INSPIREMD, INC.

FORM 10-Q
(Quarterly Report)

Filed 05/10/21 for the Period Ending 03/31/21

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)

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

For the quarterly period ended: March 31, 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	**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
Series A 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 May 10, 2021: 7,906,476

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CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED MARCH 31, 2021

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

	March 31 2021	December 31 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 44,034	$ 12,645
Accounts receivable:		
Trade, net	708	476
Other	117	146
Prepaid expenses	207	334
Inventory	1,184	1,415
Receivable for sale of Shares	-	323
TOTAL CURRENT ASSETS	46,250	15,339
NON-CURRENT ASSETS:		
Property, plant and equipment, net	422	448
Operating lease right of use assets	1,240	1,265
Fund in respect of employee rights upon retirement	723	725
TOTAL NON-CURRENT ASSETS	2,385	2,438
TOTAL ASSETS	$ 48,635	$ 17,777

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

	March 31 2021	December 31 2020
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	401	236
Other	2,465	3,469
TOTAL CURRENT LIABILITIES	2,866	3,705
LONG-TERM LIABILITIES-		
Operating lease liabilities	894	999
Liability for employees rights upon retirement	921	910
TOTAL LONG-TERM LIABILITIES	1,815	1,909
COMMITMENTS AND CONTINGENT LIABILITIES (Note 8)		
TOTAL LIABILITIES	4,681	5,614
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2021 and December 31, 2020; 7,852,791 and 3,284,322 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	1	*
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at March 31, 2021 and December 31, 2020; 0 and 17,303 shares issued and outstanding at March 31, 2021 and December 31, 2020	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2021 and December 31, 2020; 1,718 and 2,343 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital	215,372	180,339
Accumulated deficit	(171,419)	(168,176)
Total equity	43,954	12,163
Total liabilities and equity	$ 48,635	$ 17,777

* Represents an amount less than $1 thousand

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 March 31	
	2021	**2020**
REVENUES	$ 1,006	$ 1,034
COST OF REVENUES	900	739
GROSS PROFIT	106	295
OPERATING EXPENSES:		
Research and development	839	523
Selling and marketing	708	624
General and administrative	1,873	1,169
Total operating expenses	3,420	2,316
LOSS FROM OPERATIONS	(3,314)	(2,021)
FINANCIAL INCOME, net	71	43
NET LOSS	$ (3,243)	$ (1,978)
NET LOSS PER SHARE - basic and diluted	$ (0.53)	$ (6.42)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	6,122,690	308,202

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	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT January 1, 2020	**261,075**	*	**17,303**	*	**34,370**	*	$ 163,015	$ (157,632)	$ 5,383
Net loss								(1,978)	(1,978)
Exercise of pre-funded warrants	**18,000**	*					3		3
Settlement of restricted stock units in shares of common stock	**11,000**	*					*		*
Conversion of Series C Convertible Preferred Stock to common shares	**1,852**	*			**(7,812)**	*			
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 40,000 shares	**(2,666)**	*					69		69
BALANCE AT March 31, 2020	**289,261**	*	**17,303**	*	**26,558**	*	$ 163,087	$ (159,610)	$ 3,477

* Represents an amount less than $1 thousand

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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 January 1, 2021	**3,284,322**	*	**17,303**	*	**2,343**	*	$ 180,339	$ (168,176)	$ 12,163
Net loss								(3,243)	(3,243)
Issuance of common shares, including at the market offering net of $2,018 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 shares	**207,528**	*	**(17,303)**	*			*		*
Conversion of Series C Convertible Preferred Stock to common shares	**831**	*			**(625)**	*	*		*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 3,276 shares	**923**	*					**323**		**323**
BALANCE AT March 31, 2021	**7,852,791**	**1**	**-**	*	**1,718**	*	$ 215,372	$ (171,419)	$ 43,954

* 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)

	Three months ended March 31	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,243)	$ (1,978)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	51	51
Loss from sale of property, plant and equipment	1	
Change in liability for employees rights upon retirement	11	32
Financial income and interest paid	15	19
Change in right of use asset and leasing liability	(99)	(31)
Share-based compensation expenses	323	69
Changes in operating asset and liability items:		
Decrease in prepaid expenses	127	24
Increase in trade receivables	(232)	(33)
Decrease (Increase) in other receivables	29	(24)
Decrease in inventory	231	34
Increase (Decrease) increase in trade payables	165	(84)
Decrease in other payables	(1,020)	(433)
Net cash used in operating activities	(3,641)	(2,354)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(26)	-
Amounts (withdrawn) in respect of employee rights upon retirement, net	2	(3)
Net cash used in investing activities	(24)	(3)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants	35,068	3
Net cash provided by financing activities	35,068	3
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(14)	(19)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	31,389	(2,373)
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	$ 44,034	$ 3,141
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Issuance Costs	$ 35	-

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.

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 common stock are traded on NYSE American and have been approved for listing on The Nasdaq Capital Market ("Nasdaq"). the Company is taking steps to commence trading on Nasdaq under the symbol NSPR.

b. COVID-19 Pandemic

In an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. As of the beginning of the second quarter of 2020, we began to experience a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. To the best of our knowledge, most European countries in which we operate are reinstating elective procedures, but we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures in light of recent increases in COVID-19 cases in the territories we sell into. We anticipate that the continuation of the pandemic and related restrictions and safety measures would likely result in a continued 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. 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 March 31, 2021 and its results of operations and cash flows for the three months ended March 31, 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 months ended March 31, 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, which decreased the number of issued and outstanding shares of common stock and restricted stock as of March 31, 2021 from 117.8 million shares to 7.9 million shares.

All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented.

b. On February 8, 2021, the Company closed an underwritten public 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 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 a compensation warrant 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 three months ended March 31, 2021, the Company sold 818,523 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with an Underwriter. 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 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, or 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 three months ended March 31, 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 three months ended March 31, 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 three months ended March 31, 2021, 625 shares of Series C Convertible Preferred Stock were converted into 831 shares of common stock.

h. On January 11, 2021 the Company granted to employees options to purchase a total of 1,400 shares of the Company's common stock. The options have an exercise prices of $10.05 per share, which was the fair market value of the Company's common stock on the date of the grant. The options are subject to a three-year vesting period, with one-third of such awards vesting each year.
In calculating the fair value of the above options the Company used the following assumptions: dividend yield of 0% and expected term of 5.5-6.5 years; expected volatility of 129.12%-136.78%; and risk-free interest rate of 0.59%-0.76%.
The fair value of the above options, using the Black-Scholes option-pricing model, was approximately $12,635.

i. On January 11, 2021, the Company granted 4,200 restricted shares of the Company's common stock to employees and directors. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.
The fair value of the above restricted shares was approximately $42,207.

j. As of March 31, 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 March 31, 2021, the Company has outstanding warrants to purchase an aggregate of 1,794,158 shares of common stock as follows:

	Number of underlying Common stock		Weighted average 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	51,500	$	225.000 and above
Total Warrants	1,794,158	$	35.207

As of March 31, 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, restricted stock, restricted stock units, Series C Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 2,164,985 for the three-month period ended March 31, 2021.

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 March 31, 2021, and December 31, 2020, allowance for doubtful accounts was $0.

NOTE 6 - INVENTORY:

	March 31, 2021	December 31, 2020
	($ in thousands)	
Finished goods	$ 215	$ 350
Work in process	223	376
Raw materials and supplies	746	689
	$ 1,184	$ 1,415

NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:

	March 31, 2021	December 31, 2020
	($ in thousands)	
Employees and employee institutions	731	1,236
Accrued vacation and recreation pay	322	278
Accrued expenses	906	886
Accrual for settlement payment	-	580
Current Operating lease liabilities	381	400
Other	125	89
	$ 2,465	$ 3,469

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 March 31	
	2021	2020
	($ in thousands)	
Germany	$ 244	$ 171
Italy	209	194
Poland	90	121
Russia	70	116
Other	393	432
	$ 1,006	$ 1,034

By product:

	Three months ended March 31	
	2021	2020
	($ in thousands)	
CGuard	$ 969	$ 971
MGuard	37	63
	$ 1,006	$ 1,034

By principal customers:

	Three months ended March 31	
	2021	2020
Customer A	23%	16%
Customer B	13%	16%
Customer C	9%	12%
Customer D	7%	11%

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 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;
- 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;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;

- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- price increases for supplies and components;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- loss or retirement of key executives and research scientists.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. For a discussion of these and other risks that relate to our business and investing in our common stock, you should carefully review the risks and uncertainties described in this Quarterly Report on Form 10-Q, and those described from time to time in our future reports filed with the Securities and Exchange Commission. The forward-looking statements contained in this Quarterly Report on Form 10-Q are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. Our MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. In September 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020 and, 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, CARENET-III, for prevention of stroke in patients in the United States. CARENET-lll 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. Additional sites in Europe may also participate in the study, contributing a maximum of ~50% of the total enrollees. The primary endpoint of the study will be the composite of the following: incidence of the following major adverse events: death (all- cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication or ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication.

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

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

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

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

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

Recent Developments

Reverse Stock Split

On April 14, 2021, our stockholders approved a reverse stock split of our common stock, following which, and on the same date, our board of directors approved a ratio of 1-for-15 for the reverse stock split, or the Reverse Stock Split. On April 14, 2021, the Delaware Secretary of State approved our Certificate of Amendment to our Amended and Restated Certificate of Incorporation, which set an effective date of April 26, 2021 for the Reverse Stock Split, or the Effective Date. The post-Reverse Stock Split CUSIP number for our common stock is 45779A 846.

On the Effective Date, the total number of shares of our common stock held by each stockholder was converted automatically into the number of whole shares of common stock equal to (i) the number of issued and outstanding shares of common stock held by such stockholder immediately prior to the Reverse Stock Split, divided by (ii) 15.

No fractional shares were issued in connection with the Reverse Stock Split, and no cash or other consideration was be paid. Instead, we issued one whole share of the post-Reverse Stock Split common stock to any shareholder who otherwise would have received a fractional share as a result of the Reverse Stock Split.

Public Offering

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 our 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 our common stock and Series G Warrants to purchase 145,161 shares of our 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 our common stock with an exercise price of $10.23 per share and which are exercisable for five years from February 3, 2021. 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 expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series G Warrants sold in the offering.

Distribution and Purchase Agreement with Chinese Partners

On February 3, 2021, we entered into a 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 our products in China, followed by an eight-year exclusive distribution right to sell our 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, we entered into an investment transaction with QIDI, which included (i) a securities purchase agreement, or SPA, pursuant to which QIDI Asia Medical Limited, a Hong Kong limited company, or 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 investor rights agreement, or 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 transactions closed on February 5, 2021.

ATM Offering

On July 28, 2020, we entered into a Sales Agreement with A.G.P. pursuant to which we may offer and sell, from time to time, at our option, through or to A.G.P., up to an aggregate of approximately $9,300,000 of shares of our common stock (the "ATM Facility"). On January 11, 2021, we increased the aggregate amount of shares of our 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.

COVID-19 Developments

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

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

Effective April 1, 2020, the Board approved a 50% decrease in the annual cash compensation for non-employee directors from an aggregate amount of $154,000 to $77,000. Effective as of the same date, we reduced the annual salaries of most of our employees by 20% to 30% until further notice.

On April 21, 2020, Marvin Slosman, our President, Chief Executive Officer and Director, and Craig Shore, our Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer, each signed waivers reducing their monthly base salaries for the period beginning April 1, 2020 and which, pursuant to their independent determinations, ended on June 1, 2020. Each of the salaries for the remaining officers, directors and employees was similarly reinstated by no later than June 30, 2020.

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

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 March 31, 2021 compared to the three months ended March 31, 2020

Revenues. For the three months ended March 31, 2021, revenue decreased by $28,000, or 2.7%, to $1,006,000, from $1,034,000 during the three months ended March 31, 2020. CGuard revenue remained essentially unchanged at $969,000 during the three months ended March 31, 2021 as compared to $971,000 during the three months ended March 31, 2020, in spite of the continued postponement of many elective procedures as a result of the residual COVID directed resources. However, MGuard Prime EPS revenue decreased by a 41.3% from $63,000 during the three months ended March 31, 2020, to $37,000 during the three months ended March 31, 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 decrease in revenue was primarily attributable to a $25,000 decrease in revenue from Asia and the Middle East (primarily driven by a $22,000 decrease of CGuard EPS for the reasons discussed in the paragraph above), a decrease of $12,000 in revenue from sales made in Europe (primarily driven by a $17,000 decrease of MGuard Prime EPS sales for the reasons discussed in the paragraph above), offset, in part, by an increase of $15,000 in revenue from sales made in Latin America (primarily driven by a $20,000 increase of CGuard EPS sales for the reasons discussed in the paragraph above).

Gross Profit. For the three months ended March 31, 2021, gross profit (revenue less cost of revenues) decreased by 64.1%, or $189,000, to $106,000, from $295,000 during the three months ended March 31, 2020. This decrease in gross profit resulted from an increase in write-offs of $156,000, which were driven mainly by a component supply issue during the three months ended March 31, 2021 and an increase of $33,000 in miscellaneous expenses during the three months ended March 31, 2021. Gross margin (gross profits as a percentage of revenue) decreased to 10.5% during the three months ended March 31, 2021 from 28.5% during the three months ended March 31, 2020, driven by the factors mentioned above.

Research and Development Expenses. For the three months ended March 31, 2021, research and development expenses increased by 60.4%, or $316,000, to $839,000, from $523,000 during the three months ended March 31, 2020. This increase resulted primarily from an increase of $136,000 in development expenses related to CGuard EPS new delivery system and accessory solutions, an increase of $112,000 in compensation expenses and an increase of $68,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the three months ended March 31, 2021, selling and marketing expenses increased by 13.5%, or $84,000, to $708,000, from $624,000 during the three months ended March 31, 2020. This increase resulted primarily from an increase in compensation expenses of $162,000 relating to increased activity associated with expansion of existing and new markets, offset, in part, by a decrease in travel expenses of $59,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19, offset, and by a decrease of $19,000 in miscellaneous expenses.

General and Administrative Expenses. For the three months ended March 31, 2021, general and administrative expenses increased by 60.2%, or $704,000, to $1,873,000, from $1,169,000 during the three months ended March 31, 2020. This increase resulted primarily from an increase in compensation expenses of $431,000, mainly due to an increase in salary expenses and related accruals of $195,000, and an increase of approximately $209,000 of share-based compensation-related expenses in the three months ended March 31, 2021, due to the expense recognition of grants made in the second half of 2020, an increase in Directors' and Officers' Liability Insurance expenses of $118,000, partially due to increased premiums caused by recent trends in the overall insurance industry, an increase in shareholder related expenses of $108,000 mainly due to a special shareholders meeting (which occurred in 2021, but not in 2020, during the first quarter of the fiscal year) and an increase of $47,000 in miscellaneous expenses.

Financial Income. For the three months ended March 31, 2021, financial income increased by 65.1%, or $28,000, to $71,000, from $43,000 during the three months ended March 31, 2020. The increase in financial income primarily resulted from an increase of $46,000 in financial income related to changes in exchange rates, offset, in part, by an increase of $18,000 in miscellaneous expenses.

Tax Expenses. For the three months ended March 31, 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 $1,265,000, or 64.0%, to $ 3,243,000, for the three months ended March 31, 2021, from $1,978,000 during the three months ended March 31, 2020. The increase in net loss resulted primarily from an increase of $1,104,000 in operating expenses and a decrease of $189,000 in gross profit.

Liquidity and Capital Resources

As of March 31, 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. in connection with the ATM Facility. Any shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to the Company's Registration Statement on Form S-3 (File No. 333-223130), filed with the SEC on February 21, 2018 and the prospectus supplement thereto filed with the SEC on July 28, 2020, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by us, by any other method permitted by law. On 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) an 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.

Three months ended March 31, 2021 compared to the three months ended March 31, 2020

General. At *March 31, 2021*, we had cash and cash equivalents of $44,034,000, 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 three months ended March 31, 2021, net cash used in our operating activities increased by $1,287,000 to $3,641,000, from $2,354,000 during the same period in 2020. The primary reason for the increase in cash used in our operating activities was an increase of $647,000 in payments for third party related expenses and for professional services (primarily due to a settlement payment made to a former distributor) and an increase of $410,000 in compensation costs paid during the three months ended March 31, 2021, from $1,904,000 in the three months ended March 31, 2020 to $2,314,000 during the same period in 2021 as well as a decrease of $230,000 in payments received from customers, to $759,000 during the nine months ended March 31, 2021, from $989,000 during the same period in 2020.

Cash used in our investing activities was $24,000 during the three months ended March 31, 2021, compared to $3,000 during the three months ended March 31, 2020. The primary reasons for the increase in cash used by our investing activities were: an increase of $26,000 in payments made for purchase of property, plant and equipment to $26,000 during the three months ended March 31, 2021, from $0 during the same period in 2020.

Cash provided by financing activities for the three months March 31, 2021, was $35,068,000, compared to $3,000 during the same period in 2020. The principal sources of the cash provided by financing activities during the three months ended March 31, 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 $35,068,000 of aggregate net proceeds. The principal source of the cash provided by financing activities during the three months ended March 31, 2020, was the funds received from the exercise of pre-funded warrants that resulted in approximately $3,000 of aggregate net proceeds.

As of March 31, 2021, our current assets exceeded our current liabilities by a multiple of 16.1. Current assets increased by $30,911,000 during the period and current liabilities decreased by $839,000 during the period. As a result, our working capital increased by $31,750,000 to $43,384,000 as of March 31, 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 three months ended March 31, 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 March 31, 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 March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 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

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not aware of any material changes from the information set forth in "Item 3. Legal Proceedings" in the Form 10-K filed with the SEC on March 8, 2021 and available at the following link:

https://www.sec.gov/Archives/edgar/data/1433607/000149315221005564/form10-k.htm#a_003

Item 1A. Risk Factors

Except for the Risk Factors set forth herein, there have been no material changes from the information set forth in "Item 1A. Risk Factors" in the Form 10-K filed with the SEC on March 8, 2021.

The Reverse Stock Split may not result in a proportional increase in the per share price of our common stock.

On April 14, 2021, our stockholders approved the Reverse Stock Split, and, pursuant to the Certificate of Amendment to our Amended and Restated Certificate of Incorporation, which was approved by the Delaware Secretary of State on April 14, 2021, the Effective Date of the Reverse Stock Split was April 26, 2021. The primary purpose for the Reverse Stock Split was to increase the price of our common stock in order to meet the initial listing requirements of the Nasdaq Capital Market ("Nasdaq") and, secondly, to provide appropriate flexibility we require to issue shares in the event that our board of directors determines that it is necessary or appropriate to (i) raise additional capital through the sale of equity securities, (ii) enter into strategic business transactions, (iii) provide equity incentives to directors, officers and employees pursuant to equity compensation plans or (iv) further other corporate purposes. The effect of the Reverse Stock Split on the market price for our common stock cannot be accurately predicted. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines during the period following the Reverse Stock Split, the percentage decline may be greater than would occur in the absence of the Reverse Stock Split. The market price of our common stock may also be affected by other factors which may be unrelated to the Reverse Stock Split or the number of shares outstanding.

Moreover, because some investors may view the Reverse Stock Split negatively, we cannot assure you that the Reverse Stock Split will not adversely impact the market price of our common stock. Accordingly, our total market capitalization after the Reverse Stock Split may be lower than the market capitalization before the Reverse Stock Split.

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)
3.17*	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc., dated April 14, 2021
10.1	Sales Agreement, dated July 28, 2020 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 28, 2020)
10.2+	Fourth Amendment to Amended and Restated Employment Agreement, dated August 14, 2020, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 18, 2020)
10.3+	Sixth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 31, 2020)
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements

* Filed herewith.
+ Management contract or compensatory plan or arrangement.

SIGNATURES

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

INSPIREMD, INC.

Date: May 10, 2021

By: */s/ Marvin Slosman*
Name: Marvin Slosman,
Title: President and Chief Executive Officer

Date: May 10, 2021

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

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "INSPIREMD, INC.", FILED IN THIS OFFICE ON THE FOURTEENTH DAY OF APRIL, A.D. 2021, AT 4:44 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

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SR# 20211298432

Authentication: 202996771
Date: 04-19-21

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:44 PM 04/14/2021
FILED 04:44 PM 04/14/2021
SR 20211298432 - File Number 4511950

CERTIFICATE OF AMENDMENT

OF

CERTIFICATE OF INCORPORATION

OF

INSPIREMD, INC.

InspireMD, Inc., a corporation duly organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify that:

1. Resolutions were duly adopted by the Board of Directors of the Corporation setting forth this proposed Amendment to the Certificate of Incorporation of the Corporation and declaring said amendment to be advisable and calling a meeting of the stockholders of the Corporation for consideration thereof.

2. Effective as of 5:00 p.m., New York time, on April 26, 2021 (the "Effective Time"), each fifteen (15) issued and outstanding shares of the Corporation's Common Stock, par value $0.0001 per share, shall be converted into one (1) share of the Corporation's Common Stock, par value $0.0001 per share, as constituted following the Effective Time.

3. The Certificate of Incorporation of the Corporation is hereby amended by deleting subsection (B) of ARTICLE FOURTH thereof in its entirety and inserting the following in lieu thereof:

"B. Effective as of 5:00 p.m., New York time, on April 26, 2021 (the "Effective Time"), each share of the Corporation's common stock, $0.0001 par value per share (the "Old Common Stock"), either issued or outstanding or held by the Corporation as treasury stock, immediately prior to the Effective Time, will be automatically reclassified as and converted (without any further act) into 1/15 of a fully paid and nonassessable share of common stock, $0.0001 par value per share, of the Corporation (the "New Common Stock") without increasing or decreasing the amount of stated capital or paid-in surplus of the Corporation (the "Reverse Stock Split"), provided that no fractional shares shall be issued to any registered holder of Old Common Stock immediately prior to the Effective Time, and that instead of issuing such fractional shares to such holders, such fractional shares shall be rounded up to the next even number of shares of Common Stock issued as a result of this Reverse Stock Split at no cost to the stockholder. Any stock certificate that, immediately prior to the Effective Time, represented shares of the Old Common Stock will, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent the number of shares of the New Common Stock as equals the product obtained by multiplying the number of shares of Old Common Stock represented by such certificate immediately prior to the Effective Time by 1/15."

4. Pursuant to the resolution of the Board of Directors, a special meeting of the stockholders of the Corporation was duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of foregoing the amendment.

5. The foregoing amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

[SIGNATURE PAGE FOLLOWS]

[SIGNATURE PAGE TO CERTIFICATE OF AMENDMENT]

IN WITNESS WHEREOF, InspireMD, Inc. has caused this Certificate to be executed by its duly authorized officer on this 14th day of April 2021.

INSPIREMD, INC.

By: */s/ Craig Shore*

Name: Craig Shore

Title: Chief Financial Officer, Treasurer and Secretary

EXHIBIT 31.1

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

I, Marvin Slosman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of InspireMD, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2021

/s/ Marvin Slosman
Marvin Slosman
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: May 10, 2021

/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 March 31, 2021, of InspireMD, Inc. (the "Company"). I, Marvin Slosman, the Chief Executive Officer of the Company, certify that, based on my knowledge:

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

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

Date: May 10, 2021

By: */s/ Marvin Slosman*
Name: Marvin Slosman
Title: Chief Executive Officer

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

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 March 31, 2021, 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: May 10, 2021

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.