# INSPIREMD, INC.

## FORM 10-Q
(Quarterly Report)

Filed 05/11/20 for the Period Ending 03/31/20

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

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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended: March 31, 2020**

**OR**

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

**For the transition period from to**

**Commission file number: 001-35731**

# InspireMD, Inc.
(Exact name of registrant as specified in its charter)

| **Delaware** | **26-2123838** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**4 Menorat Hamaor St.**
**Tel Aviv, Israel 6744832**
(Address of principal executive offices)
(Zip Code)

**(888) 776-6204**
(Registrant's telephone number, including area code)

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

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

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

| | |
|---|---|
| Large accelerated filer [ ] | Accelerated filer [ ] |
| Non-accelerated filer [X] | Smaller reporting company [X] |
| | Emerging growth company [ ] |

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes [ ] No [X]

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

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

The number of shares of the registrant's common stock, $0.0001 par value, outstanding as of May 10, 2020: 4,338,910

**TABLE OF CONTENTS**

**INSPIREMD, INC.**
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE QUARTER ENDED MARCH 31, 2020

TABLE OF CONTENTS

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

| | March 31 2020 | December 31 2019 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 3,141 | $ 5,514 |
| Accounts receivable: | | |
| Trade, net | 856 | 823 |
| Other | 174 | 150 |
| Prepaid expenses | 63 | 87 |
| Inventory | 1,202 | 1,236 |
| **TOTAL CURRENT ASSETS** | 5,436 | 7,810 |
| | | |
| **NON-CURRENT ASSETS:** | | |
| Property, plant and equipment, net | 496 | 547 |
| Operating lease right of use assets | 864 | 937 |
| Fund in respect of employee rights upon retirement | 589 | 586 |
| **TOTAL NON-CURRENT ASSETS** | 1,949 | 2,070 |
| **TOTAL ASSETS** | $ 7,385 | $ 9,880 |

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

| | March 31 2020 | December 31 2019 |
|---|---|---|
| **LIABILITIES AND EQUITY** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accruals: | | |
| Trade | 562 | 646 |
| Other | 2,024 | 2,449 |
| Contract liability | 17 | 20 |
| **TOTAL CURRENT LIABILITIES** | 2,603 | 3,115 |
| **LONG-TERM LIABILITIES-** | | |
| Operating lease liabilities | 544 | 653 |
| Liability for employees rights upon retirement | 761 | 729 |
| **TOTAL LONG-TERM LIABILITIES** | 1,305 | 1,382 |
| **COMMITMENTS AND CONTINGENT LIABILITIES (Note 8)** | | |
| **TOTAL LIABILITIES** | 3,908 | 4,497 |
| **EQUITY:** | | |
| Common stock, par value $0.0001 per share; 150,000,000 shares authorized at March 31, 2020 and December 31, 2019; 4,338,910 and 3,916,134 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively | - | - |
| Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at March 31, 2020 and December 31, 2019; 17,303 shares issued and outstanding at March 31, 2020 and December 31, 2019. | - | - |
| Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at March 31, 2020 and December 31, 2019; 26,558 and 34,370 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively | - | - |
| Additional paid-in capital | 163,087 | 163,015 |
| Accumulated deficit | (159,610) | (157,632) |
| Total equity | 3,477 | 5,383 |
| Total liabilities and equity | $ 7,385 | $ 9,880 |

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

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

| | Three Months Ended March 31 | |
|---|---|---|
| | **2020** | **2019** |
| **REVENUES** | $ 1,034 | $ 415 |
| **COST OF REVENUES** | 739 | 488 |
| **GROSS PROFIT (LOSS)** | 295 | (73) |
| **OPERATING EXPENSES:** | | |
| Research and development | 523 | 1,125 |
| Selling and marketing | 624 | 634 |
| General and administrative | 1,169 | 1,298 |
| Total operating expenses | 2,316 | 3,057 |
| **LOSS FROM OPERATIONS** | (2,021) | (3,130) |
| **FINANCIAL EXPENSES (income), net** | (43) | 77 |
| **NET LOSS** | $ (1,978) | $ (3,207) |
| **NET LOSS PER SHARE - basic and diluted** | (0.43) | $ (3.82) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE -** basic and diluted | 4,623,034 | 839,533 |

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

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

| | Common stock | | Series B Convertible Preferred Stock | | Series C Convertible Preferred Stock | | Additional paid-in capital | Accumulated deficit | Total equity |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| **BALANCE AT January 1, 2019** | 768,615 | * | 17,303 | * | 61,423 | * | $ 156,355 | $ (147,592) | $ 8,763 |
| **Net loss** | | | | | | | | (3,207) | (3,207) |
| **Exercise of pre-funded warrants** | 32,034 | * | | | | | 16 | | 16 |
| **Conversion of Series C Convertible Preferred Stock to common shares** | 854 | | | | (2,000) | * | | | |
| **Share-based compensation related to restricted stock and stock options award, net of forfeitures of 212 shares** | 70,369 | * | | | | | 68 | | 68 |
| **BALANCE AT March 31, 2019** | 871,872 | * | 17,303 | * | 59,423 | * | $ 156,439 | $ (150,799) | $ 5,640 |

* 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**
(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** | 3,916,134 | * | 17,303 | * | 34,370 | * | $ 163,015 | $ (157,632) | $ 5,383 |
| **Net loss** | | | | | | | | (1,978) | (1,978) |
| **Exercise of pre-funded warrants** | 270,000 | * | | | | | 3 | | 3 |
| **Settlement of restricted stock units in shares of common stock** | 165,000 | * | | | | | * | | * |
| **Conversion of Series C Convertible Preferred Stock to common shares** | 27,776 | * | | | (7,812) | * | | | |
| **Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 40,000 shares** | (40,000) | * | | | | | 69 | | 69 |
| **BALANCE AT March 31, 2020** | 4,338,910 | * | 17,303 | * | 26,558 | * | $ 163,087 | $ (159,610) | $ 3,477 |

* Represents an amount less than $1 thousand

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

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

| | Three months ended March 31 | |
|---|---|---|
| | **2020** | **2019** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (1,978) | $ (3,207) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 51 | 35 |
| Change in liability for employees rights upon retirement | 32 | 37 |
| Financial income and interest paid | 19 | 5 |
| Lease liability | (31) | 34 |
| Share-based compensation expenses | 69 | 68 |
| Loss on amounts funded in respect of employee rights upon retirement, net | - | 5 |
| Changes in operating asset and liability items: | | |
| Decrease in prepaid expenses | 24 | 15 |
| Decrease (Increase) in trade receivables | (33) | 252 |
| Increase in other receivables | (24) | (82) |
| Decrease (Increase) in inventory | 34 | (313) |
| (Decrease) increase in trade payables | (84) | (57) |
| (Decrease) increase in other payables and contract liability | (433) | (277) |
| Net cash used in operating activities | (2,354) | (3,485) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Purchase of property, plant and equipment | - | (66) |
| Amounts (withdrawn) in respect of employee rights upon retirement, net | (3) | (39) |
| Net cash used in investing activities | (3) | (105) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from exercise of Pre-Funded Warrants | 3 | 16 |
| Net cash provided by financing activities | 3 | 16 |
| **EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS** | (19) | (3) |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | (2,373) | (3,577) |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE PERIOD** | 5,514 | 9,384 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE PERIOD** | $ 3,141 | $ 5,807 |
| **SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:** | | |
| Issuance Costs | $ - | 49 |

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

## NOTE 1 - DESCRIPTION OF BUSINESS

### a. General

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

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

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

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

### b. Liquidity

The Company has an accumulated deficit as of March 31, 2020, as well as a history of net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™ EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company has sufficient resources to fund operations until the end of August 2020. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Management's plans include the continued commercialization of the Company's products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that the Company will be successful in obtaining the level of financing needed for its operations. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations.

### c. COVID-19 Pandemic

During the three months ended March 31, 2020, in an effort to contain and mitigate the spread of a strain of coronavirus, COVID-19, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. Procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, have mostly been postponed as hospitals shift resources to patients affected by COVID-19, and we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures. In addition, most of our sales have historically come from Europe, where the pandemic has had a severe impact. At this point, the extent to which COVID-19 may impact our business cannot be estimated; however, we anticipate that the continuation of the pandemic and related restrictions and safety measures may result in a significant decline in sales of our products for the upcoming periods.

In response to the significant market volatility and uncertainties relating to COVID-19, the Company board of directors, management and most of the employees have taken reductions of compensation as a measure of fiscal responsibility.

**NOTE 2 - BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, the financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2019, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 10, 2020. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of results that could be expected for the entire fiscal year.

**NOTE 3 - EQUITY:**

**a.** During the three months ended March 31, 2020, the Company issued a total of 270,000 shares of its common stock in connection with the exercise of 270,000 Pre-Funded Warrants issued in September 2019. As of March 31, 2020, there are no outstanding Pre-Funded Warrants.

**b.** During the three months ended March 31, 2020, 7,812 shares of Series C Convertible Preferred Stock were converted into 27,776 shares of common stock.

**c.** As of March 31, 2020, the number of preferred shares and the amount each class is convertible into is below:

| | Number of Preferred Stock | Number of underlying Common stock |
|---|---|---|
| Series B Convertible Preferred Stock | 17,303 | 555,138* |
| Series C Convertible Preferred Stock | 26,558 | 94,428 |
| Total | | 649,566 |

* Including the shares of common stock the holders of Series B Convertible Preferred Stock are entitled to receive as cumulative dividends at the rate per share of 15% per annum of the stated value for five years, payable in cash or common stock, at the Company's discretion, but excluding effect of future conversion price adjustment, if any.

As of March 31, 2020, the Company has outstanding warrants to purchase an aggregate of 4,016,597 shares of common stock as follows:

| | Number of underlying Common stock | | Weighted average exercise price |
|---|---|---|---|
| Series A Warrants | 1,102 | $ | 8,750.00 |
| Series B Warrants | 2,448 | $ | 3,500.00 |
| Series D Warrants | 806,698 | $ | 15.19 |
| Series E Warrants | 2,972,221 | $ | 1.80 |
| April 2019 Underwriter Warrants | 34,955 | $ | 6.25 |
| September 2019 Underwriter Warrants | 194,444 | $ | 2.25 |
| Other warrants | 4,729 | $ | 587 |
| | | | |
| Total Warrants | 4,016,597 | $ | 9.77 |

As of March 31, 2020, the Company had 155,000,000 authorized shares of capital stock, par value $0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of "blank check" preferred stock.

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

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

**NOTE 4- NET LOSS PER SHARE:**

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

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units, Series C Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 4,437,453 for the three-month period ended March 31, 2020.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 913,320 for three-month period ended March 31, 2019.

**NOTE 5 - FAIR VALUE MEASURMENT:**

**Fair value of financial instruments**

The carrying amounts of financial instruments included in working capital approximate their fair value either because these amounts are presented at fair value or due to the relatively short-term maturities of such instruments.

As of March 31, 2020, and December 31, 2019, allowance for doubtful accounts was $0.

**NOTE 6 - INVENTORY:**

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| | ($ in thousands) | |
| Finished goods | $ 33 | $ 173 |
| Work in process | 281 | 81 |
| Raw materials and supplies | 888 | 982 |
| | $ 1,202 | $ 1,236 |

**NOTE 7 - ACCOUNTS PAYABLE AND ACCRUALS - OTHER:**

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| | ($ in thousands) | |
| Employees and employee institutions | 729 | 1,238 |
| Accrued vacation and recreation pay | 209 | 188 |
| Accrued expenses | 660 | 604 |
| Provision for sales commissions | 15 | - |
| Current Operating lease liabilities | 367 | 362 |
| Other | 44 | 57 |
| | $ 2,024 | $ 2,449 |

**NOTE 8 - COMMITMENTS AND CONTINGENT LIABILITIES:**

**a. Lease Agreements**

1) The Company's Israeli subsidiary has a lease agreement for a facility in Israel, which expires on December 31, 2020 with an option to extend the agreement for two additional years until December 31, 2022 under the terms stipulated in the agreement (the Option Period). The Option Period was taken in consideration when calculating the operating lease right of use assets and liabilities since it is reasonably certain that the company will exercise the option.

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

b. **Litigation:**

In July 2019, a former distributor filed a suit seeking damages from the Company's subsidiary for pre-paid goods subject to the voluntary field action (from April 2014) amounting to €1,830,000 (which is approximately $2.0 million), or alternatively €1,024,000 (which is approximately $1.1 million). After considering the views of its legal counsel as well as other factors, the Company's management believes that there is a reasonably possible likelihood of a loss from any related future proceedings would range from a minimal amount up to €1,830,000.

**NOTE 9 - DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES**:

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

| | Three months ended March 31 | |
|---|---|---|
| | 2020 | 2019 |
| | ($ in thousands) | |
| Italy | $ 194 | $ 80 |
| Germany | 171 | 128 |
| Poland | 121 | - |
| Russia | 116 | - |
| Other | 432 | 207 |
| | $ 1,034 | $ 415 |

By product:

| | Three months ended March 31 | |
|---|---|---|
| | 2020 | 2019 |
| | ($ in thousands) | |
| CGuard | $ 971 | $ 376 |
| MGuard | 63 | 39 |
| | $ 1,034 | $ 415 |

By principal customers:

| | Three months ended March 31 | |
|---|---|---|
| | 2020 | 2019 |
| Customer A | 16% | 29% |
| Customer B | 16% | 6% |
| Customer C | 12% | - |
| Customer D | 11% | - |
| Customer E | 3% | 13% |

All tangible long lived assets are located in Israel.

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

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

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

**Forward-Looking Statements**

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

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- our ability to regain or maintain compliance with NYSE American listing standards;
- the impact of the recent COVID-19 outbreak on our manufacturing, sales, business plan and the global economy;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- market acceptance of our products;
- negative clinical trial results or lengthy product delays in key markets;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;

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

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

**Overview**

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

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We expect to receive approval to launch CGuard EPS in Brazil, and we are seeking strategic partners for potential launch of CGuard EPS in Japan and China.

In April 2017, we had a pre-investigational device exemption ("IDE") submission meeting with the U.S. Food and Drug Administration ("FDA") regarding CGuard EPS where we presented materials that we believed would support a formal IDE submission seeking approval to conduct a human clinical trial in the United States which included our draft synopsis for the clinical trial design. The FDA agreed to our pre-clinical test plan and clinical trial design. On July 26, 2019, we submitted an IDE application for CGuard EPS. In connection with such application, on August 23, 2019, we received a request for additional information from the FDA in support of our application. We continue to work closely with the FDA to address FDA's information and testing requests in support of our pending IDE application, as the initiation of clinical testing in the U.S. is one of our top priorities. Following resolution of all comments from the FDA, we plan to re-submit the IDE application in May 2020, as IDE approval by the FDA would be a critical step toward the commencement of a human clinical trial using CGuard EPS in the United States.

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

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

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

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

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

**Recent Developments**

*COVID-19 Developments*

In December 2019, a strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China, and has reached multiple other countries, and, on March 12, 2020, the World Health Organization (the "WHO") declared COVID-19 to be a 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. We have not experienced significant COVID-19 related impact on our financial condition and results of operations in the first quarter 2019. However, procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, have mostly been postponed as hospitals shift resources to patients affected by COVID-19. 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 addition, most of our sales have historically come from Europe, where the pandemic has had a severe impact. We anticipate that the continuation of the pandemic and related restrictions and safety measures may result in a significant decline in sales of our products for the upcoming periods. For more discussion on our risks related to COVID-19, please see risk factors included under "Item 1A. Risk Factors" herein.

In response to significant market volatility and uncertainties relating to COVID-19, our board of directors (the "Board") and management have taken the following voluntary reductions of compensation as a measure of fiscal responsibility.

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

On April 21, 2020, Marvin Slosman, our President, Chief Executive Officer and Director, signed a waiver reducing his annual base salary from $400,000 to $200,000 for the period beginning April 1, 2020 and ending on such date as Mr. Slosman shall determine, and Craig Shore, our Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer, signed a waiver reducing his monthly base salary from NIS 80,125 to NIS 40,063 for the period beginning April 1, 2020 and ending on such date as Mr. Shore shall determine. In addition, effective April 1, 2020, we reduced the annual salaries of most of our employees by 20% to 30% until further notice. We expect that such reductions of the base salaries of our employees, including Mr. Slosman and Mr. Shores, will result in a decrease of approximately $300,000 in operating expenses in the second quarter of 2020.

*NYSE American Deficiency*

On August 7, 2019, we received notification from the NYSE American that we do not meet continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (the "Company Guide"). Specifically, we are not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of June 30, 2019, and net losses in our five most recent fiscal years ended December 31, 2018. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide.

On October 11, 2019, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020. We are subject to periodic review during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

**Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 2 of the Notes to the Consolidated Financial Statements included in the Annual Report on Form 10-K for the year ended December 31, 2019. There have not been any material changes to such critical accounting policies since December 31, 2019.

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

**Contingencies**

We and our subsidiaries are involved in legal proceedings that arise from time to time in the ordinary course of business. We record accruals for these types of contingencies to the extent that we conclude the occurrence of such contingencies is probable and that the related liabilities are estimable. When accruing these costs, we recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. Legal costs are expensed as incurred.

**Results of Operations**

*Three months ended March 31, 2020 compared to the three months ended March 31, 2019*

*Revenues*. For the three months ended March 31, 2020, revenue increased by $619,000, or 149.2%, to $1,034,000, from $415,000 during the three months ended March 31, 2019. This increase was predominantly driven by a 158.2% increase in sales volume of CGuard EPS from $376,000 during the three months ended March 31, 2019, to $971,000 during the three months ended March 31, 2020, mainly due to our previous third-party sterilizer equipment failures, which caused a significant interruption in sterilized product supply for the majority of the first quarter 2019 as well as our continued focus in expanding revenue base in our major markets. In addition, MGuard Prime EPS sales increased from $39,000 during the three months ended March 31, 2019, to $63,000 during the three months ended March 31, 2020, due to the delayed shipments of sterilized products during the three months ended March 31, 2019, as mentioned above.

With respect to geographical regions, the increase in revenue was primarily attributable to a $567,000 increase in revenue from sales made in Europe (driven by a $559,000 increase of CGuard EPS sales for reasons discussed in the paragraph above), as well as an increase of $35,000 in revenue from sales made in Asia and Middle East (driven by a $33,000 increase of CGuard EPS sales for reasons discussed in the paragraph above), as well as an increase of $17,000 in revenue from sales of CGuard EPS made in Australia and South Africa.

*Gross Profit (Loss)*. For the three months ended March 31, 2020, gross profit (revenue less cost of revenues) increased by $368,000, to a gross profit of $295,000, compared to a gross loss of $73,000 during the same period in 2019. This increase in gross profit resulted from a $223,000 increase in revenues (as mentioned above), less the related material and labor costs, resulting from delays related to product sterilization interruption during the three months ended March 31, 2019 as discussed above, which did not occur during the three months ended in March 31, 2020, a decrease of $118,000 in write-offs of inventory during the three months ended March 31, 2020 due to the same sterilization issue mentioned above and a decrease of $27,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 28.5% during the three months ended March 31, 2020 from (17.6)% during the three months ended March 31, 2019, driven mainly by delays in product sterilization and write-offs of CGuard EPS inventory during the three months ended in March 31, 2019.

*Research and Development Expenses*. For the three months ended March 31, 2020, research and development expenses decreased by 53.5%, or $602,000, to $523,000, from $1,125,000 during the three months ended March 31, 2019. This decrease resulted primarily from a decrease of $328,000 in clinical expenses associated with CGuard EPS, mainly related to IDE approval process, a decrease of $354,000 due to a settlement expenses made to a former service provider pursuant to settlement agreement during the three months ended March 31, 2019, which did not occur during the three months ended on March 31, 2020 (see Part II, Item 1. “Legal Proceedings” below) and a decrease of $25,000 in miscellaneous expenses. These decreases were partially offset by an increase of $105,000 in development expenses related to CGuard EPS.

*Selling and Marketing Expenses*. For the three months ended March 31, 2020, selling and marketing expenses decreased by 1.6%, or $10,000, to $624,000, from $634,000 during the three months ended March 31, 2019.

*General and Administrative Expenses*. For the three months ended March 31, 2020, general and administrative expenses decreased by 9.9%, or $129,000, to $1,169,000, from $1,298,000 during the three months ended March 31, 2019. This decrease resulted primarily from a decrease of $175,000 in legal expenses due to the reduced need for legal services partially offset by an increase of $46,000 in miscellaneous expenses.

*Financial Expenses (Income)*. For the three months ended March 31, 2020, financial income increased by 155.8%, or $120,000, to $43,000 of financial income, from $77,000 of financial expenses during the three months ended March 31, 2019. The increase in financial income primarily resulted from an increase of $122,000 in financial income related to changes in exchange rates and a decrease of $2,000 in miscellaneous expenses.

*Tax Expenses (Income)*. For the three months ended March 31, 2020, there was no material change in our tax expenses as compared to the three months ended March 31, 2019.

*Net Loss*. Our net loss decreased by $1,229,000, or 38.3%, to $1,978,000, for the three months ended March 31, 2020, from $3,207,000 during the three months ended March 31, 2019. The decrease in net loss resulted primarily from a decrease of $741,000 in operating expenses, an increase of $368,000 in gross profit and an increase of $120,000 in financial income.

**Liquidity and Capital Resources**

We had an accumulated deficit as of March 31, 2020, of approximately $160 million, as well as a net loss of $1,978,000 and negative operating cash flows for the three months ended March 31, 2020. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we only have sufficient resources to fund operations through the end of August 2020. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include continued commercialization of our products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

*Anti-Dilution Provisions*

Our outstanding shares of Series B Preferred Stock and Series C Preferred Stock contain anti-dilution provisions that may result in the reduction of the conversion price thereof in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of additional shares of common stock issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock as a result of anti-dilution adjustments will dilute the interests of other security holders and may depress the price of our common stock. Accordingly, we may find it more difficult to raise additional equity capital while any of our Series B Preferred Stock or Series C Preferred Stock is outstanding. As of May 10, 2020, 17,303 shares of Series B Preferred Stock and 26,558 shares of Series C Preferred Stock were outstanding.

*Three months ended March 31, 2020 compared to the three months ended March 31, 2019*

*General*. At March 31, 2020, we had cash and cash equivalents of $3,141,000, as compared to $5,514,000 as of December 31, 2019. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

For the three months ended March 31, 2020, net cash used in our operating activities decreased by $1,131,000 to $2,354,000, from $3,485,000 during the same period in 2019. The primary reason for the decrease in cash used in our operating activities was a decrease of payments for third party related expenses and for professional services of $975,000 (primarily due to production related payments) and an increase of $323,000 in payments received from customers to $989,000 during the three months ended March 31, 2020, from $666,000 during the same period in 2019. These changes that decreased the cash used in our operating activities were partially offset by an increase of $167,000 paid during the three months ended March 31, 2020 in compensation costs from $1,737,000 in the three months ended March 31, 2019 to $1,904,000 during the same period in 2020 (mainly driven by an increase of $280,000 in termination payments to James Barry, Ph. D., our former chief executive officer, president and director, in connection with his resignation effective December 31, 2019 offset by other payroll and bonus payouts change of $113,000).

Cash used by our investing activities was $3,000 during the three months ended March 31, 2020 compared to $105,000 during the three months ended March 31, 2019. The primary reasons for the decrease in cash used by our investing activities were a decrease of $66,000 in payments made for purchase of property, plant and equipment to $0 during the three months ended March 31, 2020, from $66,000 during the same period in 2019 and a decrease of $36,000 deposited to employee funds to $3,000 during the three months ended March 31, 2020, from $39,000 during the same period in 2019.

Cash provided by financing activities for the three months March 31, 2020 was $3,000, compared to $16,000 during the same period in 2019. The principal source of the cash provided by financing activities during the three months ended March 31, 2020 and March 31, 2019 was the funds received from the exercise of pre-funded warrants that resulted in approximately $3,000 and $16,000, respectively.

As of March 31, 2020, our current assets exceeded our current liabilities by a multiple of 2.1. Current assets decreased by $2,374,000 during the period and current liabilities decreased by $512,000 during the period. As a result, our working capital decreased by $1,862,000 to $2,833,000 as of March 31, 2020.

**Off Balance Sheet Arrangements**

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

**Factors That May Affect Future Operations**

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the impact of the COVID-19 pandemic, cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products. For a discussion of these and other risks that relate to our business, you should carefully review the risks and uncertainties described under the heading "Part II – Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2019, and those described from time to time in our future reports filed with the Securities and Exchange Commission.

The ultimate impact of the COVID-19 pandemic on the Company's operations is unknown and will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the COVID-19 outbreak, 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, 2020, there were no material changes to our contractual obligations and commitments.

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

Not applicable

**Item 4. Controls and Procedures**

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

As of March 31, 2020, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of March 31, 2020.

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

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

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

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

In December 2019, a strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China, and has reached multiple other countries, and, on March 12, 2020, the WHO declared COVID-19 to be a 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. Procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, have mostly been postponed as hospitals shift resources to patients affected by COVID-19, and we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures. In addition, most of our sales have historically come from Europe, where the pandemic has had a severe impact. At this point, the extent to which COVID-19 may impact our business cannot be estimated; however, we anticipate that the continuation of the pandemic and related restrictions and safety measures may result in a significant decline in sales of our products for the upcoming periods.

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

Moreover, we only have sufficient resources to fund operations through the end of August 2020. Consequently, management is pursuing various financing alternatives to fund our operations so we can continue as a going concern. However, the COVID-19 pandemic has created significant economic uncertainty and volatility in the credit and capital markets. Management plans to secure the necessary financing through the issue of new equity and/or the entering into of strategic partnership arrangements; however, there is no assurance that our management will be able to obtain such financing on reasonable terms or at all. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital and on the market price of our common stock, and we may not be able to successfully raise capital through the sale of our securities. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

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

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

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

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

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

**Item 5. Other Information**

Not applicable

**Item 6. Exhibits**

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 3.1 | 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) |

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| 3.9 | Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 4, 2017) |
| 3.10 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017) |
| 3.11 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 22, 2017) |
| 3.12 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018) |
| 3.13 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 1, 2018) |
| 3.14 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 3, 2018) |
| 3.15 | Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on July 5, 2018) |
| 3.16 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019) |
| 10.1+ | First Amendment to General Release and Severance Agreement, dated December 31, 2019, by and between the Company and James J. Barry, Ph.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 6, 2020). |
| 10.2+ | First Amendment to Employment Agreement, dated December 31, 2019, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 6, 2020). |
| 10.3+ | Nonqualified Stock Option Agreement, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K filed on March 9, 2020). |
| 10.4+ | Restricted Stock Unit Award agreement, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.61 to the Annual Report on Form 10-K filed on March 9, 2020). |
| 31.1* | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2* | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101* | The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) the Notes to the Condensed Consolidated Financial Statements |

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

**SIGNATURES**

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

INSPIREMD, INC.

Date: May 11, 2020

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

Date: May 11, 2020

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

**EXHIBIT 31.1**

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

**I, 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 11, 2020

*/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 11, 2020

*/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, 2020 of InspireMD, Inc. (the "Company"). I, Marvin Slosman, the Chief Executive Officer of the Company, certify that, based on my knowledge:**

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

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

Date: May 11, 2020

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

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

**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, 2020, of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer and Principal Financial Officer of the Company, certify that, based on my knowledge:**

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

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

Date: May 11, 2020

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer

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