

INSPIREMD, INC.

FORM 10-Q (Quarterly Report)

Filed 08/09/21 for the Period Ending 06/30/21

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

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended: **June 30, 2021**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-35731**

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

26-2123838

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

4 Menorat Hamaor St.

Tel Aviv, Israel 6744832

(Address of principal executive offices)
(Zip Code)

(888) 776-6204

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

Emerging growth company

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

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

Yes No

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	NSPR	Nasdaq Capital Market
Series B Warrants, exercisable for one share of Common Stock	NSPRZ	Nasdaq Capital Market

The number of shares of the registrant's common stock, \$0.0001 par value, outstanding as of August 6, 2021: 7,913,756



TABLE OF CONTENTS

	Page
PART I	
Item 1. Financial Statements	F-1
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	3
Item 3. Quantitative and Qualitative Disclosures About Market Risk	11
Item 4. Controls and Procedures	11
PART II	
Item 1. Legal Proceedings	12
Item 1A. Risk Factors	12
Item 5. Other Information	13
Item 6. Exhibits	13

INSPIREMD, INC.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED JUNE 30, 2021

TABLE OF CONTENTS

	<u>Page</u>
CONSOLIDATED FINANCIAL STATEMENTS:	
Consolidated Balance Sheets	F-2 - F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Changes in Equity	F-5 - F-8
Consolidated Statements of Cash Flows	F-9
Notes to the Consolidated Financial Statements	F-10 - F-14

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

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 41,419	\$ 12,645
Accounts receivable:		
Trade, net	962	476
Other	136	146
Prepaid expenses	63	334
Inventory	1,342	1,415
Receivable for sale of shares	-	323
TOTAL CURRENT ASSETS	43,922	15,339
NON-CURRENT ASSETS:		
Property, plant and equipment, net	443	448
Operating lease right of use assets	1,251	1,265
Fund in respect of employee rights upon retirement	759	725
TOTAL NON-CURRENT ASSETS	2,453	2,438
TOTAL ASSETS	\$ 46,375	\$ 17,777

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

	June 30, 2021	December 31, 2020
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	739	236
Other	2,940	3,469
TOTAL CURRENT LIABILITIES	3,679	3,705
LONG-TERM LIABILITIES-		
Operating lease liabilities	904	999
Liability for employees' rights upon retirement	962	910
TOTAL LONG-TERM LIABILITIES	1,866	1,909
TOTAL LIABILITIES	5,545	5,614
EQUITY:		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at June 30, 2021 and December 31, 2020; 7,914,339 and 3,284,322 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1	*
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at June 30, 2021 and December 31, 2020; 0 and 17,303 shares issued and outstanding at June 30, 2021 and December 31, 2020		*
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at June 30, 2021 and December 31, 2020; 1,718 and 2,343 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	*	*
Additional paid-in capital	215,755	180,339
Accumulated deficit	(174,926)	(168,176)
Total equity	40,830	12,163
Total liabilities and equity	\$ 46,375	\$ 17,777

* Represents an amount less than \$1 thousand

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

INSPIREMD, INC.
(Unaudited)
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
REVENUES	\$ 1,038	\$ 313	\$ 2,044	\$ 1,347
COST OF REVENUES	776	433	1,676	1,172
GROSS PROFIT (LOSS)	<u>262</u>	<u>(120)</u>	<u>368</u>	<u>175</u>
OPERATING EXPENSES:				
Research and development	1,290	444	2,129	967
Selling and marketing	636	377	1,344	1,001
General and administrative	1,776	1,505	3,649	2,674
Total operating expenses	<u>3,702</u>	<u>2,326</u>	<u>7,122</u>	<u>4,642</u>
LOSS FROM OPERATIONS	<u>(3,440)</u>	<u>(2,446)</u>	<u>(6,754)</u>	<u>(4,467)</u>
FINANCIAL INCOME (EXPENSES), net:	<u>(67)</u>	<u>(34)</u>	<u>4</u>	<u>9</u>
LOSS BEFORE TAX EXPENSES	<u>(3,507)</u>	<u>(2,480)</u>	<u>(6,750)</u>	<u>(4,458)</u>
TAX EXPENSES	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
NET LOSS	<u>\$ (3,507)</u>	<u>\$ (2,480)</u>	<u>\$ (6,750)</u>	<u>\$ (4,458)</u>
NET LOSS PER SHARE - basic and diluted	<u>\$ (0.46)</u>	<u>\$ (2.93)</u>	<u>\$ (0.98)</u>	<u>\$ (7.73)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	<u>7,704,707</u>	<u>845,451</u>	<u>6,918,090</u>	<u>576,827</u>

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

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

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2020	261,075	*	17,303	*	34,370	*	\$ 163,015	\$ (157,632)	\$ 5,383
Net loss								(4,458)	(4,458)
Exercise of pre-funded warrants	990,427	*					18		18
Settlement of restricted stock units in shares of common stock	11,000	*							
Issuance of common stock, net of \$835 issuance costs	731,273	*					10,651		10,651
Exercise of Warrants F	191,107	*					1,418		1,418
Exercise of Unit Purchase Option	16,906	*					82		82
Conversion of Series C Convertible Preferred Stock to common stock	24,812	*			(32,027)	*			
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 2,667 shares	(2,667)	*					120		120
BALANCE AT June 30, 2020	<u>2,223,933</u>	<u>*</u>	<u>17,303</u>	<u>*</u>	<u>2,343</u>	<u>*</u>	<u>\$ 175,304</u>	<u>\$ (162,090)</u>	<u>\$ 13,214</u>

* Represents an amount less than \$1 thousand

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)

	<u>Common stock</u>		<u>Series B Convertible Preferred Stock</u>		<u>Series C Convertible Preferred Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
BALANCE AT April 1, 2020	289,261	*	17,303	*	26,558	*	\$ 163,087	\$ (159,610)	\$ 3,477
Net loss								(2,480)	(2,480)
Exercise of pre-funded warrants	972,427	*					14		14
Issuance of common stock, net of \$835 issuance costs	731,273	*					10,651		10,651
Exercise of Warrants F	191,106	*					1,418		1,418
Exercise of Unit Purchase Option to common stock	16,906	*					82		82
Conversion of Series C Convertible Preferred Stock to common stock	22,960	*			(24,215)	*			
Share-based compensation related to restricted stock and stock options award		-					52		52
BALANCE AT June 30, 2020	<u>2,223,933</u>	<u>*</u>	<u>17,303</u>	<u>*</u>	<u>2,343</u>	<u>*</u>	<u>\$ 175,304</u>	<u>\$ (162,090)</u>	<u>\$ 13,214</u>

* Represents an amount less than \$1 thousand

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

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

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT January 1, 2021	3,284,322	*	17,303	*	2,343	*	\$ 180,339	\$ (168,176)	\$ 12,163
Net loss								(6,750)	(6,750)
Issuance of common stock, including at the market offering net of \$2,024 issuance costs	3,133,775	1	-	-	-	-	25,241	-	25,242
Exercise of Warrants F	1,093,536	*	-	-	-	-	8,120	-	8,120
Exercise of Warrants G	131,876	*	-	-	-	-	1,349	-	1,349
Conversion of Series B Convertible Preferred Stock to common stock	207,528	*	(17,303)	*	-	-	*	-	*
Conversion of Series C Convertible Preferred Stock to common stock	831	*	-	-	(625)	*	*	-	*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 5,959 shares	15,083	*	-	-	-	-	706	-	706
Round up of shares due to reverse stock split effectuated on April 26, 2021	47,388	*	-	-	-	-	-	-	-
BALANCE AT June 30, 2021	<u>7,914,339</u>	<u>1</u>	<u>-</u>	<u>-</u>	<u>1,718</u>	<u>*</u>	<u>\$ 215,755</u>	<u>\$ (174,926)</u>	<u>\$ 40,830</u>

* Represents an amount less than \$1 thousand

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)

	<u>Common stock</u>		<u>Series B Convertible Preferred Stock</u>		<u>Series C Convertible Preferred Stock</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
BALANCE AT April 1, 2021	7,852,791	1	-	-	1,718	*	\$ 215,372	\$ (171,419)	\$ 43,954
Net loss								(3,507)	(3,507)
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 2,683 shares	14,160	*	-	-	-	-	383	-	383
Round up of shares due to reverse stock split effectuated on April 26, 2021	47,388	*	-	-	-	-	-	-	-
BALANCE AT June 30, 2021	<u>7,914,339</u>	<u>1</u>	<u>-</u>	<u>-</u>	<u>1,718</u>	<u>*</u>	<u>\$ 215,755</u>	<u>\$ (174,926)</u>	<u>\$ 40,830</u>

* Represents an amount less than \$1 thousand

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

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

	Six months ended June 30	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (6,750)	\$ (4,458)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	84	88
Loss from sale of property, plant and equipment	1	-
Change in liability for employees' rights upon retirement	52	72
Financial expense	12	19
Change in operating right of use asset and operating leasing liability	(69)	(18)
Share-based compensation expenses	706	120
Changes in operating asset and liability items:		
Decrease in prepaid expenses	271	47
Decrease (increase) in trade receivables	(486)	407
Decrease (increase) in other receivables	10	(2)
Decrease (increase) in inventory	73	(166)
Increase (decrease) in trade payables	503	(188)
Increase (decrease) in other payables	(576)	242
Net cash used in operating activities	<u>(6,169)</u>	<u>(3,837)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(80)	-
Amounts funded in respect of employee rights upon retirement, net	(34)	(34)
Net cash used in investing activities	<u>(114)</u>	<u>(34)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of \$1,989 and \$767 issuance costs, respectively	35,069	12,237
Net cash provided by financing activities	<u>35,069</u>	<u>12,237</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	<u>(12)</u>	<u>(19)</u>
INCREASE IN CASH AND CASH EQUIVALENTS	28,774	8,347
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD	12,645	5,514
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD	<u>\$ 41,419</u>	<u>\$ 13,861</u>
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	91	-
Issuance Costs	<u>\$ 35</u>	<u>68</u>

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

INSPIREMD, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the “Company”), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

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

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

The Company markets its products through distributors in international markets, mainly in Europe.

As of the date of issuance of the consolidated financial statements, the Company has the ability to fund its planned operations for at least the next 12 months. However, the Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™ EPS) reach commercial profitability. Therefore, in order to fund the Company’s operations until such time that the Company can generate substantial revenues, the Company may need to raise additional funds.

The Company’s shares that previously traded on the NYSE American were approved for listing on the Nasdaq Capital Market (“Nasdaq”) and such shares began trading on Nasdaq on May 21, 2021 under the symbol, “NSPR.” The Company’s warrants that previously traded on the NYSE American were approved for listing on Nasdaq, and such warrants began trading on Nasdaq on June 8, 2021.

b. COVID-19 Pandemic

The COVID-19 global pandemic has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of COVID-19, including government-imposed quarantines, lockdowns, and other public health safety measures. To date, the Company has experienced a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals have shifted resources to patients affected by COVID-19. To the best of our knowledge, most European countries in which we operate reinstated non-emergency procedures. However, in light of recent increases in COVID-19 cases in, Europe as well as Latin America, both territories in which we sell our products, we anticipate that the continuation of the pandemic and related restrictions and safety measures will likely result in continued fluctuations in sales of our products for the upcoming periods.

NOTE 2 - BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements for the year ended December 31, 2020. In the opinion of the company, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of its financial position as of June 30, 2021 and its results of operations and cash flows for the three and six months ended June 30, 2021 and 2020. 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, 2020, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 8, 2021. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of results that could be expected for the entire fiscal year.

NOTE 3 - EQUITY:

- a. On April 19, 2021, 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-fifteen reverse stock split of its common stock, par value \$0.0001 per share, effective as of April 26, 2021. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.
- b. On February 8, 2021, the Company closed an underwritten public offering (the "Offering") of 1,935,484 units ("Units"), with each Unit being comprised of one share of the Company's common stock, par value \$0.0001 per share, and one Series G warrant (the "Series G Warrants") to purchase one-half of one share of Common Stock. In connection with this public offering, the underwriter exercised its over-allotment option in full and purchased an additional 290,322 shares of common stock and 145,161 Series G Warrants. The offering price to the public was \$9.30 per Unit. The Series G Warrants are immediately exercisable at a price of \$10.23 per and expire five years from the date of issuance.

The Company granted the underwriter compensation warrants to purchase up to 111,290 shares of Common Stock. The underwriter warrants have an exercise price of \$10.23 per share and are exercisable immediately and for five years from the date of effectiveness of the registration statement in connection with the Offering.

The net proceeds to the Company from the Offering, after giving effect to the exercise of the underwriter's over-allotment option, were approximately \$18.9 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the Offering, but excluding the proceeds, if any, from the exercise of Series G Warrants sold in the Offering.

- c. During the six months ended June 30, 2021, the Company sold 818,523 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with a sales agent. These sales resulted aggregate gross proceeds to the Company of approximately \$5,659,000.

- d. On February 3, 2021, the Company entered into a distribution agreement (the “Distribution Agreement”) with three China-based partners, pursuant to which the Chinese partners will be responsible for conducting the necessary registration trials for commercial approval of the Company’s products in China, followed by an eight-year exclusive distribution right to sell the Company’s products in China with the term of the agreement continuing on a year-to-year basis unless terminated. Under the Distribution Agreement, the China-based partners will be subject to minimum purchase obligations. The Distribution Agreement may be terminated for cause upon failure to meet minimum purchase obligations, failure to obtain regulatory approvals or for other material breaches.

In addition, and on the same day, the Company entered into an investment transaction with one of the Chinese parties to the Distribution Agreement, which included (i) a Securities Purchase Agreement (the “SPA”), pursuant to which investor agreed to invest \$900,000 in exchange for 89,445 shares of the Company’s common stock at a purchase price of \$10.062 per share.

- e. During the six months ended June 30, 2021, Series F and Series G warrants to purchase shares of common stock were exercised by investors at an exercise price of \$7.425 and \$ 10.23 per share, resulting in the issuance of 1,225,412 shares of common stock for proceeds of approximately \$9,469,000.
- f. During the six months ended June 30, 2021, all the remaining 17,303 shares of Series B Convertible Preferred Stock were converted into 207,528 shares of common stock.
- g. During the six months ended June 30, 2021, 625 shares of Series C Convertible Preferred Stock were converted into 831 shares of common stock.
- h. During the six month ended June 30, 2021, the Company granted to employees, directors and consultants’ options to purchase a total of 78,678 shares of the Company’s common stock. The options have an exercise prices ranging from \$10.05 - \$5.04 per share, which was the fair market value of the Company’s common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.

In calculating the fair value of the above options, the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility ranging from 129.12%-136.78%; and risk-free interest rate ranging from 0.59%-1.17%.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$477,243.

- i. During the six month ended June 30, 2021, the Company granted 21,042 restricted shares of the Company’s common stock to employees. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above restricted shares was approximately \$138,776.

- j. As of June 30, 2021, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 2,280 shares of our common stock.

As of June 30, 2021, the Company has outstanding warrants to purchase an aggregate of 1,794,156 shares of common stock as follows:

	Number of underlying Common stock	Exercise price
Series E Warrants	198,159	\$ 27.000
Series F Warrants	433,878	\$ 7.425
Series G Warrants	1,092,344	\$ 10.230
Underwriter Warrants	18,277	\$ 7.425
Other warrants	51,498	\$ 225.000 and above
Total Warrants	1,794,156	\$

As of June 30, 2021, 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.

NOTE 4- NET LOSS PER SHARE:

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

The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 2,251,468 for the six and three-month periods ended June 30, 2021.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units and Series C Preferred Stock excluded from the calculations of diluted loss per share were 1,800,123 for the six and three month periods ended June 30, 2020.

NOTE 5 - FINANCIAL INSTRUMENTS:

a. 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.

b. As of June 30, 2021, and December 31, 2020, allowance for doubtful accounts was \$0.

NOTE 6 - INVENTORY:

	June 30, 2021	December 31, 2020
	(\$ in thousands)	
Finished goods	\$ 169	\$ 350
Work in process	332	376
Raw materials and supplies	841	689
	<u>\$ 1,342</u>	<u>\$ 1,415</u>

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	June 30, 2021	December 31, 2020
	(\$ in thousands)	
Employees and employee institutions	1,018	1,236
Accrued vacation and recreation pay	382	278
Accrued expenses	992	886
Accrual for settlement payment	-	580
Current Operating lease liabilities	412	400
Other	136	89
	<u>\$ 2,940</u>	<u>\$ 3,469</u>

NOTE 8 - 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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
	(\$ in thousands)			
Italy	\$ 249	\$ 53	\$ 458	\$ 247
Germany	232	89	477	259
Poland	104	-	193	121
Other	453	171	916	720
	<u>\$ 1,038</u>	<u>\$ 313</u>	<u>\$ 2,044</u>	<u>\$ 1,347</u>

By product:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
	(\$ in thousands)			
CGuard	\$ 1,019	\$ 271	\$ 1,987	\$ 1,242
MGuard	19	42	57	105
	<u>\$ 1,038</u>	<u>\$ 313</u>	<u>\$ 2,044</u>	<u>\$ 1,347</u>

By principal customers:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Customer A	22%	26%	23%	18%
Customer B	13%	-	13%	12%
Customer C	11%	17%	10%	6%
Customer D	10%	-	10%	9%

All tangible long lived assets are located in Israel.

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

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

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

Forward-Looking Statements

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

- the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq Capital Market listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to successfully obtain, maintain and adequately protect our intellectual property rights;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards;
- our ability 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;
- 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 our stockholders’ ownership interests;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having 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;
- adverse federal, state and local government regulation in the United States, Europe, 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 volatility in certain jurisdictions;
- 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.

All information in this Quarterly Report on Form 10-Q relating to shares or price per share reflects the 1-for-15 reverse stock split effected by us on April 26, 2021.

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. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system (“CGuard EPS”) combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. In September 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020 and, as discussed below, on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in China. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan.

On September 8, 2020, we received approval from the U.S. Food and Drug Administration (“FDA”) of our Investigation Device Exemption (“IDE”), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States. C-Guardians is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial will enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication.

On July 22, 2021, we announced the initiation of enrollment and successful completion of the first cases of our C-Guardian trial of CGuard EPS. The first patients, who were under the care of principal investigator, Chris Metzger, M.D., system chair of clinical research at Ballard Health System in Eastern Tennessee, were successfully implanted with the CGuard EPS stent device. These are the first of 315 patients who are expected to be enrolled in the trial and receive CGuard EPS in the treatment of carotid artery stenosis in symptomatic and asymptomatic patients undergoing carotid artery stenting.

Additionally, we intend to continue to invest in current and future potential product and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery system. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are exploring adding new delivery systems and accessory solutions for procedural protection to our portfolio.

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

Our MGuard™ Prime™ embolic protection system (“MGuard Prime EPS”) is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or 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, or drug-coated, stents, in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES™. Due to limited resources, however, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES™.

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

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

We were organized in the State of Delaware on February 29, 2008.

Recent Developments

Nasdaq Listing

On May 10, 2021, we announced that our shares that previously traded on the NYSE American were approved for listing on the Nasdaq Capital Market (“Nasdaq”) and such shares began trading on Nasdaq on May 21, 2021 under the symbol, “NSPR.” On May 27, 2021, we announced that our warrants that previously traded on the NYSE American were approved for listing on Nasdaq, and such warrants began trading on June 8, 2021. On July 7, 2021, our Series A warrants that previously traded under symbol “NSPRW” expired.

COVID-19 Developments

The COVID-19 global pandemic has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of COVID-19, including government-imposed quarantines, lockdowns, and other public health safety measures. To date, the Company has experienced a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals have shifted resources to patients affected by COVID-19. To the best of our knowledge, most European countries in which we operate reinstated non-emergency procedures. However, in light of recent increases in COVID-19 cases in Europe as well as Latin America, both territories in which we sell our products, we anticipate that the continuation of the pandemic and related restrictions and safety measures will likely result in continued fluctuations in sales of our products for the upcoming periods.

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, 2020. There have not been any material changes to such critical accounting policies since December 31, 2020.

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 June 30, 2021 compared to the three months ended June 30, 2020

Revenues. For the three months ended June 30, 2021, revenue increased by \$725,000, or 231.6%, to \$1,038,000, from \$313,000 during the three months ended June 30, 2020. This increase was predominantly driven by a 276.0% increase in sales volume of CGuard EPS from \$271,000 during the three months ended June 30, 2020, to \$1,019,000 during the three months ended June 30, 2021. This sales increase was mainly due to the fact that in the three months ended June 30, 2021, procedures with CGuard EPS, which are generally scheduled for non-emergency cases, began to return to normal levels as compared to the three months ended June 30, 2020, when procedures with CGuard EPS were mostly postponed as hospitals shifted resources to patients affected by COVID-19. This increase in sales of CGuard EPS was partially offset by a decrease of 54.8% in sales of MGuard Prime EPS from \$42,000 during the three months ended June 30, 2020, to \$19,000 during the three months ended June 30, 2021, 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 geographical regions, the increase in revenue was primarily attributable to a \$677,000 increase in revenue from Europe (primarily driven by a \$697,000 increase of CGuard EPS sales for the reasons discussed in the paragraph above) as well as a \$38,000 increase of CGuard EPS revenue from sales made in Latin America.

Gross Profit. For the three months ended June 30, 2021, gross profit (revenue less cost of revenues) increased by \$382,000, to \$262,000, from a gross loss of \$120,000 during the three months ended June 30, 2020. This increase in gross profit resulted from a \$237,000 increase in revenues less the related material and labor costs (as mentioned above), a decrease in write-offs of \$144,000, which were driven mainly by changes related to components supply issues and a decrease of \$1,000 in miscellaneous expenses during the three months ended June 30, 2021. Gross margin (gross profits as a percentage of revenue) increased to 25.2% during the three months ended June 30, 2021 from (38.3)% during the three months ended June 30, 2020, driven mainly by the decrease in write-offs mentioned above.

Research and Development Expenses. For the three months ended June 30, 2021, research and development expenses increased by 190.5%, or \$846,000, to \$1,290,000, from \$444,000 during the three months ended June 30, 2020. This increase resulted primarily from an increase of \$437,000 in expenses related to the commencement of the C-Guardians FDA study, \$297,000 in development expenses related to CGuard EPS accessory solutions, an increase of \$183,000 in compensation expenses primarily due to additional resources required to support various development projects, offset, in part, by a decrease of \$71,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended June 30, 2021, selling and marketing expenses increased by 68.7%, or \$259,000, to \$636,000, from \$377,000 during the three months ended June 30, 2020. This increase resulted primarily from an increase in compensation expenses of \$250,000 relating to increased activity associated with expansion of existing and new markets and an increase of \$9,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended June 30, 2021, general and administrative expenses increased by 18.0%, or \$271,000, to \$1,776,000, from \$1,505,000 during the three months ended June 30, 2020. This increase resulted primarily from an increase in compensation expenses of \$599,000. This was mainly due to an increase in salary expenses and related accruals of \$327,000 primarily related to temporary salary reductions during the three months ended June 30, 2020, that were implemented in response to the COVID-19 effect on revenues as well as additional headcount. In addition, compensation expenses increased due to an increase in \$259,000 of share-based compensation-related expenses following the expense recognition of grants made after June 30, 2020. In addition, we had an increase in Directors' and Officers' Liability Insurance expenses of \$108,000, due to increased premiums caused by recent trends in the overall insurance industry. These increases were partially offset by a decrease of \$400,000 due to expenses for a settlement agreement with an underwriter of prior offerings which occurred in the three months ended June 30, 2020, and a decrease of \$36,000 in miscellaneous expenses.

Financial Expenses (Income). For the three months ended June 30, 2021, financial expenses increased by 97.1%, or \$33,000, to \$67,000, from \$34,000 during the three months ended June 30, 2020. The increase in financial income primarily resulted from an increase of \$29,000 in financial expenses related to changes in exchange rates and an increase of \$4,000 in miscellaneous expenses.

Tax Expenses. For the three months ended June 30, 2021, there was no change in our tax expenses as compared to the three months ended March 31, 2020.

Net Loss. Our net loss increased by \$1,027,000, or 41.4%, to \$3,507,000, for the three months ended June 30, 2021, from \$2,480,000 during the three months ended June 30, 2020. The increase in net loss resulted primarily from an increase of \$1,376,000 in operating expenses offset by an increase of \$382,000 in gross profit.

Six months ended June 30, 2021 compared to the six months ended June 30, 2020

Revenues. For the six months ended June 30, 2021, revenue increased by \$697,000, or 51.7%, to \$2,044,000, from \$1,347,000 during the six months ended June 30, 2020. This increase was predominantly driven by a 60.0% increase in sales volume of CGuard EPS from \$1,242,000 during the six months ended June 30, 2020, to \$1,987,000 during the six months ended June 30, 2021. This sales increase was mainly due to the fact that in the six months ended June 30, 2021, procedures with CGuard EPS, which are generally scheduled for non-emergency procedures began to return to normal levels as compared to the six months ended June 30, 2020, when procedures with CGuard EPS were postponed as hospitals shifted resources to patients affected by COVID-19 beginning in February 2020. This increase in sales of CGuard EPS was partially offset by a decrease of 45.7% in sales of MGuard Prime EPS from \$105,000 during the six months ended June 30, 2020, to \$57,000 during the six months ended June 30, 2021, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients.

With respect to geographical regions, the increase in revenue was primarily attributable to a \$665,000 increase in revenue from sales made in Europe (driven by a \$702,000 increase of CGuard EPS sales, offset, in part, by a \$37,000 decrease of MGuard Prime EPS sales for reasons discussed in the paragraph above), as well as a \$53,000 increase in CGuard EPS revenue from sales made in Latin America.

Gross Profit. For the six months ended June 30, 2021, gross profit (revenue less cost of revenues) increased by 110.3%, or \$193,000, to \$368,000, compared to a \$175,000 for the same period in 2020. This increase in gross profit resulted from a \$257,000 increase in revenues less the related material and labor costs (as mentioned above). This increase was partially offset by an increase of \$64,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 18.0% during the six months ended June 30, 2021 from 13.0% during the six months ended June 30, 2020, driven by the reasons mentioned above.

Research and Development Expenses. For the six months ended June 30, 2021, research and development expenses increased by 120.2%, or \$1,162,000, to \$2,129,000, from \$967,000 during the six months ended June 30, 2020. This increase resulted primarily from an increase of \$521,000 in development expenses related to CGuard EPS accessory solutions, \$483,000 in expenses related to the commencement of the C-Guardians FDA study, and an increase of \$294,000 in compensation expenses, offset, in part, by a decrease of \$136,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the six months ended June 30, 2021, selling and marketing expenses increased by 34.3%, or \$343,000, to \$1,344,000, from \$1,001,000 during the six months ended June 30, 2020. This increase resulted primarily from an increase in compensation expenses of \$412,000 relating to increased activity associated with expansion of existing and new markets partially offset by a decrease of \$69,000 in miscellaneous expenses.

General and Administrative Expenses. For the six months ended June 30, 2021, general and administrative expenses increased by 36.5%, or \$975,000, to \$3,649,000, from \$2,674,000 during the six months ended June 30, 2020. This increase resulted primarily from an increase in compensation expenses of \$1,033,000 mainly due to increases in salary expenses and related accruals of \$524,000 primarily related to temporary salary reductions during the six months ended June 30, 2020 that were implemented in response to the COVID-19 effect on revenues as well as additional headcount. In addition, compensation expenses increased due to an increase in \$469,000 of share-based compensation-related expenses following the expense recognition of grants made after June 30, 2020. In addition, we had an increase in Directors' and Officers' Liability insurance expenses of \$226,000, due to increased premiums caused by recent trends in the overall insurance industry and an increase in shareholder related expenses of \$118,000 mainly due to a special shareholders meeting (which occurred in 2021, but not in 2020, during the first half of the fiscal year). These increases were partially offset by a decrease of \$400,000 due to expenses for a settlement agreement with an underwriter of prior offerings which occurred in the three months ended March 31, 2020 and a decrease of \$2,000 in miscellaneous expenses.

Financial Expenses (Income). For the six months ended June 30, 2021, financial income decreased by 55.6%, or \$5,000, to \$4,000 of financial income, from \$9,000 of financial income during the six months ended June 30, 2020. The decrease in financial income primarily resulted from an increase of \$19,000 in miscellaneous expenses, offset, in part, by an increase of \$14,000 in financial income related to changes in exchange rates.

Tax Expenses. For the six months ended June 30, 2021, there was no material change in our tax expenses as compared to the six months ended June 30, 2020.

Net Loss. Our net loss increased by \$2,292,000, or 51.4%, to \$6,750,000, for the six months ended June 30, 2021, from \$4,458,000 during the six months ended June 30, 2020. The increase in net loss resulted primarily from an increase of \$2,480,000 in operating expenses, offset by an increase of \$193,000 in gross profit.

Liquidity and Capital Resources

As of June 30, 2021, we have the ability to fund our planned operations for at least the next 12 months from issuance date of the financial statement. However, we expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard™ EPS) reach commercial profitability. Therefore, in order to fund our operations until such time that we can generate substantial revenues, we may need to raise additional funds.

On July 28, 2020, we entered into a Sales Agreement with A.G.P. pursuant to which we were able to offer and sell, from time to time, at our option, through or to A.G.P., up to an aggregate of approximately \$9,300,000 of shares of our common stock (the “ATM Facility”). On January 11, 2021, we increased the aggregate amount of our shares of common stock that may be sold under the Sales Agreement from \$9,300,000 to \$10,382,954, and, as a result, utilized and sold the maximum amount allowable under the ATM Facility, which resulted in an aggregate amount of \$10,381,958.

On February 3, 2021, we entered into a Distribution Agreement with three China-based partners and on the same day, we entered into an investment transaction with QIDI, which included (i) a securities purchase agreement (“SPA”), pursuant to which QIDI agreed to invest \$900,000 in exchange for shares of our common stock at a purchase price of \$10.062 per share, and (ii) an IRA, whereby QIDI was provided certain customary registration rights, including a commitment by us to file a registration statement with the SEC on Form S-1 or Form S-3 and have such registration statement become effective not later than 150 days following the closing of the transactions under the SPA. The transaction closed on February 5, 2021.

On February 8, 2021, we closed an underwritten public offering of 1,935,484 units, with each such unit being comprised of one share of our common stock, par value \$0.0001 per share, and one Series G Warrant to purchase one-half of one share of common stock. The offering price to the public was \$9.30 per unit. The Series G Warrants were immediately exercisable at a price of \$10.23 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance. We also granted the underwriter of the offering an option to purchase an additional 290,322 shares of common stock and Series G Warrants to purchase 145,161 shares of common stock, which the underwriter exercised in full. In connection with the offering, we granted to the underwriter a compensation warrant to purchase up to 111,290 shares of common stock with an exercise price of \$10.23 per share and which are exercisable for five years from February 3, 2021, the date of effectiveness of the registration statement filed in connection with the offering. Our net proceeds from the offering, after giving effect to the exercise of the underwriter’s over-allotment option, were approximately \$18.9 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series G Warrants sold in the offering.

Six months ended June 30, 2021 compared to the six months ended June 30, 2020

General. At June 30, 2021, we had cash and cash equivalents of \$41,419,000, as compared to \$12,645,000 as of December 31, 2020. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative costs, capital expenditures and general working capital.

For the six months ended June 30, 2021, net cash used in our operating activities increased by \$2,317,000 to \$6,154,000, from \$3,837,000 during the same period in 2020. The primary reason for the increase in cash used in our operating activities was an increase of \$1,102,000 in payments for third party related expenses and for professional services (primarily due to the commencement of the C-Guardians study and a settlement payment made to a former distributor) and an increase of \$1,006,000 in compensation costs paid during the six months ended June 30, 2021, from \$3,006,000 in the six months ended June 30, 2020 to \$4,012,000 during the same period in 2021 as well as a decrease of \$209,000 in payments received from customers, to \$1,545,000 during the six months ended June 30, 2021, from \$1,754,000 during the same period in 2020.

Cash used in our investing activities was \$114,000 during the six months ended June 30, 2021, compared to \$34,000 during the six months ended June 30, 2020. The primary reasons for the increase in cash used by our investing activities were an increase of \$80,000 in payments made for purchase of property, plant and equipment to \$80,000 during the six months ended June 30, 2021, from \$0 during the same period in 2020.

Cash provided by financing activities for the six months June 30, 2021, was \$35,069,000, compared to \$12,237,000 during the same period in 2020. The principal sources of the cash provided by financing activities during the six months ended June 30, 2021 were our February 2021 public offering of common stock and warrants, exercise of Series F and Series G warrants, proceeds from an At-the-market offering as well as proceeds from the issuance of shares to Chinese distributor that resulted in approximately \$35,069,000 of aggregate net proceeds. The principal sources of the cash provided by financing activities during the six months ended June 30, 2020 were our June 2020 public offering of common stock, pre-funded warrants and warrants, the subsequent exercise of the pre-funded warrants sold in the offering, as well as exercise of our Series F warrants and unit purchase options that resulted in approximately \$12,237,000 of aggregate net proceeds.

As of June 30, 2021, our current assets exceeded our current liabilities by a multiple of 11.9. Current assets increased by \$28,583,000 during the period and current liabilities decreased by \$26,000 during the period. As a result, our working capital increased by \$28,609,000 to \$40,243,000 as of June 30, 2021.

Off Balance Sheet Arrangements

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

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the impact of the COVID-19 pandemic, cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products. For a discussion of these and other risks that relate to our business, you should carefully review the risks and uncertainties described under the heading “Part II – Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2020, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

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

Contractual Obligations and Commitments

During the six months ended June 30, 2021, 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 June 30, 2021, 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 June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2021, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

There have been no material changes to our legal proceedings as described in “Part I, Item 3. Legal Proceedings” in our Annual Report on Form 10-K filed with the SEC on March 8, 2021.

Item 1A. Risk Factors

Except for the Risk Factors included in our previous filings made with the SEC, there have been no material changes to our risk factors from those disclosed in “Part I. Item 1A. Risk Factors” in the Form 10-K filed with the SEC on March 8, 2021.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation, as amended through September 30, 2015 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2021)</u>
3.3	<u>Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)</u>
3.4	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)</u>
3.5	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)</u>
3.6	<u>Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)</u>
3.7	<u>Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)</u>
3.8	<u>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)</u>
3.9	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)</u>
3.10	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019)</u>
3.11	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc., dated April 14, 2021 (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed on May 10, 2021)</u>
10.1+*	<u>Seventh Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101*	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, formatted in inline XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of

104* Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

+ Management contract or compensatory plan or arrangement.

SIGNATURES

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

INSPIREMD, INC.

Date: August 9, 2021

By: /s/ Marvin Slosman

Name: Marvin Slosman,

Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2021

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer, Secretary and Treasurer
(Principal Financial and Accounting Officer)

**SEVENTH AMENDMENT TO THE
INSPIREMD, INC. 2013 LONG-TERM INCENTIVE PLAN**

This SEVENTH AMENDMENT TO THE INSPIREMD, INC. 2013 LONG-TERM INCENTIVE PLAN (this "*Amendment*"), dated as of June 20, 2021 (the "*Effective Date*") is made and entered into by InspireMD, Inc., a Delaware corporation (the "*Company*"). Terms used in this Amendment with initial capital letters that are not otherwise defined herein shall have the meanings ascribed to such terms in the InspireMD, Inc. 2013 Long-Term Incentive Plan, as amended (the "*Plan*").

RECITALS

WHEREAS, Article 9 of the Plan provides that the Company's Board of Directors (the "*Board*") may amend the Plan at any time and from time to time; and

WHEREAS, the Board desires to amend the Plan to permit a participant to assign the awards under the Plan to other types of entities, in addition to partnerships, in which all the equity holders are immediate family members of the participant.

NOW, THEREFORE, in accordance with Article 9 of the Plan, the Company hereby amends the Plan, effective as of the date hereof, as follows:

1. The third particular of the second sentence of the second paragraph of Section 15.8 is hereby deleted in its entirety and replaced with the following:

“(iii) an entity in which all equity holders are (1) such Immediate Family Members and/or (2) entities which are controlled by Immediate Family Members,”
 2. Except as expressly amended by this Amendment, the Plan shall continue in full force and effect in accordance with the provisions thereof, and all awards granted under the Plan prior to the Effective Date shall continue to be governed pursuant to the terms of the Plan as in effect immediately prior to the Effective Date.
-

IN WITNESS WHEREOF, the Company has caused this Amendment to be duly executed as of the date first written above.

INSPIREMD, INC.

By:



Name: Craig Shore

Title: Chief Financial Officer, Chief Administrative Officer, Treasurer and Secretary

CERTIFICATION

I, Marvin Slosman, certify that:

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

Date: August 9, 2021

/s/ Marvin Slosman

Marvin Slosman
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

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: August 9, 2021

/s/ Craig Shore

Craig Shore
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION
PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the “Company”) for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Marvin Slosman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

- (1) The Report 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 Report 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: August 9, 2021

By: /s/ Marvin Slosman

Name: Marvin Slosman

Title: Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION
PURSUANT TO
18 U.S.C. SECTION 1350**

In connection with the Quarterly Report on Form 10-Q of InspireMD, Inc. (the "Company") for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Craig Shore, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, that, to my knowledge:

- (1) The Report 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 Report 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: August 9, 2021

By: /s/ Craig Shore

Name: Craig Shore

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)
