11,419
NON-CURRENT ASSETS:		
Property, plant and equipment, net	538	421
Right of use	975	-
Fund in respect of employee rights upon retirement	535	448
TOTAL NON-CURRENT ASSETS	2,048	869
TOTAL ASSETS	$ 11,622	$ 12,288

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

	September 30 2019	December 31 2018
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	687	929
Other	1,617	1,966
Contract liability	19	25
TOTAL CURRENT LIABILITIES	2,323	2,920
LONG-TERM LIABILITIES:		
Leasing liability	699	-
Liability for employees rights upon retirement	704	605
TOTAL LONG-TERM LIABILITIES	1,403	605
COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)		
TOTAL LIABILITIES	3,726	3,525
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2019 and December 31, 2018; 3,456,915 and 768,615 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	-	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at September 30, 2019 and December 31, 2018; 17,303 shares issued and outstanding at September 30, 2019 and December 31, 2018.	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at September 30, 2019 and December 31, 2018; 36,869 and 61,423 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	-	-
Additional paid-in capital	162,971	156,355
Accumulated deficit	(155,075)	(147,592)
Total equity	7,896	8,763
Total liabilities and equity	$ 11,622	$ 12,288

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 September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
REVENUES	$ 939	$ 769	$ 2,708	$ 2,779
COST OF REVENUES	811	571	2,211	2,011
GROSS PROFIT	128	198	497	768
OPERATING EXPENSES:				
Research and development	442	416	2,432	898
Selling and marketing	537	605	1,791	1,677
General and administrative	1,146	1,156	3,584	3,598
Total operating expenses	2,125	2,177	7,807	6,173
LOSS FROM OPERATIONS	(1,997)	(1,979)	(7,310)	(5,405)
FINANCIAL INCOME (EXPENSES), net:	(73)	(32)	(173)	378
LOSS BEFORE TAX EXPENSES	(2,070)	(2,011)	(7,483)	(5,027)
TAX EXPENSES	-	-	-	-
NET LOSS	$ (2,070)	$ (2,011)	$ (7,483)	$ (5,027)
NET LOSS PER SHARE - basic and diluted	$ (1.26)	$ (2.47)	$ (5.79)	$ (16.24)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	1,648,302	815,283	1,293,321	334,581

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 Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Additional paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT DECEMBER 31, 2017	30,106	*	27,075	*	741,651	*	750	*	$ 143,079	$ (140,352)	$ 2,727
Net loss										(5,027)	(5,027)
Issuance of common shares, warrants, pre-funded warrants and exercise of pre-funded warrants, net of $2,171 issuance costs	677,477	*							15,809		15,809
Redemption of Series D Preferred Stock							(750)	*	(750)		(750)
Conversion of Series B Preferred Stock to common shares	1,613	*	(9,772)	*					274		274
Conversion of Series C Preferred Stock to common shares	22,896	*			(326,436)	*			936		936
Exercise of Unit Purchase Option	2,229	*							557		557
Accretion of redeemable preferred shares									(438)		(438)
Redemption of Series C Preferred Stock					(353,792)	*			(3,200)		(3,200)
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 4 shares	(4)								64		64
BALANCE AT September 30, 2018	734,317	*	17,303	*	61,423	*	-	*	$ 156,331	$ (145,379)	$ 10,952

* Represents an amount less than $1 thousand

	Common stock		Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Additional paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT June 30, 2018	129,505	*	17,303	*	378,840	*	300	*	$ 147,466	$ (143,368)	$ 4,098
Net loss										(2,011)	(2,011)
Issuance of common shares, warrants, pre-funded warrants and exercise of pre-funded warrants, net of $2,171 issuance costs	600,334	*							8,867		8,867
Conversion of Series C Preferred Stock to common shares	4,480	*			(10,500)	*			-		-
Redemption of Series D Preferred Stock							(300)	*	-		-
Redemption of Series C Preferred Stock					(306,917)	*			-		-
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 2 shares	(2)	*							(2)		(2)
BALANCE AT September 30, 2018	734,317	*	17,303	*	61,423	*	-	*	$ 156,331	$ (145,379)	$ 10,952

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

* Represents an amount less than $1 thousand

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	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT December 31, 2018	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 $1,177 issuance costs	**2,588,828**	*					**6,331**		**6,331**
Conversion of Series C Convertible Preferred Stock to common shares	**29,728**				**(24,554)**	*			
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 837 shares	**69,744**	*					**285**		**285**
BALANCE AT September 30, 2019	**3,456,915**	*	**17,303**	*	**36,869**	*	**$ 162,971**	**$ (155,075)**	**$ 7,896**

* Represents an amount less than $1 thousand

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT June 30, 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 $710 issuance costs	**2,057,444**	*					**4,285**		**4,285**
Conversion of Series C Convertible Preferred Stock to common shares	**2,480**				**(1,937)**	*			
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 142 shares	**(142)**	*					**107**		**107**
BALANCE AT September 30, 2019	**3,456,915**	*	**17,303**	*	**36,869**	*	**$ 162,971**	**$ (155,075)**	**$ 7,896**

* Represents an amount less than $1 thousand

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

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Nine months ended September 30	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,483)	$ (5,027)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	114	115
Change in liability for employees rights upon retirement	99	(16)
Financial income	(1)	(425)
Lease liability	76	-
Share-based compensation expenses	285	64
Changes in operating asset and liability items:		
Increase in prepaid expenses	(74)	(83)
Increase in trade receivables	(80)	(67)
Decrease (Increase) in other receivables	(82)	29
Increase in inventory	(149)	(283)
Increase (Decrease) in trade payables	(242)	128
Decrease in other payables and contract liability	(705)	(238)
Net cash used in operating activities	(8,242)	(5,803)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(231)	(30)
Amounts withdrawn (funded) in respect of employee rights upon retirement, net	(87)	30
Net cash used in investing activities	(318)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants and exercise of pre-funded warrants and unit purchase option, net of $1,177 and $2,161 issuance costs, respectively	6,331	16,365
Redemption of series C and D preferred stock	-	(3,014)
Net cash provided by financing activities	6,331	13,351
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(1)	(11)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,230)	7,537
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	9,384	3,710
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	$ 7,154	$ 11,247
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Classification of Redemption Obligation of Preferred Shares to Mezzanine and Embedded Derivative	$ -	164

The accompanying notes are an integral part of 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, 2019, 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 until the end of May 2020. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

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

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2018, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 19, 2019. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 – RECENTLY ADOPTED AND ISSUED ACCOUNTING PRONOUNCEMENTS

a. Newly issued accounting pronouncements

1) In February 2016, the FASB established ASC Topic 842, Leases (Topic 842), by issuing ASU No. 2016-02, which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. The new standard establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. We adopted the new standard on January 1, 2019 using the modified retrospective transition method and we did not restate comparative periods. The new standard provides a number of optional practical expedients in transition. We have elected the 'package of practical expedients', which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs for leases entered into prior to adoption of Topic 842.

   Additionally, we did not separate lease and non-lease components for all of our leases. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. Instead, we will continue to recognize the lease payments for those leases in profit or loss on a straight-line basis over the lease term.

   The new standard had a material effect on the Company's financial statements. The most significant effects of the adoption relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for real estate operating leases; and (2) providing significant new disclosures about its leasing activities.

   Upon adoption, we recognized additional operating lease liabilities, of approximately $1.2 million based on the present value of the remaining lease payments under current leasing standards for existing operating leases. The Company also recognized corresponding ROU assets of approximately $1.2 million. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term. Our leases may include variable payments based on measures that include changes in price index which are expensed as incurred and presented as operating expense on the consolidated statements of operations in the same line item as expense arising from fixed lease payments.

   The new standard also provides practical expedients for an entity's ongoing accounting. Beginning in 2019, the Company changed its disclosed lease recognition policies and practices, as well as to other related financial statement disclosures due to the adoption of this standard. See Note 9.

NOTE 4 - EQUITY:

a. On March 27, 2019, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a one-for-fifty reverse stock split of its common stock, par value $0.0001 per share, effective as of March 29, 2019. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

b. During the nine months ended September 30, 2019, the Company issued a total of 32,034 shares of its common stock in connection with the exercise of 32,034 pre-funded warrants issued in July 2018. The Company received aggregate cash proceeds equal to approximately 16,000 in connection with such exercises. As of September 30, 2019, all of the pre-funded warrants issued in July 2018 have been exercised.

c. During the nine months ended September 30, 2019, the Company issued a total of 1,518,444 shares of its common stock in connection with the exercise of 1,518,444 Pre-Funded Warrants (as defined in paragraph g of this Note 4) issued in September 2019. As of September 30, 2019, there are 720,333 outstanding Pre-Funded Warrants issued in September 2019. Each Pre-Funded Warrant is exercisable for one share of our common stock at an exercise price of $0.01 per share.

d. During the nine months ended September 30, 2019, 24,554 shares of Series C Convertible Preferred Stock were converted into 29,728 shares of common stock.

e. As of September 30, 2019, the number of preferred shares and the number of shares of common stock each class of preferred stock is convertible into is as follows:

	Number of Preferred Stock	Number of underlying Common stock
Series B Convertible Preferred Stock	17,303	555,138*
Series C Convertible Preferred Stock	36,869	131,090
Total		686,228

* 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, 2019, the Company has outstanding warrants to purchase an aggregate of 4,016,817 shares of common stock as follows:

	Number of underlying Common stock	Weighted average exercise price
Series A Warrants	1,102	$ 8,750.00
Series B Warrants	2,448	$ 3,500.00
Series D Warrants	806,698	$ 15.19
Series E Warrants	2,972,221	$ 1.80
April 2019 Underwriter Warrants	34,955	$ 6.25
September 2019 Underwriter Warrants	194,444	$ 2.25
Other warrants	4,949	$ 11,258.00
Total Warrants	4,016,817	$ 22.95

The warrants indicated above do not include the Pre-Funded Warrants mentioned in Note 4(c). As of September 30, 2019, 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.

On March 21, 2019, the stockholders approved the amendment of its Long Term Incentive Plan which was adopted by our board of directors on February 4, 2019, to increase the total number of shares of common stock issuable under such plan by 500,000 shares.

f. On April 8, 2019, the Company closed an underwritten public offering of 486,957 shares of the Company's common stock at the offering price to the public of $5.00 per share. The Company received net proceeds of approximately $2 million from the offering, after deducting underwriter discounts and commissions and other fees and expenses payable by the Company. In connection with this public offering, on April 12, 2019, the underwriter partially exercised its over-allotment option and purchased an additional 12,393 shares of our common stock at a price to the public of $5.00 per share. The Company received net proceeds of approximately $47,000 from the exercise of the over-allotment option.

In connection with the offering, the Company issued to the underwriter warrants to purchase up to 34,955 shares of common stock, or 7% of the shares sold in the offering, including the shares issued pursuant to the over-allotment option (the "April Underwriter Warrants"). The April

Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending on April 4, 2024, at an exercise price of $6.25 per share (125% of the offering price to the public per share).

Upon execution of the underwriting agreement, the respective conversion price of the outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock was reduced to $5.00 pursuant to the anti-dilution adjustment provisions of the Series B Convertible Preferred Stock and of the Series C Convertible Preferred Stock, and the number of shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock had increased as follows:

- an aggregate of 133,233 additional shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock, including the payment of the cumulative dividends accrued thereunder in common stock, based on 17,303 shares of Series B Convertible Preferred Stock outstanding as of April 4, 2019.
- an aggregate of 50,708 additional shares of common stock issuable upon conversion of the Series C Convertible Preferred Stock, based on 59,423 shares of Series C Convertible Preferred Stock outstanding as of April 4, 2019.

g. On September 19, 2019, the Company entered into an underwriting agreement relating to an underwritten public offering (the "September 2019 Offering") of (i) 539,000 common units ("Common Units"), with each Common Unit being comprised of one share of the Company's common stock, par value $0.0001 per share, and one Series E warrant (collectively, the "Series E Warrants") to purchase one share of common stock and (ii) 2,238,777 pre-funded units ("Pre-Funded Units"), with each Pre-Funded Unit being comprised of one pre-funded warrant (collectively, the "Pre-Funded Warrants") to purchase one share of common stock and one Series E Warrant, which closed on September 24, 2019. The offering price to the public was $1.80 per Common Unit and $1.79 per Pre-Funded Unit. In connection with this public offering, on September 24, 2019, the underwriter partially exercised its over-allotment option and purchased an additional 194,444 Series E Warrants at a purchase price of $0.01 per Series E Warrant.

The Series E Warrants included in the Common Units and the Pre-Funded Units are immediately exercisable at a price of $1.80 per share of common stock, subject to adjustment in certain circumstances, and expire September 24, 2024. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series E Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately.

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

In connection with the offering, the Company issued to the underwriter warrants to purchase up to 194,444 shares of common stock, or 7% of the shares sold in the offering, including the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants sold in the offering (the "September Underwriter Warrants"). The September Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending on September 19, 2024, at an exercise price of $2.25 per share (125% of the offering price to the public per Common Unit).

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 $1.80 per share, effective as of the date of the underwriting agreement entered for the September 2019 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 355,288 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 September 19, 2019.
- an aggregate of 88,305 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 37,025 shares of Series C Preferred Stock outstanding as of September 19, 2019.

On September 24, 2019, the Company closed the September 2019 Offering. The Company received gross proceeds of $5.0 million from the offering, before deducting underwriter discounts and commissions and other fees and expenses payable by the Company.

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

NOTE 5- NET LOSS PER SHARE:

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	($ in thousands)			
NET LOSS	$ (2,070)	$ (2,011)	$ (7,483)	$ (5,027)
Adjustments due to extinguishment and accretion of series D and series C preferred shares				(407)
Adjusted Loss	$ (2,070)	$ (2,011)	$ (7,483)	$ (5,434)
Weighted average of Common Stock outstanding during the period	1,648,302	815,283	1,293,321	334,581
Basic and diluted loss per share (dollars)	$ (1.26)	$ (2.47)	$ (5.79)	$ (16.24)

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

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Convertible Preferred Stock, Series Convertible D Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 915,599 for the nine and three month period ended September 30, 2018.

* 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. 720,333 Pre-funded Warrants are included in the three and nine month calculation.

NOTE 6 - FAIR VALUE MEASURMENT:

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, 2019, and December 31, 2018, allowance for doubtful accounts was $72,000.

NOTE 7 - INVENTORY:

	September 30, 2019	December 31, 2018
	($ in thousands)	
Finished goods	$ 124	$ 284
Work in process	166	111
Raw materials and supplies	993	739
	$ 1,283	$ 1,134

NOTE 8 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	September 30, 2019	December 31, 2018
	($ in thousands)	
Employees and employee institutions	653	828
Accrued vacation and recreation pay	172	171
Accrued expenses	439	903
Provision for sales commissions	-	37
Current Operating lease liabilities	352	-
Other	1	27
	$ 1,617	$ 1,966

NOTE 9 - 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.

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

3) Operating lease cost for the nine months ended September 30, 2019 was comprised of the following:

	Nine months ended September 30 2019
	($ in thousands)
Operating lease expense	267
Short-term lease expense	6
Variable lease expense	-
	273

Supplemental information related to leases are as follows:

	September 30 2019 ($ in thousands)
Operating lease right-of-use assets	975
Current Operating lease liabilities	(352)
Non-current operating lease liabilities	(699)

Other information:

Operating cash flows from operating leases (cash paid in thousands)	(270)
Weighted Average Remaining Lease Term	1.44
Weighted Average Discount Rate	9.07%

Maturities of lease liabilities are as follows:

	Amount ($ in thousands)
2019 (excluding the nine months ended September 30, 2019)	93
2020	372
2021	375
2022	349
Total lease payments	1,189
Less imputed interest	(138)
Total	1,051

4) ASC 840 Disclosures

The Company elected the modified retrospective transition method and included the following tables previously disclosed.

Future contractual obligations under the abovementioned operating lease agreements (not including the extension option) as of December 31, 2018 are as follows:

	Amount U.S. dollars in thousands
2019	337
2020	357
2021	26
Total	720

b. **Litigation:**

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 $1.1 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.

In July 2016, a service provider filed a suit seeking damages from the Company's subsidiary amounting to $1,967,822. The Company's subsidiary and the plaintiff have entered into a confidential settlement agreement in the amount of $600,000, and on April 24, 2019, the parties filed a stipulation of dismissal, dismissing all claims in this action. On April 25, 2019, the court denied as moot all pending motions. The related increase in provision of $354,000 was recorded to "Research and development expense" within the Consolidated Statements of Operations for the nine months ended September 30, 2019.

NOTE 10 - DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	($ in thousands)			
Italy	$ 211	$ 119	$ 550	$ 512
Germany	189	178	513	650
Russia	100	9	129	168
Poland	90	61	277	179
Other	349	402	1,239	1,270
	$ 939	$ 769	$ 2,708	$ 2,779

By product:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
	($ in thousands)			
CGuard	$ 852	$ 604	$ 2,344	$ 2,268
MGuard	87	165	364	511
	$ 939	$ 769	$ 2,708	$ 2,779

By principal customers:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Customer A	17%	22%	16%	22%
Customer B	11%	10%	12%	10%
Customer C	10%	8%	10%	6%
Customer D	12%	5%	8%	8%
Customer E	11%	1%	5%	6%

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 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 regain or maintain compliance with NYSE American listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- market acceptance of our products;
- negative clinical trial results or lengthy product delays in key markets;

- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- price increases for supplies and components;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- loss or retirement of key executives and research scientists.

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 we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We expect to receive approval to launch CGuard EPS in Brazil, and we are seeking strategic partners for potential launch of CGuard EPS in Japan and China.

We consider the addressable market for our CGuard EPS to consist of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately $1.0 billion in 2017 (source: Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets).

In April 2017, we had a pre-investigational device exemption ("IDE") submission meeting with the U.S. Food and Drug Administration ("FDA") regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. The FDA agreed to our pre-clinical test plan and clinical trial design. On July 26, 2019, we submitted an IDE application for CGuard EPS. In connection with such application, on August 23, 2019, we received a request for additional information from the FDA in support of our application. We continue to work closely with the FDA to resolve these additional requests. Following resolution of all comments from the FDA, we plan to submit a formal response for CGuard EPS, as IDE approval by the FDA would be a critical step toward the commencement of a human clinical trial using CGuard EPS in the United States.

Additionally we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system. 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 cost of goods and increase penetration in our existing geographies and better position us for entry into new 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, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES™.

We also intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performance and todevelop a pipeline of other products and additional applications by leveraging our MicroNet technology to new applications to improve peripheral vascular and neurovascular procedures, such as the treatment of the superficial femoral artery disease, vascular disease below the knee and neurovascular stenting to seal aneurysms in the brain.

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

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

Recent Developments

*Public Offering*s

On April 8, 2019, we closed an underwritten public offering of 486,957 shares of our common stock at a price to the public of $5.00 per share. We received net proceeds of approximately $2.0 million from the offering, after deducting underwriter discounts and commissions and offering expenses payable by us. As a result of such offering, the conversion price for each of our Series B Preferred Stock and Series C Preferred was reduced to $5.00 per share. In connection with this public offering, on April 12, 2019, the underwriter partially exercised its over-allotment option and purchased an additional 12,393 shares of our common stock at a price to the public of $5.00 per share. We received net proceeds of approximately $47,000 from the exercise of the over-allotment option.

On September 24, 2019, we closed an underwritten public offering of (i) 539,000 common units, with each common unit being comprised of one share of our common stock and one Series E Warrant to purchase one share of common stock and (ii) 2,238,777 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 E Warrant. In connection with this public offering, the underwriter partially exercised its over-allotment option and purchased an additional 194,444 Series E Warrants to purchase 194,444 shares of common stock. The offering price to the public was $1.80 per common unit and $1.79 per pre-funded unit. The net proceeds to the us from the offering of common units and pre-funded units and the exercise of the underwriter's option to purchase 194,444 additional Series E Warrants to purchase an aggregate of 194,444 shares of common stock was approximately $4.2 million, excluding the proceeds, if any, from the exercise of the Series E Warrants and the pre-funded warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that were payable by us.

NYSE American Notification

Stockholder's Equity

On August 7, 2019, we received notification from the NYSE American that we do not meet continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the "Company Guide"). Specifically, we are not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of June 30, 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, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020. We are subject to periodic review during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

Low Trading Price

On January 7, 2019, we received notification from the NYSE American that we are not in compliance with the NYSE American continued listing standards because our shares of common stock had been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the NYSE American Company Guide (the "Company Guide"), the NYSE American staff determined that our continued listing was predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 7, 2019. In addition, the NYSE American advised us that its policy is to immediately suspend trading in shares of, and commence delisting procedures with respect to, a listed company if the market price of its shares falls below $0.06 per share at any time during the trading day.

Effective as of 5:00 p.m. Eastern Time on March 29, 2019, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-50 reverse stock split of our outstanding shares of common stock.

On July 8, 2019, we received notice from NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide. We are subject to NYSE Regulation's normal continued listing monitoring. However, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of July 8, 2019, NYSE American will examine the relationship between the two incidents of noncompliance and re-evaluate our method of financial recovery from the first incident. NYSE Regulation will then take the appropriate action, which depending on the circumstances, may include truncating the compliance procedures described in Section 1009 of the Company Guide or immediately initiating delisting proceedings. If in the future we fall below the continued listing criterion of a minimum average share price of $0.20 over a 30-day trading period, our common stock will be subject to immediate review by NYSE American. There can be no assurance that the market price of our common stock will remain above the levels viewed as abnormally low for a substantial period of time.

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, 2018. There have not been any material changes to such critical accounting policies since December 31, 2018 other than a change to the accounting policy of Leases following the adoption of ASU No. 2016-02. See Note 3(a) to our unaudited consolidated financial statements included in Item 1, "Unaudited Financial Statements," of this Quarterly Report on Form 10-Q.

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, 2019 compared to the three months ended September 30, 2018

Revenues. For the three months ended September 30, 2019, revenue increased by 170,000, or 22.1%, to $939,000, from $769,000 during the three months ended September 30, 2018. This increase was predominantly driven by a 41.1% increase in sales volume of CGuard EPS from $604,000 during the three months ended September 30, 2018, to $852,000 during the three months ended September 30, 2019, mainly due to our continued focus on expanding existing markets such as Italy and Russia. This increase in sales of CGuard EPS was partially offset by a 47.3% decrease in sales of MGuard Prime EPS from $165,000 during the three months ended September 30, 2018, to $87,000 during the three months ended September 30, 2019, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients.

With respect to regions, the increase in revenue was primarily attributable to a $158,000 increase in revenue from sales made in Europe (driven by a $227,000 increase in sales volume of CGuard EPS for reasons discussed in the paragraph above, offset by a $69,000 decrease in sales of MGuard Prime EPS).

Gross Profit (Loss). For the three months ended September 30, 2019, gross profit (revenue less cost of revenues) decreased by 35.4%, or $70,000, to $128,000, compared to a gross profit of $198,000 during the same period in 2018. This decrease in gross profit resulted from a $65,000 increase in write-offs predominantly driven by a non-recurring component supply issue and a $11,000 decrease associated with the higher sales volume of CGuard EPS (as mentioned above), sold at a lower average selling price for the three months ended September 30, 2019, compared to the average selling price of CGuard EPS for the three months ended September 30, 2018. These decreases in gross profit were partially offset by a decrease of $6,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased to 13.6% during the three months ended September 30, 2019, from 25.7% during the three months ended September 30, 2018, driven mainly by the write offs and the effect of the average selling price as mentioned above.

Research and Development Expenses. For the three months ended September 30, 2019, research and development expenses increased by 6.3%, or $26,000, to $442,000, from $416,000 during the three months ended September 30, 2018. This increase resulted primarily from an increase of $77,000 in compensation expenses primarily due to expenses incurred to support various development projects, an increase of $39,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process. These increases in research and development expenses were partially offset by a decrease of $81,000 related to sterilization validation efforts expenses we incurred during the three months ended September 30, 2018, which we did not incur during the three months ended in September 30, 2019, and a decrease of $9,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended September 30, 2019, selling and marketing expenses decreased by 11.2%, or $68,000, to $537,000 from $605,000 during the three months ended September 30, 2018. This decrease resulted from a decrease of $41,000 in consulting expenses and a decrease of $27,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended September 30, 2019, general and administrative expenses decreased by 0.9%, or $10,000, to $1,146,000, from $1,156,000 during the three months ended September 30, 2018. This decrease resulted primarily from not incurring any costs associated with a shareholders meeting during the three months ended September 30, 2019, and a decrease in miscellaneous expenses. These decreases in general and administrative expenses were partially offset by an increase of travel expenses.

Financial Expenses (Income). For the three months ended September 30, 2019, financial expenses increased by 128.1% or $41,000, to $73,000, from $32,000 during the three months ended September 30, 2018. The increase in financial expenses primarily resulted from an increase of $42,000 in financial expenses related to changes in exchange rates. These increases in financial expenses were partially offset by a decrease of $1,000 in miscellaneous expenses during the nine months ended September 30, 2019.

Tax Expenses (Income). For the three months ended September 30, 2019, there was no material change in our tax expenses as compared to the three months ended September 30, 2018.

Net Loss. Our net loss increased by $59,000, or 2.9%, to $2,070,000, for the three months ended September 30, 2019, from $2,011,000 during the three months ended September 30, 2018.

Nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

Revenues. For the nine months ended September 30, 2019, revenue decreased by $71,000, or 2.6%, to $2,708,000, from $2,779,000 during the nine months ended September 30, 2018. This decrease was predominantly driven by a 28.8% decrease in sales volume of MGuard Prime EPS from $511,000 during the nine months ended September 30, 2018, to $364,000 during the nine months ended September 30, 2019, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients. This decrease was offset by a 3.4% increase in sales volume of CGuard EPS from $2,268,000 during the nine months ended September 30, 2018, to $2,344,000 during the nine months ended September 30, 2019. This increase was primarily due to our continued focus on expanding existing markets such as Poland, Switzerland, India, Italy and Spain and expansion into new geographies such as Australia and South Africa. The overall increase was offset across the board due to shipment delays in the three months ended March 31, 2019 associated with us changing sterilization companies and sales decreases in certain of our markets. The transition to our new sterilization company is now complete and we do not currently anticipate any future disruptions in fulfilling new orders and sales decreases in certain of our markets.

With respect to regions, the decrease in revenue was primarily attributable to a $127,000 decrease in revenue from sales made in Europe (driven by a $96,000 decline in the sales volume of MGuard Prime EPS for reasons discussed in the paragraph above), offset by a $74,000 increase in revenue of CGuard EPS from sales made in Australia and Africa.

Gross Profit. For the nine months ended September 30, 2019, gross profit (revenue less cost of revenues) decreased by 35.3%, or $271,000, to $497,000, compared to a $768,000 for the same period in 2018. This decrease in gross profit resulted from a $106,000 increase in write-offs predominantly driven by a non-recurring component supply issue, a $92,000 decrease in revenues (as mentioned above), less the related material and labor costs, $69,000 of expenses related to upgrades made to our production facilities and $46,000 of expenses pertaining to annual and new employee training of the production workers, offset by a decrease of $42,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) decreased to 18.4% during the nine months ended September 30, 2019 from 27.6% during the nine months ended September 30, 2018, driven mainly by the write-offs and the increased expenses incurred in connection with the upgrades made to our production facilities and employee trainings incurred during the nine months ended September 30, 2019.

Research and Development Expenses. For the nine months ended September 30, 2019, research and development expenses increased by 170.8%, or $1,534,000, to $2,432,000, from $898,000 during the nine months ended September 30, 2018. This increase resulted primarily from an increase of $881,000 in clinical expenses associated with CGuard EPS, mainly related to IDE application process, a settlement payment of $354,000 made to a former service provider pursuant to a settlement agreement (see Part II, Item 1. "Legal Proceedings" below), an increase of $270,000 in compensation and quality assurance expenses primarily due to expenses incurred to support various development projects and an increase of $29,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the nine months ended September 30, 2019, selling and marketing expenses increased by 6.8%, or $114,000, to $1,791,000, from $1,677,000 during the nine months ended September 30, 2018. This increase resulted from an increase of $71,000 in travel expenses associated with the continued focus on expanding existing and new markets and an increase of $68,000 in promotional expenses, primarily related to operating our social media infrastructure. These increases in selling and marketing expenses were partially offset by a decrease of $25,000 in miscellaneous expenses during the nine months ended September 30, 2019.

General and Administrative Expenses. For the nine months ended September 30, 2019, general and administrative expenses decreased by 0.4%, or $14,000, to $3,584,000, from $3,598,000 during the nine months ended September 30, 2018. This decrease resulted primarily from a decrease of $453,000 in legal expenses, primarily due to reduced legal work required for a litigation with a former service provider (which settled in April 2019) during the nine months ended September 30, 2019, compared to the amount of legal work required for the same litigation during the nine months ended September 30, 2018. This decrease in general and administrative expenses was partially offset by an increase of $329,000 in compensation expenses, mainly due to a salary accrual reversal of approximately $230,000 during the nine months ended September 30, 2018, which did not occur during the nine months ended in September 30, 2019, an increase of approximately $192,000 of share-based compensation-related expenses in the nine months ended September 30, 2019, due to the grants made in the first quarter of 2019 and an increase of $110,000 in miscellaneous expenses.

Financial Expenses (Income). For the nine months ended September 30, 2019, financial expenses increased by 145.8%, or $551,000, to $173,000, from $378,000 of financial income during the nine months ended September 30, 2018. The increase in financial expenses primarily resulted from the $438,000 of financial income related to the revaluation of the embedded derivative of the Series C Preferred Stock recorded during the nine months ended September 30, 2018, which did not occur during the nine months ended in September 30, 2019, and an increase of $117,000 in financial expenses related to changes in exchange rates. These increases in financial expenses were partially offset by a decrease of $4,000 in miscellaneous expenses during the nine months ended September 30, 2019.

Tax Expenses (Income). For the nine months ended September 30, 2019, there was no material change in our tax expenses as compared to the nine months ended September 30, 2018.

Net Loss. Our net loss increased by $2,456,000, or 48.9%, to $7,483,000, for the nine months ended September 30, 2019, from $5,027,000 during the nine months ended September 30, 2018. The increase in net loss resulted primarily from an increase of $1,634,000 in operating expenses, an increase of $551,000 in financial expenses and a decrease of $271,000 in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of September 30, 2019, of $155 million, as well as a net loss of $7,483,000 and negative operating cash flows for the nine months ended September 30, 2019. 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 until the end of May 2020. 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 sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

On March 1, 2018, we closed an underwritten public offering of 20,000 shares of our common stock at a price to the public of $150.00 per share. We received gross proceeds of approximately $3.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, we used $450,000 of the proceeds from the offering to redeem 450 shares of Series D Preferred Stock. As a result of such offering, the conversion price for each of our Series C Preferred Stock and our Series D Preferred Stock was reduced to $150.00 per share.

On April 2, 2018, we closed an underwritten public offering of 57,143 shares of our common stock at a price to the public of $87.50 per share. We received gross proceeds of approximately $5.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, we used $300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to $87.50 per share.

On July 3, 2018, we closed an underwritten public offering of (i) 10,851,417 common units, with each common unit being comprised of one fiftieth share of our common stock, and one Series D Warrant to purchase one fiftieth share of common stock, (ii) 22,481,916 pre-funded units, with each pre-funded unit being comprised of one pre-funded warrant to purchase one fiftieth share of common stock and one Series D Warrant, and (iii) additional Series D Warrants to purchase 100,000 shares of common stock pursuant to the underwriter's option. We received net proceeds from the offering and the exercise of the underwriter's option to purchase additional Series D Warrants to purchase 100,000 shares of common stock of approximately $8.7 million, excluding the proceeds, if any, from the exercise of the Series D Warrants and the pre-funded warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that are payable by us. We used $2,264,269 of the net proceeds of the offering to redeem 306,917 shares of Series C Preferred Stock and 300 shares of Series D Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price of the outstanding shares of the Series B Preferred Stock and the Series C Preferred Stock was reduced to $15.00 per share, effective as of June 29, 2018.

Our outstanding shares of Series B Preferred Stock and Series C Preferred Stock contain anti-dilution provisions that may result in the reduction of the conversion price thereof in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of additional shares of common stock issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock as a result of anti-dilution adjustments will dilute the interests of other security holders and may depress the price of our common stock. Accordingly, we may find it more difficult to raise additional equity capital while any of our Series B Preferred Stock or Series C Preferred Stock is outstanding. As of September 30, 2019, 17,303 shares of Series B Preferred Stock and 36,869 shares of Series C Preferred Stock were outstanding.

During January and February 2018, the placement agent from the public offering that closed in July 2016 exercised its unit purchase option to purchase 13,508 units and received 13,508 shares of Series B Preferred Stock and Series A warrants to purchase 31 shares of common stock. The placement agent subsequently converted its Series B Preferred Stock and received an aggregate of 2,229 shares of common stock. We received an aggregate of $557,205 from the placement agent for the exercise of the unit purchase option.

On April 8, 2019, we closed an underwritten public offering of 486,957 shares of our common stock at a price to the public of $5.00 per share. We received net proceeds of approximately $2.0 million from the offering, after deducting underwriter discounts and commissions and offering expenses payable by us. As a result of such offering, the conversion price for each of our Series B Preferred Stock and Series C Preferred was reduced to $5.00 per share. In connection with this public offering, on April 12, 2019, the underwriter partially exercised its over-allotment option and purchased an additional 12,393 shares of our common stock at a price to the public of $5.00 per share. We received net proceeds of approximately $47,000 from the exercise of the over-allotment option.

On September 24, 2019, we closed an underwritten public offering of (i) 539,000 common units, with each common unit being comprised of one share of our common stock and one Series E Warrant to purchase one share of common stock and (ii) 2,238,777 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 E Warrant. In connection with this public offering, the underwriter partially exercised its over-allotment option and purchased an additional 194,444 Series E Warrants to purchase 194,444 shares of common stock. The offering price to the public was $1.80 per common unit and $1.79 per pre-funded unit. The net proceeds to us from the offering of common units and pre-funded units and the exercise of the underwriter's option to purchase 194,444 additional Series E Warrants to purchase an aggregate of 194,444 shares of common stock was approximately $4.2 million, excluding the proceeds, if any, from the exercise of the Series E Warrants and the pre-funded warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that were payable by us,

Nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

General. At September 30, 2019, we had cash and cash equivalents of $7,154,000, as compared to $9,384,000 as of December 31, 2018. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

For the nine months ended September 30, 2019, net cash used in our operating activities increased by $2,439,000 to $8,242,000, from $5,803,000 during the same period in 2018. The primary reason for the increase in cash used in our operating activities was an increase of payments for third party related expenses and for professional services of $1,665,000 (primarily due to production related payments, payments related to IDE application process and a settlement payment made to a former service provider pursuant to a settlement agreement), an increase of $673,000 in salary and bonus payments from $3,705,000 in the nine months ended September 30, 2018 to $4,378,000 during the same period in 2019 and a decrease of $101,000 in payments received from customers to $2,610,000 during the nine months ended September 30, 2019, from $2,711,000 during the same period in 2018.

Cash used by our investing activities was $318,000 during the nine months ended September 30, 2019 compared to $0 during the nine months ended September 30, 2018 resulting primarily from purchases related to upgrades made to our production facilities and our information technology infrastructure.

Cash provided by financing activities for the nine months ended September 30, 2019 was $6,331,000 compared to $13,351,000 during the same period in 2018. 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. The principal source of the cash provided by financing activities during the nine months ended September 30, 2018, was the funds received from our July 2018 public offering of common stock, pre-funded warrants and warrants, as well as the subsequent exercise of the pre-funded warrants sold in the offering, that resulted in approximately $8,866,000 of aggregate net proceeds, funds received from our April 2018 public offering of common stock that resulted in approximately $4,439,000 of aggregate net proceeds. and the funds received from our March 2018 public offering of common stock that resulted in approximately $3,060,000 of aggregate net proceeds, offset by a redemption of Series C and Series D Preferred Stock from the proceeds of the offering in an aggregate amount of $3,014,000.

As of September 30, 2019, our current assets exceeded our current liabilities by a multiple of 4.1. Current assets decreased by $1,845,000 during the period and current liabilities decreased by $597,000 during the period. As a result, our working capital decreased by $1,248,000 to $7,251,000 as of September 30, 2019.

Off Balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 3 – "Recently Adopted and Issued Accounting Pronouncements" in the accompanying financial statements.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products. For a discussion of these and other risks that relate to our business, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2018, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

Contractual Obligations and Commitments

During the nine months ended September 30, 2019, 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, 2019, 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, 2019.

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, 2019, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation that arises through the normal course of business.

On July 10, 2019, Bosti Trading Ltd., a former distributor in Russia ("Bosti"), filed suit with the Tel Aviv-Jaffa District Court in Israel against InspireMD Ltd., claiming damages for alleged breaches by InspireMD Ltd. under the Distribution Agreement, dated May 26, 2011, between Bosti and InspireMD Ltd., in connection with the voluntary field corrective action of our MGuard Prime EPS we initiated in 2014. Bosti claims that Bosti and its Russian subsidiary returned 1,830 units of MGuard Prime EPS to InspireMD Ltd. upon initiation of the voluntary filed action, and, since the Russian Ministry of Health prohibited distribution of MGuard Prime EPS on August 28, 2014, and did not approve distribution MGuard Prime EPS until September 20, 2016, Bosti was entitled to recover from InspireMD Ltd. €1,830,000 (which is approximately $2 million), the amount Bosti was due to receive from its Russian subsidiary, or alternatively, €1,024,000 (which is approximately $1.1 million), the amount Bosti paid to InspireMD Ltd., for the MGuard Prime EPS returned to InspireMD Ltd. InspireMD Ltd. intends to contest this matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that InspireMD Ltd. will prevail on any claims made against InspireMD Ltd. in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

As of the date of this filing, we are not aware of any other material legal proceedings to which we or any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation or any such proceedings known to be contemplated by governmental authorities other than other than the foregoing suit filed by Bosti.

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

Item 1A. Risk Factors

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with our business previously disclosed in Part I, Item 1A of the Annual Report on Form 10-K for the year ended December 31, 2018, under the heading "Risk Factors." Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Form 10-Q. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-Q.

Risks Related to Our Business

We have a history of net losses and may experience future losses.

We have yet to establish any history of profitable operations. We reported a net loss of $7.2 million for the fiscal year ended December 31, 2018. We had a net loss of approximately $7.5 million during the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $155 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

The report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, the report of Kesselman & Kesselman, our independent registered public accounting firm, with respect to our financial statements for the year ended December 31, 2018, includes an explanatory paragraph as to our potential inability to continue as a going concern. The doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

We will 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 our stockholders' ownership interests.

Without materially curtailing our operations, we estimate that we have sufficient capital to fund operations until the end of May 2020. As such, in order for us to pursue our business objectives, we will need to raise additional capital, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- furthering our efforts to ultimately seek the U.S. Food and Drug Administration approval for commercial sales of CGuard EPS in the United States;
- development of our current and future products, including CGuard EPS enhancements;
- pursuing growth opportunities, including more rapid expansion and funding regional distribution systems;
- making capital improvements to improve our infrastructure;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. The respective certificate of designation for our Series B Preferred Stock and Series C Preferred Stock contains a full ratchet anti-dilution price protection to be triggered upon issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price in effect. See "*Risk Factors—Risks Related to Our Common Stock, Preferred Stock and Warrants—The respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price 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 these shares will dilute the interests of other security holders and may depress the price of our common stock*." Such obligations may make any additional financing difficult to obtain or unavailable to us while any shares of our Series B Preferred Stock or Series C Preferred Stock are outstanding. If we are unable to obtain additional financing on a timely basis, we may have to curtail our development activities and growth plans and/or be forced to sell assets, perhaps on unfavorable terms, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately could be forced to discontinue our operations and liquidate, in which event it is unlikely that stockholders would receive any distribution on their shares. Further, we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition. If we do not have a sufficient number of available shares for any Series B Preferred Stock or Series C Preferred Stock conversions or upon conversion of Series B Preferred Stock or Series C Preferred Stock, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive.

Our products may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation and financial results.

We expect to derive our revenue from sales of our CGuard EPS and MGuard Prime EPS stent products and other products we may develop, such as CGuard EPS with enhancements. If we fail to generate revenue from these sources, our results of operations and the value of our business would be materially and adversely affected.

We expect our revenue to be generated from sales of our CGuard EPS and MGuard Prime EPS stent products and other products we may develop. Future sales of CGuard EPS will be subject to the receipt of regulatory approvals and commercial and market uncertainties that may be outside our control. In addition, sales of MGuard Prime EPS have been hampered by weakened demand for bare metal stents, which may never improve, and we may not be successful in developing a drug-eluting stent product. In addition, there may be insufficient demand for other products we are seeking to develop, such as CGuard EPS with enhancements. If we fail to generate expected revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Similarly, the ability to protect our trademark rights might be important to prevent third party counterfeiters from selling poor quality goods using our designated trademarks/trade names. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patent applications and patents may not provide us with commercially meaningful protection for our products or may not afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us now or in the future may not be valid or enforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States.

In addition, statutory differences in patentable subject matter depending on the jurisdiction may limit the protection we obtain on certain of the technologies we develop. The laws of some foreign jurisdictions do not offer the same protection to, or may make it more difficult to effect the enforcement of, proprietary rights as in the United States, risk that may be exacerbated if we move our manufacturing to certain countries in Asia. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

We may initiate litigation to enforce our patent rights on any patents issued on pending patent applications, which may prompt adversaries in such litigation to challenge the validity, scope, ownership, or enforceability of our patents. Third parties can sometimes bring challenges against a patent holder to resolve these issues, as well. If a court decides that any such patents are not valid, not enforceable, not wholly owned by us, or are of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patent rights are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor do they provide us with freedom to operate unimpeded by the patent and other intellectual property rights of others that may cover our products. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

If our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our CGuard EPS and MGuard Prime EPS products at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our CGuard EPS or MGuard Prime EPS stents until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our CGuard EPS or MGuard Prime EPS stents to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

Additionally, any damage to or destruction of our Tel Aviv facility or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce either CGuard EPS or MGuard Prime EPS stents.

Finally, the production of our stents must occur in a highly controlled, clean environment to minimize particles and other yield and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and results of operations.

Before we may conduct clinical trials for CGuard EPS in the United States, we must obtain the U.S. Food and Drug Administration's approval of our IDE application and meet a number of other regulatory requirements, and, if we obtain IDE approval and meet all other applicable requirements, all clinical trials must be conducted in compliance with the U.S. Food and Drug Administration's IDE regulations. Failure to complete the applicable prerequisites before beginning clinical trials and/or to maintain compliance with IDE regulations thereafter could have a material adverse effect on our business.

Clinical trials involve use of a medical device candidate (or drug, biological, or other product candidate, as applicable) on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, including the requirement that all research subjects provide informed consent for their participation in the clinical study. The U.S. Food and Drug Administration classifies medical device candidates into "significant risk" and "non-significant risk" devices. Significant risk devices present a potential for serious risk to the health, safety, or welfare of a subject. Examples may include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. If a medical device candidate presents a significant risk, an IDE application must be submitted and approved prior to commencing any human clinical trials in the United States in connection with such device. The U.S. Food and Drug Administration may approve, conditionally approve, or deny an IDE or it may require further information and, thus, delay approval.

IDE applications may be denied for a number of reasons. For example, commonly cited deficiencies in U.S. Food and Drug Administration disapproval letters include, but are not limited to, the following:

- Inadequate report of prior investigations due to:
    - Limited rationale and/or description of lab or animal studies;
    - No scientific justification for the number of animals selected in report of animal studies;
    - Failure to identify relevant information in literature research summary; or
    - Omission of adverse information in reports of prior publications;
- Inadequate investigational plan due to:
    - failure to clearly develop or define study objectives;
    - inadequate description of the protocol;
    - failure to identify all risks;
    - failure to develop proper monitoring procedures; or
    - inadequate informed consent documents;
- Inadequate characterization or description of the device and its operation due to inadequate or omitted:
    - Design/engineering drawing of device;
    - Rationale for device design;
    - Device and performance specifications;
    - Description of materials (including biocompatibility information); or
    - Description of function.

CGuard EPS is a significant risk device under the U.S. Food and Drug Administration's definition. Accordingly, to conduct clinical trials with human subjects in the U.S., we must obtain IDE approval from the U.S. Food and Drug Administration. On July 26, 2019, we submitted an original IDE application for CGuard EPS. In connection with such application, on August 23, 2019, we received a request for additional information from the U.S. Food and Drug Administration in support of our application. We intend to continue to work closely with the U.S. Food and Drug Administration to resolve these additional requests. Following resolution of all comments from the U.S. Food and Drug Administration, we plan to submit a formal response for CGuard EPS. There is no guarantee that we will obtain IDE approval from the U.S. Food and Drug Administration for CGuard EPS or any other current or future product candidate we may develop.

In addition to IDE approval, we must apply for and obtain IRB approval of the proposed CGuard EPS clinical study in connection with each clinical site before commencing any study activities. A written protocol with predefined end points, an appropriate sample size, and pre-determined patient inclusion and exclusion criteria, is also required before we may initiate or conduct the CGuard EPS trial. If we obtain IDE approval, IRB approval, and meet all of the other applicable requirements that must be met before beginning clinical trials in the United States, we will, then, be able to lawfully initiate the clinical investigation of the safety and effectiveness of CGuard EPS in the United States.

Importantly, the CGuard EPS clinical trial, if applicable, and any others that we may conduct in the future, must be conducted in accordance with the U.S. Food and Drug Administration's IDE regulations, which, among other things, establish requirements for investigational device labeling, prohibit pre-approval promotion of a device candidate, and specify recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators.

We may not be able to obtain U.S. Food and Drug Administration and/or IRB approval to undertake clinical trials in the United States for CGuard EPS or any new devices we intend to market in the United States in the future. If we do obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

Relatedly, certainty that clinical trials will meet desired endpoints, produce meaningful or useful data, and be free of unexpected adverse effects, or that the U.S. Food and Drug Administration will accept the validity of foreign clinical study data, as applicable, cannot be guaranteed, and such uncertainty could preclude or delay regulatory approvals and commercialization, resulting in significant financial costs and reduced revenue. Moreover, the timing of the commencement, continuation, and completion of any future clinical trial may be subject to significant delays attributable to various causes, including, but not limited to, scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to meet regulatory and/or IRB requirements to conduct a clinical trial at a one or more prospective sites, and shortages of supply in the investigational device.

Though necessary to pursue U.S. Food and Drug Administration premarket approval, pre-clinical and clinical trials are inherently lengthy and expensive and subject to any number of regulatory and/or clinical difficulties that can cause further delays, additional costs, and/or rejection by the U.S. Food and Drug Administration, and any such delay, added cost, or failure in connection with any future clinical trials could prevent us from commercializing our MicroNet products in the United States, which would materially and adversely affect our results of operations and the value of our business.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including, if we seek in the future to sell our products in the United States, the U.S. Food and Drug Administration. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. They require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. In some trials, a greater number of patients and a longer follow-up period may be required. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our existing products and those under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials. In addition, market demand may change for products being tested due to the length of time needed to complete requisite clinical trials.

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, among other standard-of-care considerations, that the use of our stents provides a safe and effective alternative to other existing treatments for coronary artery disease and carotid artery disease.

We believe that physicians will not widely adopt our products unless they determine, based on experience, long-term clinical data, published peer reviewed journal articles and payor coverage policies, among other factors, that the use of our products provide a safe and effective alternative to other existing treatments for the conditions we are seeking to address.

If we fail to demonstrate safety and efficacy that is at least comparable to existing and future therapies available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Clinical trials conducted with our products may involve procedures performed by physicians who are technically proficient and are high-volume stent users of such products. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our products will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

Physicians currently consider drug-eluting stents to be the industry standard for treatment of coronary artery disease. MGuard Prime EPS, our current coronary product, is not drug-eluting, and this may adversely affect our business.

Our ability to attract customers depends to a large extent on our ability to provide goods that meet the customers' and the market's demands and expectations. If we do not have a product that is expected by the market, we may lose customers. The market demand has shifted away from bare metal stents in favor of drug-eluting stents for coronary artery disease. Our MGuard Prime EPS is a bare-metal stent product and has experienced no growth in sales over the past three years. Such sales may never grow and we do not currently have the resources to develop a drug-eluting stent product. Our failure to provide industry standard devices could adversely affect our business, financial condition and results of operations.

We have only limited experience in regulatory affairs, which may affect our ability or the time required to navigate complex regulatory requirements and obtain necessary regulatory approvals, if such approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Because long-term success measures have not been completely validated for our products, especially CGuard EPS, regulatory agencies may take a significant amount of time in evaluating product approval applications. Treatments may exhibit a favorable measure using one metric and an unfavorable measure using another metric. Any change in accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only four employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. There can be no assurance that such approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us. Furthermore, there can be no assurance that all necessary regulatory approvals will be obtained for the manufacture, marketing and sale in any market of any new product developed or that any potential licensee will develop using our licensed technology.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any regulatory approvals that we receive for our products will require surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. In addition, if a regulatory authority approves our products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements.

Moreover, if we obtain regulatory approval for any of our products, we will only be permitted to market our products for the indication approved by the regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products. In addition, later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The U.S. Food and Drug Administration also requires that our sales and marketing efforts, as well as promotions, be consistent with various laws and regulations. Approved medical device promotions must be consistent with and not contrary to labeling, balanced, truthful and not false or misleading, adequately substantiated (when required), and include adequate directions for use. In addition to the requirements applicable to approved products, we may also be subject to enforcement action in connection with any promotion of an investigational new device. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new device is safe or effective for the purposes for which it is under investigation or otherwise promote the device.

If the U.S. Food and Drug Administration investigates our marketing and promotional materials or other communications and finds that any of our investigational devices, or future commercial products, if any, are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to the enforcement actions listed above, among others. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable device promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any devices that may be approved for marketing in the U.S. in the future.

The applicable regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We are, or may be, subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there are laws and regulations specific to the healthcare industry which may affect all aspects of our business, including development, testing, marketing, sales, pricing, and reimbursement. Additionally, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal healthcare programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

We may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation, ordering and utilization of any products for which we obtain regulatory approval. If we obtain U.S. Food & Drug Administration approval for any of our products and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our potential sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

● federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which may be pursued through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

● federal criminal statutes created through the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

● the federal transparency requirements under The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, enacted into law in the United States in March 2010 (known collectively as the "Affordable Care Act"), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

● state and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. Several states impose marketing restrictions or require medical device companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the False Claims Act as well, as under the false claims laws of several states.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any such actions instituted against us could have a significant adverse impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business. In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of our employees, agents, or the physicians or other providers or entities with whom we expect to do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events could adversely affect our ability to operate our business and our results of operations.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products in such jurisdictions.

We market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from the appropriate governing body in each applicable country. The approval processes vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE mark or U.S. Food and Drug Administration approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE mark or U.S. Food and Drug Administration approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE mark approval or any future U.S. Food and Drug Administration approval does not ensure approval by regulatory authorities in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in certain markets.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our current products and products under development. We face intense competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Abbott Laboratories, Boston Scientific Corporation, Medtronic, Inc., and Johnson and Johnson, Gore Medical and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent, respectively. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

We may become subject to claims by much larger and better capitalized competitors enforcing their intellectual property rights against us or seeking to invalidate our intellectual property or our rights thereto.

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our stents based on one or more of these patents. These companies also own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange that might be alleged to cover one or more of our products. A number of stent-related patents are owned by very large and well-capitalized companies that are active participants in the stent market. In addition, it is possible that a lawsuit asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us of which we are not aware. As the number of competitors in the stent market grows and as the geographies in which we commercially market grow in number and scope, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

Our competitors have maintained their position in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All of the major companies in the stent and related markets, including Boston Scientific Corporation, C.R. Bard, Inc., W.L. Gore & Associates, Inc. and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The stent and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in the stent and related markets. Accordingly, many of these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from commercializing our products. Such litigation or claims would divert attention and resources away from the development and/or commercialization of our products and product development, and could result in an adverse court judgment that would make it impossible or impractical to sell our products in one or more territories.

If we fail to maintain or establish satisfactory agreements or arrangements with suppliers or if we experience an interruption of the supply of materials from suppliers, we may not be able to obtain materials that are necessary to develop our products.

We depend on outside suppliers for certain raw materials. These raw materials or components may not always be available at our standards or on acceptable terms, if at all, and we may be unable to locate alternative suppliers or produce necessary materials or components on our own.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. For CGuard EPS and MGuard Prime EPS, we depend on MeKo Laserstrahl-Materialbearbeitung for the laser cutting of the stent, Natec Medical Ltd. for the supply of catheters, and Biogeneral Inc. for the fiber. We may have difficulty obtaining similar components from other suppliers that are acceptable to the U.S. Food and Drug Administration or foreign regulatory authorities if it becomes necessary.

If we have to switch to a replacement supplier, we will face additional regulatory delays and the interruption of the manufacture and delivery of our stents for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the U.S. Food and Drug Administration or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

We may be exposed to product liability claims and insurance may not be sufficient to cover these claims.

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in the market or clinical trials. We may also be exposed to product liability claims based on the sale of any products under development following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our business. Insurance coverage is becoming increasingly expensive and we may not be able to maintain current coverage, or expand our insurance coverage to include future clinical trials or the sale of new products or existing products in new territories, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

We face risks associated with litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, fraud and abuse, personal injury and product liability matters.

We are subject to a lawsuit filed by Bosti in July 2019, seeking €1,830,000 (which is approximately $2 million), the amount Bosti was due to receive from its Russian subsidiary, or alternatively, €1,024,000 (which is approximately $1.1 million), the amount Bosti paid to InspireMD Ltd., for the MGuard Prime EPS returned to InspireMD Ltd. in connection with the voluntary field corrective action of our MGuard Prime EPS we initiated in 2014. See "*Part II, Item 1 — Legal Proceedings*". While we believe that the claims in this suit are without merit, due to the uncertainties of litigation, however, we can give no assurance that we will prevail on the claims made against us in such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results. Adverse outcomes in some or all of these claims may result in significant monetary damages that could adversely affect our ability to conduct our business.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists and laboratory and field personnel could adversely affect our business.

We depend on the skills, experience and performance of our senior management and research personnel. The efforts of each of these persons will be critical to us as we continue to further develop our products, increase sales and broaden our product offerings. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the intense competition among medical device, biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced management, scientists, researchers, sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our operations, and our results of operations may be materially and adversely affected.

We are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations.

We operate globally and develop and market products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. International sales and operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and
- general economic and political conditions in these foreign markets.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

Even if one or more of our products are approved by the U.S. Food and Drug Administration, we may fail to obtain an adequate level of reimbursement for our products by third party payors, such that there may be no commercially viable markets for our products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. The efficacy, safety, performance and cost-effectiveness of our products and of any competing products are factors that may impact the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the U.S. and in international markets. There is increasing pressure by governments worldwide to contain healthcare costs by limiting both the coverage and the level of reimbursement for therapeutic products and by refusing, in some cases, to provide any coverage for products that have not been approved by the relevant regulatory agency. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products and limit our ability to sell our products on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired, and future revenues, if any, would be adversely affected.

In the United States and European Union, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations.

The Affordable Care Act, signed into law in the United States in March 2010, contains certain provisions which are not yet fully implemented and for which it is unclear what the full impact will be from the legislation. The legislation levies a 2.3% excise tax on all sales of any U.S. medical device listed with the U.S. Food and Drug Administration under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807 on or after January 1, 2013, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. Effective January 1, 2016, the excise tax was suspended until the end of 2017, and in January 2018, another temporary two-year suspension of the tax was passed, extending the suspension to December 31, 2019. If we obtain approval to commence sales of any of our applicable devices in the United States, this tax may materially and adversely affect our business and results of operations.

The legislation also focuses on a number of provisions aimed at improving quality, broadening access to health insurance, enhancing remedies for fraud and abuse, adding transparency requirements, and decreasing healthcare costs, among others. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies, pricing and the market for our products, and the healthcare industry in general. The Affordable Care Act includes provisions affecting the Medicare program, such as value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Judicial challenges, as well as legislative initiatives to modify, limit, or repeal the Affordable Care Act have been asserted against the Affordable Care Act since its enactment and continue to evolve. While early challenges were largely unsuccessful, there have been renewed efforts to repeal and/or replace the Affordable Care Act following the 2017 changes in the U.S. presidential administration and U.S. Congress. Due to such efforts, certain elements of the Affordable Care Act have been invalidated or suspended, which has, in turn, led to additional challenges against the law as a whole. For example, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax imposed by the Affordable Care Act's "individual mandate." As a result, at least one federal court has held that the entire Affordable Care Act must be invalidated. However, the ruling in that case, *Texas, et al, v. United States of America, et al.*, (N.D. Texas), has been stayed by the ruling judge pending appeal. Additionally, an Executive Order signed by the U.S. President directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of provisions of the Affordable Care Act that would impose a fiscal or regulatory burden on individuals and certain entities to the maximum extent permitted by law.

We cannot predict the impact that such actions against the Affordable Care Act will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

In May 2017, the European parliament and the council of the European Union approved a new Medical Device Regulation (EU) 2017/745 which has replaced the existing medical device directives (93/42/EEC). The new regulations will come into full application in May 2020. The new Medical Device Regulation imposes stricter requirements on medical device manufacturers and strengthens the supervising competences of the competent authorities of European Union member states, the notified bodies and the authorized representatives. As a result, the new legislation can prevent or delay the CE marking and certifications of our products under development or impact our ability to modify our currently CE marked products on a timely basis. If we fail to comply with the modified regulation and requirements it can adversely affect our business, operating results and prospects.

Risks Related to Operating in Israel

We anticipate being subject to fluctuations in currency exchange rates because we expect a substantial portion of our revenues will be generated in Euros and U.S. dollars, while a significant portion of our expenses will be incurred in New Israeli Shekels.

We expect a substantial portion of our revenues will be generated in U.S. dollars and Euros, while a significant portion of our expenses, principally salaries and related personnel expenses, is paid in New Israeli Shekels, or NIS. As a result, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the NIS in relation to the Euro or the U.S. dollar, or that the timing of this devaluation will lag behind inflation in Israel. Because inflation has the effect of increasing the dollar and Euro costs of our operations, it would therefore have an adverse effect on our dollar-measured results of operations. The value of the NIS, against the Euro, the U.S. dollar, and other currencies may fluctuate and is affected by, among other things, changes in Israel's political and economic conditions. Any significant revaluation of the NIS may materially and adversely affect our cash flows, revenues and financial condition. Fluctuations in the NIS exchange rate, or even the appearance of instability in such exchange rate, could adversely affect our ability to operate our business.

If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.

Our executive office, sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A state of hostility, varying in degree and intensity, has caused security and economic problems in Israel. Although Israel has entered into peace treaties with Egypt and Jordan, and various agreements with the Palestinian Authority, there has been a marked increase in violence, civil unrest and hostility, including armed clashes, between the State of Israel and the Palestinians since September 2000. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created heightened unrest and uncertainty in the region. In mid-2006, Israel engaged in an armed conflict with Hezbollah, a Shiite Islamist militia group based in Lebanon, and in June 2007, there was an escalation in violence in the Gaza Strip. From December 2008 through January 2009 and again in November and December 2012, Israel engaged in an armed conflict with Hamas, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In July and August 2014, an armed conflict took place between Israel and Hamas, and since September 2015, there has been an increase in sporadic terror incidents conducted by individuals not necessarily associated with terror organizations. Political uprisings and social unrest in Syria are affecting its political stability, which has led to the deterioration of the political relationship between Syria and Israel and have raised new concerns regarding security in the region and the potential for armed conflict. Similar civil unrest and political turbulence is currently ongoing in many countries in the region. The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several countries restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

In addition, many of our officers or key employees may be called to active duty at any time under emergency circumstances for extended periods of time. See "— Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service."

Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service.

Many of our officers and employees reside in Israel and may be required to perform annual military reserve duty. Currently, all male adult citizens and permanent residents of Israel under the age of 40 (or older, depending on their position with the Israeli Defense Forces reserves), unless exempt, are obligated to perform military reserve duty annually and are subject to being called to active duty at any time under emergency circumstances. Our operations could be disrupted by the absence for a significant period of one or more of our key officers and employees due to military service. Any such disruption could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to enforce covenants not-to-compete under current Israeli law.

We have non-competition agreements with most of our employees, many of which are governed by Israeli law. These agreements generally prohibit our employees from competing with us or working for our competitors for a specified period following termination of their employment. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for relatively brief periods of time in restricted geographical areas and only when the employee has unique value specific to that employer's business and not just regarding the professional development of the employee. Any such inability to enforce non-compete covenants may cause us to lose any competitive advantage resulting from advantages provided to us by such confidential information.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our Israeli employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Israeli Patent Law"), inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Israeli Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "C&R Committee"), a body constituted under the Israeli Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. The C&R Committee (decisions of which have been upheld by the Israeli Supreme Court) has held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. We generally enter into intellectual property assignment agreements with our employees pursuant to which such employees assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

It may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers.

The majority of our assets other than cash are located outside the U.S. In addition, certain of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the U.S. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

The tax benefits that are currently available to us under Israeli law require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to pay increased taxes and would likely be denied these benefits in the future.

InspireMD Ltd. has been granted a "Beneficiary Enterprise" status by the Investment Center in the Israeli Ministry of Industry Trade and Labor, and we are therefore eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The main benefit is a two-year exemption from corporate tax, commencing when we begin to generate net income derived from the beneficiary activities in facilities located in Israel, and a reduced corporate tax rate for an additional five to eight years, depending on the level of foreign investment in each year. In addition, under the January 1, 2011 amendment to the Israeli Law for the Encouragement of Capital Investments, 1959, a uniform corporate tax rate of 16% applies to all qualifying income of "Preferred Enterprise," which we may be able to apply as an alternative tax benefit.

The tax benefits available to a Beneficiary Enterprise or a Preferred Enterprise are dependent upon the fulfillment of conditions stipulated under the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which include, among other things, maintaining our manufacturing facilities in Israel. If we fail to comply with these conditions, in whole or in part, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. If we are no longer eligible for these tax benefits, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2018 is 23% and in 2019 is 23% of taxable income. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

In addition to losing eligibility for tax benefits currently available to us under Israeli law, if we do not maintain our manufacturing facilities in Israel, we will not be able to realize certain tax credits and deferred tax assets, if any, including any net operating losses to offset against future profits.

The tax benefits available to Beneficiary Enterprises may be reduced or eliminated in the future. This would likely increase our tax liability.

The Israeli government may reduce or eliminate in the future tax benefits available to Beneficiary Enterprises and Preferred Enterprises. Our Beneficiary Enterprise status and the resulting tax benefits may not continue in the future at their current levels or at any level. The tax benefit period is twelve years from the year of election, which means that after a year of election, the two-year exemption and eight years of reduced tax rate can only be used within the next twelve years. The Company elected the year 2007, as a year of election and 2011 as an additional year of election. The 2011 amendment regarding Preferred Enterprise may not be applicable to us or may not fully compensate us for the change. The termination or reduction of these tax benefits would likely increase our tax liability. The amount, if any, by which our tax liability would increase will depend upon the rate of any tax increase, the amount of any tax benefit reduction, and the amount of any taxable income that we may earn in the future.

Risks Related to Our Common Stock, Preferred Stock and Warrants

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;
- loss of any strategic relationship;
- 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. These market fluctuations may also significantly affect the market prices of our common stock and our publicly traded warrants.

Our common stock could be delisted from the NYSE American if we fail to regain compliance with the NYSE American's stockholders' equity continued listing standards. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the NYSE American.

On August 7, 2019, we received a notice indicating that we do not meet certain of the NYSE American's continued listing standards as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of June 30, 2019, and had net losses in our five most recent fiscal years ended December 31, 2018. As a result, we had become subject to the procedures and requirements of Section 1009 of the Company Guide. On August 25, 2019, we submitted a plan of compliance to NYSE Regulation, addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020, which was accepted by NYSE American on October 11, 2019.

If we do not regain compliance by August 7, 2020, or fail to remain in compliance as of August 7, 2020, or anytime thereafter, with Section 1003(a)(iii) of the Company Guide, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE American will initiate delisting proceedings. There is no assurance that we will be able to regain compliance with Section 1003(a)(iii) of the Company Guide as of August 7, 2020. Even if the net proceeds from our capital raises provide us with sufficient stockholders' equity to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020, we will be subject to ongoing review for compliance with NYSE American requirements, and there can be no assurance that we will continue to remain in compliance with this standard.

Delisting from NYSE American would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

A low trading price could lead the NYSE American to take actions toward delisting our common stock, including immediately suspending trading in our common stock.

On January 7, 2019, we received notification from the NYSE American that our shares of common stock have been selling for a low price per share for a substantial period of time. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American could take action to delist our common stock in the event that our common stock trades at levels viewed as abnormally low for a substantial period of time. NYSE American had advised us that if our common stock trades below $0.20 on a 30 trading day average, then it will be considered non-compliant with NYSE American's low selling price requirement. On March 29, 2019, we effected a 1-for-50 reverse stock split of our common stock.

Although on July 8, 2019, we received notice from NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide, in accordance with Section 1009(h) of the Company Guide, if we are again determined to be below any of the continued listing standards within 12 months of July 8, 2019, NYSE American will examine the relationship between the two incidents of noncompliance and re-evaluate our method of financial recovery from the first incident. NYSE Regulation will then take the appropriate action, which depending on the circumstances, may include truncating the compliance procedures described in section 1009 of the Company Guide or immediately initiating delisting proceedings. If in the future we fall below the continued listing criterion of a minimum average share price of $0.20 over a 30-day trading period, our common stock will be subject to immediate review by NYSE American. There can be no assurance that the market price of our common stock will remain above the levels viewed as abnormally low for a substantial period of time. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock to fall below the levels viewed as low selling price for a substantial period of time and lead the NYSE American to immediately suspend trading in our common stock.

In addition, the NYSE American has advised us that its policy is to immediately suspend trading in shares of, and commence delisting procedures with respect to, a listed company if the market price of its shares falls below $0.06 per share at any time during the trading day.

The respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price 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 these shares will dilute the interests of other security holders and may depress the price of our common stock.

The respective certificate of designation for our Series B Preferred Stock and Series C Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the applicable conversion price, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings. In accordance with this anti-dilution price protection, because the effective common stock purchase price in each of the March 2018 public offering, the April 2018 public offering, the July 2018 public offering, the April 2019 and the September 2019 public offering was below the then current Series B Preferred Stock and the Series C Preferred Stock conversion price, we reduced the Series B Preferred Stock and the Series C Preferred Stock conversion price upon pricing of each such public offering. As a result of these obligations, if in the future, while any of our Series B Preferred Stock or Series C Preferred Stock is outstanding, we issue securities at an effective common stock purchase price of less than the applicable conversion price of our Series B Preferred Stock or Series C Preferred Stock, as then in effect, we will be required, subject to certain limitations and adjustments as provided in the respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock, to reduce the relevant conversion price. This reduction in the conversion prices will result in a greater number of shares of common stock being issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock for no additional consideration, causing greater dilution to our stockholders and investors in our offerings. Furthermore, as there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion. As such, it is possible that we may not have a sufficient number of available shares to satisfy the conversion of the Series B Preferred Stock or the Series C Preferred Stock if we enter into a future transaction that reduces the applicable conversion price. The foregoing features will increase the number of shares of common stock issuable upon conversion, assuming that the effective offering price of our common stock in a subsequent financing is lower than the conversion price of these securities then in effect, of the Series B Preferred Stock or Series C Preferred Stock for no additional consideration, and will result in a greater dilutive effect on our stockholders.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our publicly traded securities to decline.

Sales of a significant number of shares of our common stock or our warrants in the public market could harm the market prices of our common stock or warrants and make it more difficult for us to raise funds through future offerings of common stock or warrants. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock or our publicly traded warrants in the public market. In addition, we will be required to issue additional shares of common stock to the holders of our Series B Preferred Stock upon conversion of shares of our Series B Preferred Stock and the payment of the dividends thereunder in common stock and to the holders of our Series C Preferred Stock upon conversion of such shares of our Series C Preferred Stock, as a result of the full ratchet anti-dilution price protection in the respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock, if the effective common stock purchase price in a subsequent offering is less than the respective then current conversion price of the Series B Preferred Stock or the Series C Preferred Stock, which in turn will increase the number of shares of common stock available for sale. See "*Risk Factors — Risks Related to Our Common Stock, Preferred Stock and Warrants— The respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price 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 these shares will dilute the interests of other security holders and may depress the price of our common stock*."

In addition, the fact that our stockholders, option holders and warrant holders can sell substantial amounts of our common stock or our publicly traded warrants in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

We do not expect to pay dividends in the future. As a result, any return on investment may be limited to the value of our common stock.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investment in our common stock will only occur if our stock price appreciates.

The Series B Preferred Stock provides for the payment of dividends in cash or in shares of our common stock, and we may not be permitted to pay such dividends in cash, which will require us to have shares of common stock available to pay the dividends.

Each share of the Series B Preferred Stock is entitled to receive cumulative dividends at the rate per share of 15% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Preferred Stock. The dividends are payable, at our discretion, in cash, out of any funds legally available for such purpose, or in pay-in-kind shares of common stock calculated based on the conversion price, subject to adjustment as provided in the certificate of designation for the Series B Preferred Stock. The conversion price is subject to reduction if in the future we issue securities for less than the conversion price of our Series B Preferred Stock, as then in effect. As there is no floor price on the conversion price, we cannot determine the total number of shares issuable upon conversion or in connection with the dividend. It is possible that we will not have a sufficient number of available shares to pay the dividend in common stock, which would require the payment of the dividend in cash. We will not be permitted to pay the dividend in cash unless we are legally permitted to do so under Delaware law, which requires cash to be available from surplus or net profits, which may not be available at the time payment is due. In light of our recurring losses and negative cash flows from operating activities, we do not expect to have cash available to pay the dividends on our Series B Preferred Stock or to be permitted to make such payments under Delaware law, and will be relying on having available shares of common stock to pay such dividends, which will result in dilution to our shareholders. If we do not have such available shares, we may not be able to satisfy our dividend obligations.

There is no public market for our preferred stock.

There is no established trading market for our preferred stock. A trading market for our preferred stock is not expected to develop, and even if a market develops for our preferred stock, it may not provide meaningful liquidity. The absence of a trading market or liquidity for our preferred stock may adversely affect their value.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us and adversely affect how our stock trades. This could in turn negatively affect our ability to access equity markets for capital.

Delaware law and our corporate charter and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

We have a staggered board of directors, which could impede an attempt to acquire us or remove our management.

Our board of directors is divided into three classes, each of which serves for a staggered term of three years. This division of our board of directors could have the effect of impeding an attempt to take over our company or change or remove management, since only one class will be elected annually. Thus, only approximately one-third of the existing board of directors could be replaced at any election of directors.

As a former shell company, resales of shares of our restricted common stock in reliance on Rule 144 of the Securities Act are subject to the requirements of Rule 144(i).

We previously were a "shell company" and, as such, sales of our securities pursuant to Rule 144 under the Securities Act of 1933, as amended, cannot be made unless, among other things, at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 as amended, as applicable, during the preceding 12 months, other than Form 8-K reports. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, restrictive legends on certificates for shares of our common stock cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act of 1933, as amended. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we issue will have limited liquidity unless we continue to comply with such requirements.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Aspects of the tax treatment of the securities may be uncertain.

The tax treatment of our preferred stock and our warrants is uncertain and may vary depending upon whether you are an individual or a legal entity and whether or not you are domiciled in the United States. In the event you are a non-U.S. investor, you should consult your tax advisors as to the consequences, under the tax laws of the country where you are resident for tax purposes, of acquiring, holding and disposing of our preferred stock and our warrants.

Item 5. Other Information

Not applicable

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	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)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.5 to the Quarterly Report on Form 10-Q filed on August 9, 2016)

3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)
3.8	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)
3.9	Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 4, 2017)
3.10	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)
3.11	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 22, 2017)
3.12	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)
3.13	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 1, 2018)
3.14	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 3, 2018)
3.15	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 5, 2018)
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	Form of Series E Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.3	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements

* Filed or furnished herewith.

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 12, 2019

By: */s/ James Barry, Ph.D.*
Name: James Barry, Ph.D
Title: President and Chief Executive Officer

Date: November 12, 2019

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer, Secretary and Treasurer

EXHIBIT 31.1

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

I, James Barry, 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 12, 2019

/s/ James Barry
James Barry, Ph.D.
Chief Executive Officer

EXHIBIT 31.2

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 12, 2019

/s/ Craig Shore
Craig Shore
Chief Financial Officer

Exhibit 32.1

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, 2019 of InspireMD, Inc. (the "Company"). I, James Barry, 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 12, 2019

By: */s/ James Barry*
Name: James Barry, Ph.D.
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.

Exhibit 32.2

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, 2019, 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 12, 2019

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.