INSPIREMD, INC.

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

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

Registrant's telephone number, including area code: **(888) 776-6804**

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

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

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 (§ 232.405 of this chapter) 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. [ ]

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2020, based on the price at which the common equity was last sold on the NYSE American on such date, was $15,616,214. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

Indicate the number of shares outstanding of each of the registrant's classes of common stock as of the latest practicable date.

Class	Outstanding at March 8, 2021
Common Stock, $0.0001 par value	117,832,226

Documents incorporated by reference:
None

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PART I

In this Annual Report on Form 10-K, unless the context requires otherwise, the terms "we," "our," "us," or "the Company" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries, including InspireMD Ltd., taken as a whole.

Item 1. Business.

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

*Public Offering*s

On February 8, 2021, we closed an underwritten public offering of 29,032,258 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 "February 2021 Offering"). The offering price to the public was $0.62 per unit. The Series G Warrants were immediately exercisable at a price of $0.682 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 4,354,838 shares of common stock and Series G Warrants to purchase 2,177,419 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 1,669,355 shares of common stock with an exercise price of $0.682 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.

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

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) an SPA, pursuant to which QIDI agreed to invest $900,000 in exchange for shares of our common stock at a purchase price of $0.6708 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 transactions closed on February 5, 2021.

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

Effective as of August 31, 2020, our stockholders approved the Sixth Amendment to the Plan and, accordingly, increased the number of shares of common stock available for issuance pursuant to awards under such Plan by 6,500,000 shares, to a total of 7,178,395 shares of common stock.

Regained Compliance with New York Stock Exchange

On August 7, 2019, we received a notification from the NYSE American that we did not meet the continued listing standards of the NYSE American as set forth in Part 10 of the Company Guide. Specifically, we were not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of September 30, 2019, and net losses in our five most recent fiscal years ended December 31, 2018. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 11, 2019, the NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by August 7, 2020.

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

FDA Approval of IDE

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

ATM Offering

On July 28, 2020, we entered into a Sales Agreement 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 common stock (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.

Registration Clearance for CGuard™ MicroNet® in Brazil

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

New Trial Results for CGuard EPS

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

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

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

Appointment of Dr. Gary Roubin, M.D. to our Board of Directors

On October 12, 2020, our board of directors, or the Board, appointed Dr. Gary S. Roubin as a Class I member of the Board, effective as of that date, with a term expiring at the Company's 2021 annual meeting of stockholders. Dr. Roubin is an internationally renowned interventional cardiologist recognized for his pioneering work in carotid stenting and embolic and protection devices. He is also acknowledged for the development of coronary stenting and the first FDA-approved coronary stent. In connection with his appointment, Dr. Roubin was granted options to purchase 79,650 shares of common stock and 238,950 shares of restricted stock. Shortly after his appointment as a director, and on October 16, 2020, Dr. Roubin invested $100,000 in the Company in exchange for 222,223 units consisting of (i) one share of common stock and (ii) one warrant to purchase our common stock with an exercise price of $0.495. For additional biographical information about Dr. Roubin, please see "Management" herein.

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.

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

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

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

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

Release from Former Underwriter

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

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

As consideration for the final release provided to us, we paid to the prior underwriter $400,000 in cash and reduced, to $0.495, the exercise price per share of warrants to purchase 274,029 shares of our common stock that had been issued by us to the prior underwriter in various offerings that took place between March 2018 and September 2019. That reduced exercise price represents the exercise price for the Series F Warrants that we issued in our June 2020 public offering. The warrants that were repriced had existing exercise prices per share ranging from $187.50 to $2.25 and a weighted average exercise price per share of $7.32. All other terms of those warrants remained unchanged. The related increase in expenses of $400,000 was recorded during the three months ended June 30, 2020 to "General and Administrative expense" within the Consolidated Statements of Operations.

Our Industry

Carotid

Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. Carotid artery disease, also called carotid artery stenosis, is a type of atherosclerosis (hardening of the arteries) that is one of the major risk factors for ischemic stroke. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply to the brain. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke. According to the World Health Organization (https://www.who.int/cardiovascular_diseases/resources/atlas/en/) every year, 15 million people worldwide suffer a stroke, and nearly six million die and another five million are left permanently disabled. According to the same source, stroke is the second leading cause of disability, after dementia.

In 2017, 2.2 million people were diagnosed with carotid artery disease, of which, approximately 600,000 patients had high grade carotid stenosis requiring intervention for carotid artery disease *(2017 Health Research International Market Report*). Carotid artery stenting is a minimally invasive treatment option for carotid artery disease and an alternative to carotid endarterectomy, where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and carotid embolic prevention system protect against plaque and debris traveling downstream, blocking off the vessel and disrupting blood flow. We believe that the use of a stent with an embolic protection system should increase the number of patients being treated since it would avoid the need for complex surgery.

Coronary

Physicians and patients may select from a variety of treatments to address coronary artery disease, including pharmaceutical therapy, balloon angioplasty, stenting with bare metal or drug-eluting stents, and coronary artery bypass graft procedures, with the selection often depending upon the stage of the disease.

The global market for coronary stents is estimated at $5.5 billion and projected to grow to $8 billion by 2025. (Global Market Insights, Inc. Nov 06, 2019). Growth will be driven by a continued increases in incidence (Coronary heart disease burden is projected to rise from around 47 million DALYs globally in 1990 to 82 million DALYs (Disability Adjusted Life Year)in 2020 – WHO Global Burden of Coronary Heart Disease) – especially in developing countries). However, this market is dominated by drug eluting stents (DES) which limits the opportunity for MGuard.

Neurovascular

The neurovascular market focuses on catheter-delivered products used to treat strokes that already happened or unruptured brain aneurysms that could lead to strokes. In the latter case, coils are wound into blood vessel bulges to block blood flow entering the aneurysms to prevent the aneurysms from rupturing. Endovascular treatment of arterial aneurysm has evolved substantially over the past two decades, transitioning from an investigational therapy into routine clinical practice and ultimately emerging as the treatment of choice for many lesions *(source: Medtech Ventures 2009, Aneurysm Flow Modulating Device Market)*. We believe that the market for aneurysm flow modulating devices is still in the embryonic stage with windows of opportunities for early entrance.

The neurovascular market includes over-the-wire, flow-guided microcatheters, guiding catheters, coil and liquid embolics, neurovascular stents and flow diversion stents. According to iData Research, the market is expected to be driven by the conversion from surgical procedures to endovascular techniques in the treatment of aneurysms and arteriovenous malformations.

Peripheral

Peripheral vascular diseases ("PVD") are caused by the formation of atherosclerotic plaques in arteries, which carry blood to organs, limbs and head. It is also known as peripheral artery occlusive disease or peripheral artery disease. It comprises diseases pertaining to both peripheral veins and peripheral arteries, affecting the peripheral and cardiac circulation in the body. PVD includes diseases outside of the heart and brain, but most times refers to the leg and foot.

Peripheral stents are more often used in combination with balloon angioplasty to open the veins, so that blood can flow through the blocked veins in the body.

The growing prevalence of PVD is expected to cause increased demand for treatment options. PVD is age related and its prevalence increases markedly with advancing age. In addition PVD is more prevalent in lower and medium income countries than in higher income countries (https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(19)30255-4)

Our Products

Below is a summary of our current products and products under development, and their intended applications.

MicroNet

MicroNet is our proprietary circular knitted mesh which wraps around a stent to protect patients from plaque debris flowing downstream upon deployment. MicroNet is made of a single fiber from a biocompatible polymer widely used in medical implantations. The size, or aperture, of the current MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus.

CGuard – Carotid Applications

Our CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) in a single device for use in carotid artery applications. MicroNet is placed over and attached to an open cell nitinol metal stent platform which is designed to trap debris and emboli that can dislodge from the diseased carotid artery and potentially travel to the brain and cause a stroke. This danger is one of the greatest limitations of carotid artery stenting with conventional carotid stents and stenting methods. The CGuard EPS technology is a highly flexible stent system that conforms to the carotid anatomy.

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical endarterectomy, given the superior embolic protection characteristics provided by the MicroNet. We believe the MicroNet will provide acute embolic protection at the time of the procedure, but more importantly, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur up to 48 hours post-procedure. It is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain. Schofer, et al. ("Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

Our CGuard EPS with over-the-wire delivery system received CE mark approval in the European Union in March 2013. In October 2014, we initiated a limited market release of CGuard EPS with over-the-wire delivery system for use in carotid artery applications in Germany, Poland and Italy.

In September 2014, we reported the results of the CGuard CARENET trial at the Transcatheter Cardiovascular Therapeutics ("TCT") conference in Washington D.C. In the CARENET trial, the CGuard EPS system demonstrated better results over historical data using conventional commercially available carotid stents. In the third quarter of 2015 the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve-month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

In the first quarter of 2015, we introduced CGuard RX, the new rapid exchange delivery system for CGuard EPS. The rapid exchange delivery system has a guidewire that passes through the delivery system, running through the guiding catheter. It has one port, and thus, can be operated by one operator, while an over-the-wire-delivery system has two lumens and ports and requires two operators to perform the procedure. Our rapid exchange delivery system received CE mark approval in January 2015. We launched our CGuard EPS in Europe with the rapid exchange delivery system in multiple medical specialties that perform carotid artery stenting. These customers include interventional cardiologists, vascular surgeons, interventional neuroradiologists and interventional radiologists.

In September 2015, we announced 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. In September, 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020, and we are seeking strategic partners for a potential launch of CGuard EPS in Japan and China.

In April 2017, we had a pre-IDE submission meeting with the 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. On September 8, 2020, we received IDE approval for CGuard™ Carotid Stent System, CARENET-III.

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

MGuard Products– Coronary Applications

Bare-Metal Stent MGuard Product. Our MGuard Prime EPS coronary product is comprised of MicroNet wrapped around a cobalt-chromium based bare-metal stent. In comparison to a conventional bare-metal stent, we believe our MGuard Prime EPS coronary product with MicroNet mesh provides protection from dangerous embolic showers in patients experiencing ST-segment elevation myocardial infarction, the most severe form of a heart attack, referred to as STEMI. Standard stents were not engineered for heart attack patients. Rather, they were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient. In acute heart attack patients, the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages in a significant portion of heart attack patients. Our MGuard Prime EPS is integrated with a precisely engineered micro net mesh that is designed to prevent the unstable arterial plaque and thrombus that caused the heart attack blockage from breaking off.

NGuard — Neurovascular Applications

We began developing a neurovascular flow diverter, which we refer to as NGuard, which is an endovascular device that diverts blood flow away from cerebral aneurysms and ultimately seals the aneurysms. We have tested early flow diverter prototypes in initial pre-clinical testing in both simulated aneurysm bench models using various MicroNet configurations with varying aperture sizes, as well as in standard in vivo pre-clinical models, in which we observed aneurysm sealing and also wide open side branch vessels across which the device was placed. We have suspended all further development activity of NGuard until we obtain sufficient funding for such purpose.

PVGuard — Peripheral Vascular Applications

We intend to develop our MicroNet mesh sleeve and a self-expandable stent for use in peripheral vascular applications, to which we refer to as PVGuard. PVDs are usually characterized by the accumulation of plaque in arteries in the legs. This accumulation can lead to the need for amputation or even death, when untreated. PVD is treated either by trying to clear the artery of the blockage, or by implanting a stent in the affected area to push the blockage out of the way of normal blood flow.

As in carotid procedures, peripheral procedures are characterized by the necessity of controlling embolic showers both during and post-procedure. Controlling embolic showers is so important in these indications that physicians often use fully covered stents, at the risk of blocking branching vessels, to ensure that emboli do not fall into the bloodstream and move to the brain. We believe that our MicroNet design will provide substantial advantages over existing therapies in treating peripheral artery stenosis.

However, as we plan to focus our resources on the further expansion of our sales and marketing activities for CGuard EPS and, provided that we have sufficient resources, potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods and/or provide the best-in-class performing delivery system and its submission for CE mark approval, we do not intend to pursue the development of PVGuard in the near future.

Completed Clinical Trials for CGuard EPS

CARENET

The CARENET trial was the first multi-center study of CGuard EPS following the receipt of CE mark of this device in March 2013. The CARENET trial was designed to evaluate feasibility and safety of CGuard EPS in treatment of carotid lesions in consecutive patients suitable for coronary artery stenting ("CAS") in a multi-operator, real-life setting. The acute, 30 day, magnetic resonance imaging ("MRI"), ultrasound and six month clinical event results were presented at the LINC conference in Leipzig, Germany in February, 2015. In the third quarter of 2015, the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months.

MACCE (myocardial infarction ("MI"), stroke or death) rate was 0.0% at 30 days. At six months, there was one death, which was not device or procedure-related but did result in a MACCE rate of 3.6% at six months. At twelve months there were two additional deaths, which were not device or procedure-related resulting in a MACCE rate of 10.7% at one year.

	30 days (n=30)	**6 months (n=28)**	**12 months (n=28)**
MACCE (MI, stroke, death)	(0) 0.0%	(1) 3.6%	(3) 10.7%
MI	(0) 0.0%	(0) 0.0%	(0) 0.0%
stroke	(0) 0.0%	(0) 0.0 %	(0) 0.0%
death	(0) 0.0%	(1) 3.6%	(3) 10.7%

CAS carries the risk of cerebral embolization during and following the procedure, leading to life-threatening complications, mainly cerebral ischemic events. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a sensitive tool used to identify cerebral emboli during CAS by measuring "lesions" within the brain which are areas that are ischemic and do not receive oxygenated blood due to cerebral emboli. In the CARENET trial, 37.0% of patients treated with CGuard EPS had new ischemic lesions at 48 hours after the procedure, with an average volume of 0.039 cm3. Of these lesions, there was only one that remained at 30 days following the procedure and all others had resolved. Complete details appear in the following table. Where there is a second number shown below after a ± symbol, it indicates the potential error in the measurement.

	48 hours n=27	**30 days n=26**
Subjects with new Acute Ischemic Lesions ("AIL")	10	1
Incidence of new lesions	37.0%	4.0%
Total number new AIL	83	1
Avg. number new AIL per patient	3.19 ± 10.33	0.04 ± 0.20
Average lesion volume (cm^3)	0.039 ± 0.08	0.08 ± 0.00
Maximum lesion volume (cm^3)	0.445	0.116
Permanent AIL at 30 days	—	1

The healing process of the tissue and in-stent restenosis can be measured by a non-invasive form of ultrasound called duplex ultrasound. This type of ultrasound measures the velocity of the blood that flows within the carotid arteries, which increases exponentially as the lumen of the internal carotid artery narrows and the percent stenosis increases. One of the measurements is called PSV (peak systolic volume) and is known to be highly correlated to the degree of in-stent restenosis; PSV values higher than 300 cm/sec are indicative of >70% stenosis, while PSV values lower than 104 cm/sec are indicative of <30% restenosis and healthy healing. In the CARENET trial, duplex ultrasound measurements done at 30 days, 6 months and 12 months following the stenting procedure all attest to healthy normal healing without restenosis concerns, as the PSV values were 60.96 cm/sec ± 22.31, 85.24 cm/sec ± 39.56, and 90.22 cm/sec ± 37.72 respectively. The internal carotid artery was patent in all patients (100%).

The conclusions of the CARENET trial were:

- The CARENET trial demonstrated safety of the CGuard EPS stent, with a 30 day MACCE rate of 0%.
- Incidence of new ipsilateral lesions (percent of patients with new lesions on the ipsilateral side (same side where the stent was employed)) at 48 hours was reduced by almost half compared to published data, and volume was reduced almost tenfold.
- All but one lesion had resolved completely by 30 days.
- Twelve month data showed no stroke or stroke-related deaths, and no cardiac adverse events.
- CGuard EPS offers enhanced benefits for patients undergoing CAS with unprecedented safety.

Physician-Sponsored Clinical Trials for CGuard—PARADIGM-101 Study

PARADIGM-101 (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization **I**n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C**G**uard™ **M**esh-covered embolic prevention stent system-101) was an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine use of CGuard EPS in 101 consecutive unselected all-comer patients referred for carotid revascularization, initiated in 2015. In May 2016, the 30-day results were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, and in the Journal of EuroIntervention.

Key findings from the PARADIGM-101 study and the follow-up data are as follows:

- CGuard EPS delivery success was 99.1%. The clinical evaluation also found no device foreshortening or elongation;
- Angiographic diameter stenosis or vessel narrowing was reduced from 83±9% to only 6.7±5% ($p<0.001$);
- Periprocedural death/major stroke/ myocardial infarction ("MI") rates were 0%;
- One event was adjudicated by the Clinical Events Committee as a minor stroke (0.9%), with no change in NIH Stroke Scale or modified Ranking scale;

The results of the PARADIGM-101 study demonstrated that CGuard EPS can safely be used in a high risk, all-comer population of patients with carotid artery stenosis and indicated that routine use of CGuard EPS may prevent cerebral events, such as strokes, by holding plaque against the vessel wall, preventing emboli from being released into the blood stream. The PARADIGM-101 study found that CGuard EPS is applicable in up to 90% of all-comer patients with carotid stenosis.

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study

"Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study" was an investigator-led, prospective single-center study which evaluated CGuard EPS in 30 consecutive patients with internal carotid artery stenosis disease with the objective of reporting early clinical outcomes with a novel MicroNet covered stent for the internal carotid artery and the in vitro investigation of the device's mechanical properties. In October 2016, the 30-day positive results were published online-ahead-of-print in the Journal of Endovascular Therapy.

Key findings from the study are as follows:

- 100% success in implanting CGuard EPS without residual stenosis;
- No peri- or post-procedural complications;
- No deaths, major adverse events, minor or major strokes, or new neurologic symptoms during the six months following the procedure;
- Modified Rankin Scale improved for the symptomatic patients from 1.56 prior to the procedure to 0 afterwards;
- All vessels treated with CGuard EPS remained patent (open) at six months; and
- DW-MRI performed in 19 of 30 patients found no new ipsilateral lesions after 30 days and after six months compared with the baseline DW-MRI studies.

Additionally, based on engineering evaluations, the study concluded that CGuard EPS provides a high radial force and strong support in stenotic lesions. The stent is easy to use and safe to implant because it does not foreshorten and its structure adapts well to changes in diameter and direction of tortuous vascular anatomies. The MicroNet mesh of CGuard did not cause any changes to specific mechanical parameters of the underlying stent.

CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry

"CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry using CGuard EPS" was a physician initiated prospective multi-center registry that included 200 patients from 12 medical centers in Italy. The objective of the study was to report 30-day outcomes (including MACCE) in a prospective series of patients who were treated with CGuard EPS between April 2015 and June 2016. In January 2017, 30-day results were presented at the Leipzig Interventional Course (LINC) 2017 and published in the Journal of EuroIntervention in May 2017. The 12 month follow-up was published in the Journal of EuroIntevention in October 2018.

Key 30-day results presented were:

- 100% success in implanting CGuard EPS;
- No MI, major stroke or death at 30 days;
- There were two transient ischemic attacks and five periprocedural minor strokes, including one thrombosis solved by surgery.
- Total elimination of post-procedural neurologic complications by 30 days;
- DW-MRI performed pre-procedure and between 24 and 72 hours post-procedure in 61 patients, indicated that 12 patients had new micro emboli (19%).
- At 12 months, there were no new major neurological adverse events, thrombosis or external carotid occlusion recorded;
- One myocardial infarction occurred at 12 months.

Peri-procedural brain lesions prevention in CAS (3PCAS): Randomized trial comparing CGuard stent vs. WallStent™ Study

3PCAS study was an independent investigator-led single center randomized clinical trial, comparing CGuard EPS vs. WallStent™, intended to evaluate the incidence of peri-procedural diffusion-weighted-magnetic-resonance-imaging (DW-MRI) new brain lesions after carotid artery stenting. Sixty-one consecutive patients referred for carotid revascularization (between January 2015 and October 2016) were eligible for the study. The results of the 3PCAS study was published in the International Journal of Cardiology in September 2018. The discussion distinguished between peri-procedural (from procedure to 48h -72h) and post-procedural periods (72h to 30 days) where the CGuard EPS demonstrated a reduction in the post-procedural embolic effect during the carotid plaque healing period. In contrast, there was no difference between the two stent groups during the peri-procedural stage because of, according to the published article, the presence of bilateral/contralateral lesions (lesions resulting from the contralateral artery from the non-treated carotid) which suggest that the peri-procedural neurological damage may have originated from extra-carotid sources (outside of the artery which was treated and outside the stent itself).

Initial Clinical Study of the New CGuard EPS MicroNet Covered Carotid Stent: "One Size Fits All"

"Initial Clinical Study of the New CGuard EPS MicroNet Covered Carotid Stent: 'One Size Fits All'" was an investigator-led, single-center study, which evaluated CGuard EPS in 30 consecutive patients with symptomatic stenosis of the internal carotid artery with the objective of evaluating the CGuard EPS MicroNet covered stent for its ability to adjust to different vessel diameters. The results of the study were published in the Journal of Endovascular Therapy in May 2019. The conclusion of the study as reported was that CGuard EPS has high conformability combined with an almost equivalent outward radial force at expansion diameters ranging from 5.5 to 9.0 mm. The first clinical results demonstrate the "One Size Fits All" stent can be implanted in internal carotid arteries with reference diameters within this range.

Key findings from the study were as follows:

- 100% technical success in implanting CGuard EPS;
- No neurological events within 30 days;
- The chronic outward force normalized by stent length demonstrated a near-equivalent radial force outcome; and
- The stent displayed only a minor difference between the minimal radial force at 9.0 mm (0.195 N/mm) and the maximal radial force at 5.5 mm (0.330 N/mm).

Preliminary Results from a Prospective Real-World Multicenter Clinical Practice of Carotid Artery Stenting Using the CGuard Embolic Prevention System: The IRONGUARD 2 Study

"Preliminary Results From a Prospective Real-World Multicenter Clinical Practice of Carotid Artery Stenting Using the CGuard Embolic Prevention System: The IRONGUARD 2 Study" is a physician initiated prospective multi-center registry enrolling 733 patients from 20 medical centers in Italy, from January 2017 to June 2019. The objective of the study is to evaluate periprocedural (24 hours), post-procedural (up to 30 days), and 12-month outcomes in a largest, prospective, multicenter series of patients submitted for protected carotid artery stenting with the CGuard Embolic Prevention System. The 24-hour, 30-day and 12-month preliminary results (data available on 726 patients out of the 733 treated) were presented at the Leipzig Interventional Course (LINC) in January 2021. The study's preliminary results from the IRONGUAURD 2 study suggested in a real-world evaluation of carotid artery stenting, Cguard EPS can be safely used for treatment of extracranial carotid artery stenosis, allowing a low rate of post procedural adverse events by 12 months.

Key findings from the study are as follows:

- 100%% procedural success in implanting CGuard EPS;
- 1 death from hemorrhagic stroke (patient was admitted for immediate treatment of CAS due to stroke), 2 minor strokes, 6 TIAs and one nonfatal AMI at 24 hours;

  1 minor stroke, 2 TIAs, three AMIs, no deaths and no stent thrombosis/occlusions between 24 hours and 30 days; and
- 1 minor stroke, 4 TIAs, 2 AMIs and 8 deaths (the 2 mentioned AMIs, 4 malignancies, 1 suicide and 1 undefined complication in Guillain-Barré Syndrome) between 30 days and 1 year.

The SIBERIA Trial for Carotid Artery Stenosis: A Randomized Controlled Trial of Conventional Versus Micronet™-Covered Stent Use in Percutaneous Neuroprotected Carotid Artery Revascularization: Peri-procedural and 30-day Diffusion-Weighted Magnetic Resonance Imaging and Clinical Outcomes

"The SIBERIA Trial for Carotid Artery Stenosis: A Randomized Controlled Trial of Conventional Versus Micronet™-Covered Stent Use in Percutaneous Neuroprotected Carotid Artery Revascularization: Peri-procedural and 30-day Diffusion-Weighted Magnetic Resonance Imaging and Clinical Outcomes" was an investigator-initiated randomized clinical trial, single-center study, which evaluated one hundred patients who qualified for carotid revascularization with high risk for surgery and were randomized 1:1 to either CGuard EPS or Acculink™. The primary endpoints were incidence and volume of new cerebral embolic post-procedural lesions (24-48 hours) as determined by diffusion weighted magnetic resonance imaging (DW-MRI). The principal secondary endpoints included incidence of periprocedural or postprocedural stroke, myocardial infarction and death at 30 days. The results of the study were presented in a late-breaking session at the EuroPCR in June 2020. The conclusion of the study was that the CGuard™ Micronet™-covered stent use in consecutive unselected patients subjected to neuroprotected carotid artery stenting was associated with a greater than three-fold reduction in the procedure-generated mean cerebral lesion volume, and with zero post-procedural cerebral embolisms observed.

Key findings from the study are as follows:

- Post Procedure (24-48 hours), the CGuard™ arm was observed to have a 78% reduction in the average volume of new cerebral lesions (157 mm3 vs. 700 mm3), a statistically significant improvement (p=0.007;
- At 30 days, DW-MRI showed zero new cerebral lessons in the CGuard™ arm versus six in the Acculink™ arm (p=0.03);
- At 30 days, there were zero strokes, myocardia infarctions or deaths in the CGuard arm and three events the Acculink™ arm (two strokes and one myocardial infarction).

Completed Clinical Trials for MGuard Bare-Metal Coronary Products

We have completed eight clinical trials with respect to our first generation stainless steel-based MGuard coronary device and our cobalt-chromium based MGuard Prime EPS stent. Our first generation MGuard stent combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union in October 2007. We subsequently replaced the stainless steel stent with a more advanced cobalt-chromium based stent for MGuard Prime EPS.

The First in Men (FIM) study conducted in Germany from the fourth quarter of 2006 through the second quarter of 2008 focused on patients with occlusion in their stent graft. This group is considered to be in "high risk" for complications during and shortly after the procedure due to the substantial risk of occurrence of a thromboembolic event. The study demonstrated MGuard's safety in this high risk group. This study was followed by the GUARD study in Brazil in 2007 with a similar patient population which reinforced the safety profile of MGuard in patients prone to procedural complications. The MAGICAL study was a pilot study in STEMI patients conducted in Poland from 2008 through 2012 which demonstrated safety, measured by MACE rates at 30 days following the procedure, as well as efficacy results, measured by the ability of MGuard to reestablish blood flow into the infarcted area of the muscle. Furthermore, we conducted three registries (iMOS, IMR and iMOS Prime) that confirmed the feasibility of MGuard and MGuard Prime EPS for the treatment of STEMI patients and the safety of MGuard and MGuard Prime EPS in the STEMI patient group. Safety was repeatedly demonstrated in these trials and registries by the low mortality rate in the first month after the procedure.

In the second calendar quarter of 2011, we began the MGuard for Acute ST Elevation Reperfusion Trial (which we refer to as our "MASTER I trial"), a prospective, randomized study, which demonstrated that among patients with acute STEMI undergoing emergency PCI, patients treated with MGuard had superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution, or restoration of blood flow to the heart muscle after a heart attack, compared to those treated with commercially-approved bare metal or drug-eluting stents. The results of this trial are summarized in greater detail below.

Finally, the MASTER II trial, which we initially initiated as part of our efforts to seek approval of our MGuard Prime EPS by the FDA, was discontinued at our election in its current form in light of market conditions moving toward the use of drug-eluting stents over bare-metal stents. Analysis of the patients already enrolled in the MASTER II trial prior to its suspension, however, reconfirmed the MASTER I safety results due to a continued low mortality rate.

MASTER I Trial

In the second calendar quarter of 2011, we began the MASTER I trial, a prospective, randomized study in Europe, South America and Israel to compare the MGuard with commercially-approved bare metal and drug-eluting stents in achieving superior myocardial reperfusion (the restoration of blood flow) in primary angioplasty for the treatment of acute STEMI, the most severe form of heart attack. The MASTER I trial enrolled 433 subjects, 50% of whom were treated with MGuard and 50% of whom were treated with a commercially-approved bare metal or drug-eluting stents. The detailed acute and 30 days results from the trial were presented at the TCT conference on October 24, 2012 and published (Prospective, Randomized, Multicenter Evaluation of a Polyethylene Terephthalate Micronet Mesh–Covered Stent (MGuard) in ST-Segment Elevation Myocardial Infarction, Stone et. al, *JACC*, 60; 2012). The results were as follows:

- The primary endpoint of post-procedure complete ST-segment resolution (restoration of blood flow to the heart muscle after a heart attack) was statistically significantly improved in patients randomized to the MGuard compared to patients receiving a commercially-approved bare metal or drug-eluting stent (57.8% vs. 44.7%).

- Patients receiving MGuard exhibited superior rates of thrombolysis in myocardial infarction (TIMI) 3 flow, which evidences normal coronary blood flow that fills the distal coronary bed completely, as compared to patients receiving a commercially-approved bare metal or drug-eluting stent (91.7% vs. 82.9%), with comparable rates of myocardial blush grade 2 or 3 (83.9% vs. 84.7%) and corrected TIMI frame count (cTFC) (17.0 vs. 18.1

- Angiographic success rates (attainment of <50% final residual stenosis of the target lesion and final TIMI 3 flow) were higher in the MGuard group compared to commercially-approved bare metal or drug-eluting stents (91.7% vs 82.4%).

- Mortality (0% vs. 1.9%) and major adverse cardiac events (1.8% vs. 2.3%) at 30 days post procedure were not statistically significantly different between patients randomized to MGuard as opposed to patients randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between the MGuard and commercially-approved bare metal or drug-eluting stents.

The six month results from the MASTER I trial were presented at the 2013 EuroPCR Meeting, the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions, on May 23, 2013 in Paris, France. The results were as follows:

- Mortality (0.5% vs. 2.8%) and major adverse cardiac events (5.2% vs. 3.4%) at 6 months post procedure were not statistically significantly different between patients randomized to the MGuard as compared to patients randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac event components, as well as stent thrombosis, were comparable between patients treated with MGuard and those treated with commercially-approved bare metal or drug-eluting stents.

The twelve month results from the MASTER I trial were presented at the TCT conference on October 29, 2013 and published (Mesh-Covered Embolic Protection Stent Implantation in ST-Segment–Elevation Myocardial Infarction Final 1-Year Clinical and Angiographic Results From the MGUARD for Acute ST Elevation Reperfusion Trial, Dudek et. al, *Coronary Interventions*, 2014). The results were as follows:

- Mortality (1.0% vs. 3.3%) and major adverse cardiac events (9.1% vs. 3.3%) at 12 months post procedure were not statistically significantly different between patients randomized to the MGuard as opposed to those randomized to commercially-approved bare metal or drug-eluting stents. All other major adverse cardiac events, as well as stent thrombosis, were comparable between the MGuard and commercially-approved bare metal or drug-eluting stents.

In summary, the MASTER I trial demonstrated that among patients with acute STEMI undergoing emergency PCI patients treated with MGuard had superior rates of epicardial coronary flow (blood flow within the vessels that run along the outer surface of the heart) and complete ST-segment resolution compared to those treated with commercially-approved bare metal or drug-eluting stents. In addition, patients treated with MGuard showed a slightly lower mortality rate and a slightly higher major adverse cardiac event rate as compared to patients treated with commercially-approved bare metal or drug-eluting stents six and twelve months post procedure.

A detailed table with the results from the MASTER I trial is set forth below. The "p-Value" refers to the probability of obtaining a given test result. Any p value less than 0.05 is considered statistically significant.

	MGuard	Bare Metal Stents/Drug Eluting Stents	p-Value
Number of Patients	217	216	—
TIMI 0-1	1.8	5.6	0.01
TIMI 3	91.7	82.9	0.006
Myocardial blush grade 0-1	16.1	14.8	0.71
Myocardial blush grade 3	74.2	72.1	0.62
ST segment resolution >70	57.8	44.7	0.008
30 day major adverse cardiac event	1.8	2.3	0.75
6 month major adverse cardiac event	5.2	3.4	0.34
12 month major adverse cardiac event	9.1	3.3	0.02

Future Clinical Trials for CGuard EPS and MGuard Prime EPS

Post-marketing clinical trials (outside the United States) could be conducted to further evaluate the safety and efficacy of CGuard EPS in specific indications. These trials would be designed to facilitate market acceptance and expand the use of the product. We expect to be able to rely upon CE mark approval of the product and other supporting clinical data to obtain local approvals.

We do not anticipate conducting additional post-marketing clinical trials for our bare-metal MGuard coronary products.

Growth Strategy

Our primary business objective is to utilize our proprietary MicroNet technology and products to become the industry standard for treatment of stroke, complex vascular and coronary disease and to provide a superior solution to the common acute problems caused by current stenting procedures, such as restenosis, embolic showers and late thrombosis. We are pursuing the following business strategies to achieve this objective.

- **Widen the adoption of CGuard EPS**. We are seeking to expand the population of CGuard EPS patients in those countries in which CGuard EPS is commercially available. In particular, our focus is on establishing CGuard EPS as a viable alternative (in appropriate cases) to conventional carotid stents and vascular surgery within the applicable medical communities. We intend to accomplish this goal by continuing to publish and present our clinical data, support investigator-initiated clinical registries and exploring addition of a procedural protection device to our portfolio incorporating the principal of reverse flow of the carotid artery as an adjuctive alternative to femoral access. We have partnered and will continue to seek out partnerships with organizations focused on the treatment of stroke. We will also continue to engage advisory boards and to develop a network of key opinion leaders to assist us in our efforts to widen the adoption of CGuard EPS.

- **Grow our presence in existing and new markets for CGuard EPS.** We have launched CGuard EPS in most European and Latin American countries through a comprehensive distributor sales organizations network. We are continuing to focus on larger growing markets through this network by supporting our distributors with a comprehensive marketing and clinical education programs. In November 2018, we obtained approval for reimbursement and commercial sale for CGuard EPS in Australia and immediately launched the product. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, Asia and Latin America.

- **Continue to leverage our MicroNet technology to develop additional applications for interventional cardiologists and vascular surgeons.** In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary MicroNet technology to address imminent market needs for new product innovations to significantly improve patients' care. We continue to broadly develop and protect intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease, neurovascular disease, renal artery disease and bifurcation disease.

- **Establish relationships with collaborative and development partners to fully develop and market our existing and future products.** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and MGuard DES, and other potential products that are based on our MicroNet technology.

- **Resume development and successfully commercialize MGuard DES.** While we have limited the focus of product development to our carotid products, if we resume development of our coronary products, we plan to evaluate opportunities to further develop MGuard DES.

- **Portfolio expansion and pipeline development** We will continue to invest in advancing our portfolio with new delivery system alternatives to facilitate the use of CGuard by all physicians. Our delivery systems will enable all endovascular access points including accessory devices for Arterial Venous (AV) shunting**.**

Competition

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants.

Carotid

The carotid stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), and Cordis Corporation (currently part of Cardinal Health, Inc.). Gore Medical and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent, respectively. All of these larger companies have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have established reputations and relationships with our target customers, as well as worldwide distribution methods that are more effective than ours. However, we believe that the European market is somewhat fragmented, and, in our opinion, smaller competitors may be able to gain market share with greater flexibility.

Coronary

The bare-metal stent and the drug-eluting stent markets in the United States and Europe are dominated by Abbott Laboratories, Boston Scientific Corporation, and Medtronic, Inc. In Europe, the market is now almost exclusively dominated by drug eluding stents and is rapidly becoming so in the rest of the world. (Catheter Cardiovasc Interv. 2018 Oct 1;(92(4):E262-E270. doi: 10.1002/ccd.27375. Epub 2017 Oct 13. https://www.ncbi.nlm.nih.gov/pubmed/29027735). We believe physicians look to next-generation stent technology to compete with existing therapies. Such next-generation technologies include bio-absorbable stents, stents that focus on treating bifurcated lesions, and stents with superior polymer and drug coatings, and many industry participants are working to improve stenting procedures as the portfolio of available stent technologies rapidly increases.

According to the MEDTECH OUTLOOK, the three major players (Abbott Laboratories, Boston Scientific Corporation and Medtronic, Inc.) in the worldwide coronary stent market have a combined total market share of approximately 92%. To date, our sales are not significant enough to register in market share. As such, one of the challenges we face to further our product growth is the competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. Due to ongoing consolidation in the industry, there are high barriers to entry for small manufacturers in the European and the U.S. markets and the rest of the world.

Neurovascular

Leading industry players in the global neurovascular devices market include Medtronic, Stryker, Terumo and Johnson & Johnson. Acquisitions and mergers are increasingly used as a strategy for product portfolio expansion and to grow footprint. (Global Market Insights, Inc. - Devices Market Share 2018-2024 Industry Size Report. https://www.gminsights.com/industry-analysis/neurovascular-devices-market)

Sales and Marketing

Sales and Marketing

Based on the positive CGuard EPS clinical data, we initiated the commercial launch of CGuard EPS in CE marked countries in early 2015. In September 2015, we announced full market launch of CGuard EPS in Europe.

In 2017, we decided to shift our commercial strategy to focus on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Our current strategy seeks to broaden our sales efforts to transition vascular surgeons from carotid endarterectomy procedures to carotid stenting with CGuard EPS, which we believe can greatly expand our customer base. We have focused and we plan to continue to focus our marketing efforts primarily on key growth markets and to evaluate opportunities in new territories if and when they become available. In addition, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We continue to work with leading physicians to enhance our marketing effort and are developing relationships with new key opinion leaders to champion our technology and work with us in clinical studies

Currently, we are actively selling our MGuard coronary products with a bio-stable MicroNet through local distributors in Europe, Latin America, the Middle East and Asia.

Product Positioning

When treating carotid artery disease, we believe that there is an opportunity to enter the market with bare-metal stent platform and to become a competitive player without a drug-eluting stent platform. Therefore, we believe that CGuard EPS is poised for commercial growth in 2020 as more and more positive clinical data is presented.

Additionally, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods or provide the best-in-class performing delivery system. 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. Finally, we do not expect that it would be crucial to use a drug-eluting stent platform to compete in certain new markets such as the neurovascular market, and hence, we plan to continue to explore this area of opportunity.

The MGuard coronary products have initially penetrated the market by entering segments with indications that present high risks of embolic dislodgement, notably acute MI and saphenous vein graft coronary interventions. Even though MGuard technology has demonstrated its advantages with clinical data, it is based on a bare-metal platform while the market demand has shifted away from bare-metal stents in favor of drug-eluting stents.

Insurance Reimbursement

In most countries, a significant portion of a patient's medical expenses is covered by third-party payors. Third-party payors can include both government funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, payors, in many instances, have similarly established policies, and in the U.S., for example, coverage policies and reimbursement rates of private payors are often influenced by those established by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS). The CGuard products and MGuard coronary products sold to-date in applicable foreign countries have been designed and labeled to facilitate the utilization of existing reimbursement codes for such countries, and we intend to continue to design and label our present and future products in a manner consistent with this goal.

While most countries have established reimbursement codes for stenting procedures, certain countries may require additional clinical data before recognizing coverage and/or to obtain a certain level of reimbursement for one or more of our products. In these situations, we intend to complete the required clinical studies to obtain reimbursement approval in countries where it makes economic sense to do so.

Intellectual Property

Patents

We have 52 issued patents, including 14 patents issued in the U.S., and seven pending patent applications, four of which are pending in the United States. Many of these patents and applications cover aspects of our CGuard and MGuard technology. Patents outside the U.S. have been filed in Canada, China, Europe, Israel, India, Japan, Australia, and South Africa. The patents and applications fall into a number of patent families, as listed below:

Base Title of Patent Family	Pending patent applications (Countries)	Issued patents (Country and Patent No.)	Issue Date
Bifurcated Stent Assemblies		US 8,961,586	02/24/2015
		China ZL200780046676.2	9/26/2012
Deformable Tip for Stent Delivery and Methods of Use		US 10,258,491	4/16/2019
		Israel 260,945	07/01/2020
Visualization of blood flow in a venous/arterial shunting system	US		
In Vivo Filter Assembly		US 9,132,261	09/15/2015
Filter Assemblies		Israel 198,189	2/1/2014
Knitted Stent Jackets		Canada 2,666,728	6/23/2015
		Canada 2,887,189	5/1/2018
		China ZL200780046697.4	10/10/2012
		China ZL201210320950.3	12/2/2015
		Israel 198,190	2/1/2014
		EP 2076212	3/29/2017
		(Germany, France, & UK)	
		US 10,137,015	11/27/2018
		India 323792	10/28/2019
Optimized Stent Jacket	Canada	Canada 2,670,724	12/11/2018
	EPO	China ZL201210454357.8	12/9/2015
	US	China ZL200780043259.2	1/2/2013
		India 297,257	5/30/2018
		Israel 230,922	10/01/2020
		US 9,132,003	9/15/2015
		US 9,526,644	12/27/2016
		US 9,782,281	10/10/2017
		US 10,070,976	9/11/2018
		US 10,406,006	9/10/2019
		US 10,406,008	9/10/2019
		EP 2088962	10/11/2017
		(validated in 9 countries: BE, CH, DE, FR, UK, IT, IE, LX, NL)	
Stent Apparatuses for Treatment Via Body Lumens and Methods of Use	US	South Africa 2007/10751	10/27/2010
	EPO	Canada 2,609,687	4/22/2015
		Canada 2,843,097	10/27/2015
		EP 1885281	2/13/2019
		(CH, DE, FR, GB, IE, IT)	3/1/2017
		US 10,058,440	8/28/2018
		US 10,070,977	9/11/2018
Stent Thermoforming Apparatus and Methods		JP 6553178	7/12/2019
		US 9,527,234	12/27/2016
		US 10,376,393	8/13/2019
		Australia 2015326517	05/21/2020
		Canada 2962713	02/19/2019
Methods or using a self-adjusting stent assembly and kits including the same	US		
	PCT		

The patents and patent applications listed above cover various aspects of our products, specifically focusing on the mesh sleeve covering our stents, as well as methods for production and delivery mechanisms of the stents. We believe that our patents, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, as well as our pending patent applications (if issued as patents with claims substantially in their present form), create a significant barrier against other companies seeking to use similar technology. We believe these patents and patent applications collectively cover all our existing products and may be useful in protecting our future technological developments. We intend to aggressively continue patenting new technologies and to actively pursue any infringement of our key patents.

Trade Secrets

We also rely on trade secret protection to protect our interests in proprietary know-how and/or for processes for which patents are difficult to obtain or enforce. As part of our trade secret policy, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect trade secrets and other proprietary technology.

Trademarks

We have registered or applied to register the following trademarks, which we use in connection with our products:

- InspireMD® (US, European Union, and UK)
- MGuard® (European Union, and UK)
- CGuard® (US, European Union, and UK)
- MGuard Prime® (US, European Union, and UK)
- NGuard® US, European Union)
- PVGuard® (US, European Union, and UK)
- Micronet®)US(
- MNP Micronet Protection logo)European Union and UK)
- Carenet®)European Union and UK)
- SmartFit™ (US)

The trademarks are renewable indefinitely, so long as we continue using the marks and make the appropriate filings when required. We also use and may have common-law rights to various trademarks, trade names, and service marks.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the European Union CE mark and other corresponding foreign agencies.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex approval process, clinical trials and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA market authorization. These differences may affect the timeliness of international market introduction of our products. For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, we must comply with the Medical Device Directive 93/42/EEC ("MDD") by presenting comprehensive technical files for our products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by an European Notified Body. We have obtained ISO 13485 quality system certification and the products we currently distribute into the European Union display the required CE mark. In order to maintain certification, we are required to pass an annual surveillance audit conducted by Notified Body auditors. The European Union replaced the MDD with the new European Medical Devices Regulation, or MDR (MDR 2017/745). The MDR will apply after a transitional period of three years ending on May 26, 2020, which is expected to change several aspects of the existing regulatory framework in Europe. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark. After May 26, 2020, medical devices can still be placed on the market under the provision of the MDD until May 27, 2024; provided the CE Mark was issued prior to this date and the manufacturer continues to comply with this directive. By May 27, 2024, all medical devices entering the EU will need to have a CE Mark under the MDR, even if they have been on the market previously under the MDD. In our case, CGuard and MGuard can continue to be marketed under the MDD until November 12, 2022. Specifically, the EU MDR will require changes in the clinical evidence required for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, Unique Device Identification ("UDI") for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, and multiple other labeling changes. Approvals for certain of our currently-marketed products could be curtailed or withdrawn as a result of the implementation and recertification process of the EU MDR and acquiring approvals for new products could be more challenging, time consuming and costly.

As noted below, we have or had regulatory approval and made sales of CGuard EPS, MGuard Prime EPS or both products either through distributors pursuant to distribution agreements or directly, in the following countries: Argentina, Australia, Austria, Belarus, Belgium, Brazil, Bulgaria, Chile, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Germany, Hong Kong, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Netherlands, New Zealand, Norway, Peru, Poland, Portugal, Romania, Russia, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey Vietnam and the United Kingdom In addition, we are awaiting regulatory approval to sell our products in Taiwan. While each of the European Union member countries accepts the CE mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we believe that certain of the above-listed countries that are not members of the European Union accept the CE mark as a primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of our products. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America, however, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months or more, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

In October 2007, our first generation MGuard stent combining the MicroNet with a stainless steel stent received CE mark approval for the treatment of coronary artery disease in the European Union. We subsequently replaced the first generation MGuard product with MGuard Prime EPS, which uses a more advanced cobalt-chromium based stent. Our MGuard Prime EPS received CE mark approval in the European Union in October 2010 and marketing approval in those countries listed in the table below.

The CGuard EPS received CE mark approval in the European Union on March 14, 2013 and marketing approval in the countries listed in the table below. We are currently seeking marketing approval for CGuard EPS in, South Korea and Taiwan.

Please refer to the table below setting forth the approvals and sales made for CGuard EPS and the MGuard Prime EPS on a country-by-country basis

Approvals and Sales of MGuard Prime EPS and CGuard EPS on a Country-by-Country Basis

Countries	CGuard EPS Approval	CGuard EPS Sales	MGuard Prime EPS Approval	MGuard Prime EPS Sales
Argentina	Y	Y	Y	Y
Australia	Y	Y	N	Y(1)
Austria	Y	Y	Y	Y
Belarus	Y	Y	Y	Y
Belgium	Y	Y	Y	Y
Brazil	Y	Y	Y	Y
Bulgaria	Y	Y	Y	Y
Chile	Y	Y	N	Y(2)
Colombia	Y	Y	Y	Y
Croatia	Y	N	Y	Y
Cyprus	Y	Y	Y	Y
Czech Republic	Y	Y	Y	Y
Denmark	Y	Y	Y	N(3)
Dominican Republic	Y	Y	Y	Y
Ecuador	Y	Y	Y	Y
Estonia	Y	Y	Y	Y
Finland	Y	Y	Y	Y
France	Y	Y	Y	Y
Germany	Y	Y	Y	Y
Greece	Y	Y	Y	N(3)
Netherlands	Y	Y	Y	Y
Hong Kong	Y	Y	N	N
Hungary	Y	Y	Y	Y
Iceland	Y	N	Y	N
India	Y	Y	N	N
Ireland	Y	Y	Y	Y
Israel	Y	Y	Y	Y
Italy	Y	Y	Y	Y
Latvia	Y	Y	Y	Y
Lithuania	Y	Y	Y	Y
Liechtenstein	Y	N	Y	N
Luxembourg	Y	N	Y	Y
Malaysia	N	N	N	Y(3)
Malta	Y	N	Y	Y
Mexico	Y	Y	Y	Y
Montenegro	Y	N	Y	N
New Zealand	Y	N	N	N
Norway	Y	N	Y	Y
Peru	Y	Y	Y	N
Poland	Y	Y	Y	Y
Portugal	Y	Y	Y	N
Romania	Y	Y	Y	Y
Russia	Y	Y	Y	Y
Saudi Arabia	N	N	N	Y(4)
Serbia	Y	Y	Y	N
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y	Y	Y(5)	Y
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	Y
Switzerland	Y	Y	Y	Y
Turkey	Y	Y	Y	Y
Venezuela	N	N	N	N
Vietnam	Y	Y	Y	Y
Ukraine	Y	Y	N	N
United Kingdom	Y	Y	Y	Y

(1) The approval expired and per management decision it was decided not to renew it.

(2) Chile is a non-regulated market, the health system in Chile only relies on CE mark or FDA certificates.

(3) The approval expired and per management decision it was decided not to renew it.

(4) The approval expired in November 2017. We have not had sales of MGuard Prime EPS in Saudi Arabia since 2014.

(5) The certificate evidencing regulatory approval for MGuard Prime EPS in South Africa was held by our former distributor in South Africa, and we cannot guarantee that it is in full force and effect. Our distribution agreement with the distributor in South Africa expired pursuant to the terms of such distribution agreement on February 1, 2015, and we have not had sales of MGuard Prime EPS in South Africa since 2015

FDA Government Regulation of Medical Devices for Human Subjects

Many of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of medical devices.

FDA Approval/Clearance Requirements

In the United States, Class II or III medical devices must be cleared or approved by the FDA prior to commercialization. Unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or premarket approval. Medical devices that receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a premarket approval by the FDA are "approved" to market, distribute, and sell in the United States. We anticipate filing a premarket approval application in the future and do not anticipate filing a 510(k) premarket notification. Even though we do not anticipate filing a 510(k), we cannot be certain that the FDA will find it more appropriate for us to file a 510(k) premarket notification instead of a premarket approval application. Further, we cannot be sure that we will ever obtain premarket approval. Descriptions of the premarket approval and 510(k) clearance processes are provided below.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) process described below.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) process. Pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), as of October 2002, unless a specific exemption applies, 510(k) submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process. The FDA has recently indicated that it intends to modernize the 510(k) process and has issued new guidance documents that may change the way that devices are cleared by the FDA.

Class III includes devices with the greatest risk. Devices in this class must meet all of the requirements in Classes I and II. In addition, Class III devices cannot generally be marketed until they receive a premarket approval. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices require formal clinical studies to demonstrate safety and effectiveness. Under MDFUMA, premarket approval applications (and supplemental premarket approval applications) are subject to significantly higher user fees than 510(k) applications, and they also require considerably more time and resources.

The FDA decides whether a device line must undergo either the 510(k) clearance or premarket approval based on statutory criteria that utilize a risk-based classification system. Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, in many cases, Class II medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The FDA uses these criteria to decide whether a premarket approval or a 510(k) is appropriate, including the level of risk that the agency perceives is associated with the device and a determination by the agency of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. In many cases, the FDA requires the manufacturer to submit a 510(k) requesting clearance (also referred to as a premarket notification), unless an exemption applies. The 510(k) must demonstrate that the manufacturer's proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device. A "predicate device" is a pre-existing medical device to which equivalence can be drawn, that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a premarket approval application.

We expect that unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or premarket approval. Medical devices that receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a premarket approval by the FDA are "approved" to market, distribute, and sell in the United States. We anticipate that each device that we wish to commercialize will be considered a Class III device by the FDA and therefore we anticipate filing a premarket approval application in the future and do not anticipate filing a 510(k) premarket notification. Even though we do not anticipate filing a 510(k), we cannot be certain that the FDA will find it more appropriate for us to file a 510(k) premarket notification instead of a premarket approval application or that applications of our technology may not be considered Class II devices. Further, we cannot be sure that we will ever obtain a premarket approval. Descriptions of the premarket approval and 510(k) clearance processes are provided below.

Premarket Approval Pathway

We expect that current and future applications of our technology will result in medical devices that are considered Class III devices subject to premarket approval. A premarket approval application must be submitted if a device cannot be cleared through the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Before a premarket approval application is submitted, a manufacturer must apply for an IDE. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to initiation of enrollment of human subjects for clinical trials. The IDE provides the manufacturer with a legal pathway to perform clinical trials on human subjects where without the IDE, only approved medical devices may be used on human subjects.

The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board (IRB) approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If the clinical trial design is deemed to have "non-significant risk," the clinical trial may be eligible for "abbreviated" IDE requirements.

A clinical trial may be suspended by either the FDA or the IRB at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, clinical testing results may not demonstrate the safety and efficacy of the device, or they may be equivocal or otherwise insufficient to obtain approval of the product being tested. After the clinical trials have been completed, if at all, and the clinical trial data and results are collected and organized, a manufacturer may complete a premarket approval application.

After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the Quality Systems Regulations, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New premarket approval applications or premarket approval supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved premarket approval require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or a 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and it may not require as extensive clinical data or the convening of an advisory panel.

510(k) Clearance Pathway

We do not currently market, distribute, or sell any products that have market clearance by the FDA under its 510(k) process. If, in the future, we develop products where 510(k) clearance is required, we would be required to submit a 510(k) demonstrating that such proposed devices are substantially equivalent to a respective previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of 510(k). The FDA's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases, the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, a premarket approval. The FDA requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a premarket approval, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval of the modified device is obtained.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our approved devices, including the quality system regulation (which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures), the Medical Device Reporting regulations (which require that manufacturers report to the FDA specified types of adverse events involving their products), labeling regulations, and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Class II devices also can have special controls such as performance standards, post-market surveillance, patient registries, and FDA guidelines that do not apply to Class I devices.

A noncomprehensive list of the regulatory requirements that apply to our approved products classified as medical devices include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality Systems Regulations, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and,
- notices of corrections or removals.

We do not currently have a registered establishment with the FDA. If we are approved or cleared to manufacture, prepare, or process a device in the United States, we and any third-party manufacturers that we may use must will be required to register our establishments with the FDA. As such, we and our manufacturing facilities will be subject to FDA inspections for compliance with the FDA's Quality System Regulation. Additionally, some of our subcontractors may also be subject to FDA announced and unannounced inspections for compliance with the FDA's Quality System Regulation. These regulations will require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As a medical device manufacturer, we will further be required to comply with FDA requirements regarding the reporting of adverse events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. FDA regulations also govern product labeling and prohibit a manufacturer from marketing a medical device for unapproved applications.

Our CGuard EPS is classified as a Class III medical device by the FDA. Class III medical devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control by the FDA, since the FDA process of premarket approval involves scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices for the purpose(s) intended. The FDA will either approve or deny a premarket approval application and we cannot market a device unless or until the FDA approves a premarket approval application.

We expect the approval process in the U.S. to take a significant amount of time, require the expenditure of significant resources, involve rigorous clinical investigations and testing, and potentially require changes to products. The approval process may result in limitations on the indicated uses of the medical devices for which we are able to obtain approval (since the FDA can take action against a company that promotes off-label uses) and will also require increased post-market surveillance.

U.S. Healthcare Laws and Regulations

In addition to the FDA regulations, there are a variety of other healthcare laws and regulations to which we may be subject if any of our products are marketed, sold, distributed, and/or utilized in the United States. Of specific note are federal and state fraud and abuse laws, which prohibit the payment or receipt of kickbacks, bribes or other remuneration, including the offer or solicitation of such payment, intended to induce or reward the purchase, recommendation or generation of business involving healthcare products any item or service payable by a health-care program. Other provisions of federal and state laws prohibit presenting, or causing to be presented, to third party payors (including, government program, such as Medicare and Medicaid) for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, other healthcare laws and regulations may apply, such as transparency and reporting requirements, and privacy and security requirements. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal and state healthcare programs, any of which could have a material adverse effect on our business. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other institutional or individual providers that may refer or purchase such products. The healthcare laws that may be applicable to our business or operations include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal healthcare program;

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which includes provisions that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, also imposes obligations and requirements on healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information;

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payors, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Customers

Our customer base is varied. We began shipping our product to customers in Europe in January 2008 and have since expanded our global distribution network to Southeast Asia, India, Latin America and Israel. We currently have distribution agreements for our CE mark-approved MGuard Prime EPS and/or CGuard EPS with medical product distributors based in Europe, the Middle East, Asia Pacific and Latin America. We are currently in discussions with additional distribution companies in Europe, Asia, and Latin America.

Most of our current agreements with our distributors stipulate that, and we expect our future agreements with our distributors to stipulate that, while we shall assist in training by providing training materials, marketing guidance, marketing materials, and technical guidance, each distributor will be responsible for carrying out local registration, sales and marketing activities. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. Under current agreements, distributors purchase stents from us at a fixed price. Our current agreements with distributors are generally for a term of two to three years.

Manufacturing and Suppliers

The polymer fiber for MicroNet is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications.

Natec Medical Ltd. supplies us with catheters that help create the base for our CGuard EPS stents. Our agreement with Natec Medical Ltd., as amended, may be terminated by us upon eight months' notice. On August 1, 2017, we amended the agreement with Natec Medical Ltd., so that we are responsible for purchasing and handling inventory of CGuard EPS delivery system, and Natec Medical Ltd.is responsible for the manufacturing process.

Natec Medical Ltd. supplies us with catheters that help create the base for our MGuard Prime EPS. Our agreement with Natec Medical Ltd., which may be terminated by either party upon six months' notice, calls for non-binding minimum orders.

The cobalt-chromium stent for our MGuard Prime EPS was designed by Svelte Medical Systems Inc. We have an agreement with Svelte Medical Systems Inc., as amended, that grants us a non-exclusive, worldwide license for production and use of the MGuard Prime cobalt-chromium stent for the life of the stent's patent, subject to the earlier termination of the agreement upon the bankruptcy of either party or the uncured default by either party under any material provision of the agreement. Our royalty payments to Svelte Medical Systems Inc. are determined by the sales volume of MGuard Prime EPS. Currently, the royalty rate is 2.9% of all net sales.

We manufacture our CGuard EPS and MGuard Prime EPS at our own facility. The bare-metal cobalt-chromium stents for our MGuard Prime EPS and the self-expanding bare-metal stents for our CGuard EPS are being manufactured and supplied by MeKo Laserstrahl-Materialbearbeitung. Our agreement with MeKo Laserstrahl-Materialbearbeitung for the production of electro polished L605 bare-metal stents for MGuard Prime EPS and CGuard EPS is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for MGuard Prime EPS and CGuard EPS, including knitting and securing the sleeve to the stent and the crimping of the sleeve stent on to a delivery catheter, is done at our Israel manufacturing site. Once MGuard Prime EPS and CGuard EPS have been assembled, they are sent for sterilization in a third-party facility in Israel, and then back to our facility for final packaging and distribution.

During the quarter ended March 31, 2019, our former third-party sterilizer's equipment failures resulted in significant interruption in sterilized product supply for the majority of the quarter. As a result of this interruption in the delivery of sterilized products and our limited inventory levels on hand prior to this interruption, we were unable to fulfill a significant portion of the orders received during the three months ended March 31, 2019.

Each MGuard stent is manufactured from two main components, the stent and the mesh polymer. The stent is made out of cobalt chromium. This material is readily available, and we acquire it in the open market. The mesh is made from polyethylene terephthalate (polyester). This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications.

A CGuard EPS consists of a CGuard stent and the delivery system. Each CGuard stent is manufactured from two main components, a self-expending nickel-titanium stent and the mesh polymer. This material is readily available and we acquire it in the open market. The mesh is made from polyethylene terephthalate (polyester). We have pending patent rights that cover the proposed CGuard stent with mesh. This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. The delivery system for CGuard is made out of polymer tubes we acquire from an original equipment manufacturer. In the event that our supplier can no longer supply this material, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications.

Properties

Our headquarters are located in Tel Aviv, Israel, where we lease a 1,000 square meter office and manufacturing facility that has the capacity to manufacture and assemble 1,200 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Legal Proceedings

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

On July 10, 2019, Bosti Trading Ltd., a former distributor in Russia ("Bosti"), filed suit with the Tel Aviv-Jaffa District Court in Israel, or the Complaint, against InspireMD Ltd., claiming damages for alleged breaches by InspireMD Ltd. under the Distribution Agreement, dated May 26, 2011, between Bosti and InspireMD Ltd., in connection with the voluntary field corrective action of our MGuard Prime EPS we initiated in 2014. Bosti claimed that Bosti and its Russian subsidiary returned 1,830 units of MGuard Prime EPS to InspireMD Ltd. upon initiation of the voluntary filed action, and, since the Russian Ministry of Health prohibited distribution of MGuard Prime EPS on August 28, 2014, and did not approve distribution MGuard Prime EPS until September 20, 2016, Bosti was entitled to recover from InspireMD Ltd. €1,830,000 (which is approximately $2 million), the amount Bosti was due to receive from its Russian subsidiary, or alternatively, €1,024,000 (which is approximately $1.1 million), the amount Bosti paid to InspireMD Ltd., for the MGuard Prime EPS returned to InspireMD Ltd. On January 31, 2020, InspireMD Ltd. filed with court its letter of defense in which it contested this matter vigorously. On January 21, 2021, we executed a Mediation Agreement with Bosti and InspireMD Ltd., pursuant to which Bosti agreed to release the Company from all claims stated in the Complaint in exchange for a payment of $580,000, which we paid on January 25, 2021.

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

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

Human Capital Management

As of December 31, 2020, we had 48 employees 45 full-time and 3 part-time, consisting of two in executive management, five in research and development, four in quality assurance and compliance, five in finance and accounting, 18 in operations/production, 11 in sales, marketing and clinical, and three in all other miscellaneous roles, including business development, information technology services, and administration. Except for four of our employees in Europe, our employees are not party to any collective bargaining agreements. We do not expect the collective bargaining agreements to which our employees are party to have a material effect on our business or results of operations. We also employ two independent contractors in Poland.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. In particular, we depend on the skills, experience and performance of our senior management and research personnel. We compete for qualified personnel with other medical device, biotechnology, pharmaceutical and healthcare companies, as well as universities and non-profit research institutions.

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs (which vary by country/region and employment classification) include incentive compensation plan, pension, healthcare and insurance benefits, paid time off, family leave, and on-site services, among others. We also use targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly for our key employees.

The success of our business is fundamentally connected to the well-being of our people. Accordingly, we are committed to the health and safety of our employees. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes having employees work from home, while implementing additional safety measures for employees continuing critical on-site work.

We consider our relations with our employees to be good.

Item 1A. Risk Factors.

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Annual Report on Form 10-K, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

- the COVID-19 pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business;
- we have a history of net losses and may experience future losses;
- we will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests;
- we may become subject to claims by much larger and better capitalized competitors enforcing their intellectual property rights against us or seeking to invalidate our intellectual property or our rights thereto;
- there are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected;
- clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business;
- our products may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results;
- completing clinical trials for CGuard EPS in the United States require meeting a number of regulatory requirements and must be conducted in compliance with the FDA's IDE regulations. Failure to maintain compliance with IDE regulations could have a material adverse effect on our business;
- though necessary to pursue FDA premarket approval, pre-clinical and clinical trials are inherently lengthy and expensive and subject to any number of regulatory and/or clinical difficulties that can cause further delays, additional costs, and/or rejection by the FDA, and any such delay, added cost, or failure in connection with any future clinical trials could prevent us from commercializing our MicroNet products in the United States, which would materially and adversely affect our results of operations and the value of our business;
- we may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings;
- we may be exposed to product liability claims and insurance may not be sufficient to cover these claims;
- even if one or more of our products are approved by the FDA, we may fail to obtain an adequate level of reimbursement for our products by third party payors, such that there may be no commercially viable markets for our products or the markets may be much smaller than expected;
- in the United States and European Union, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations;
- if we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue;

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

- 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;

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

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

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

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

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

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

Risks Related to Our Business

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

In an effort to contain and mitigate the spread of COVID-19, a strain of coronavirus 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. At this point, the extent to which COVID-19 may impact our business cannot be estimated; 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, and it is highly plausible that this trend will continue. 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.

Certain component parts of our delivery system are sourced from countries that have been impacted by COVID-19, and the continued pandemic and spreading of COVID-19 may adversely impact our suppliers and in turn our manufacture of CGuard EPS. Although the manufacturing of our products in Israel has not been materially impacted by COVID-19 as of February 2021, we cannot guarantee that we will continue to manufacture at full capacity in the event that pandemic persists and further restrictions are imposed.

The extent to which COVID-19 will impact 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 the coronavirus. The actions to contain COVID-19 or treat its impact, the efficacy and scale of the various vaccines currently deployed across the world, among others. Moreover, COVID-19 has had 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 continues to harm the global economy generally.

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

We have yet to establish any history of profitable operations. We reported a net loss of $10.5 million for the fiscal year ended December 31, 2020, and had a net loss of approximately $10 million during the fiscal year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $168 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

We will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests.

In order for us to pursue our business objectives without materially curtailing our operations, we will need to raise additional capital, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

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

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

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

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

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

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

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

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

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

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

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

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

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

In addition, we rely on a third-party vendor to perform the sterilization process. A third-party vendor's failure to properly sterilize a component may cause delays or disruptions in our manufacturing process. During the fiscal year ended December 31, 2019, our third-party sterilizer's equipment failures resulted in significant interruption in sterilized product supply for the majority of the first quarter. As a result of this interruption in the delivery of sterilized products and our limited inventory levels on hand prior to this interruption, we were unable to fulfill a significant portion of the orders received during the fiscal year ended December 31, 2019.

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

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

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

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

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

Risks Related to our Products, Clinical Trials and Regulatory Matters

Clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Clinical trials necessary to support a pre-market approval application to the FDA for our CGuard EPS stent will be expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

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

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

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

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

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

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

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

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

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

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

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

Completing clinical trials for CGuard EPS in the United States require meeting a number of regulatory requirements and must be conducted in compliance with the FDA's IDE regulations. Failure to maintain compliance with IDE regulations could have a material adverse effect on our business.

Clinical trials involve use of a medical device candidate (or drug, biological, or other product candidate, as applicable) on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, including the requirement that all research subjects provide informed consent for their participation in the clinical study. The FDA classifies medical device candidates into "significant risk" and "non-significant risk" devices. Significant risk devices present a potential for serious risk to the health, safety, or welfare of a subject. Examples may include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. If a medical device candidate presents a significant risk, an IDE application must be submitted and approved prior to commencing any human clinical trials in the United States in connection with such device. The FDA may approve, conditionally approve, or deny an IDE or it may require further information and, thus, delay approval. On September 8, 2020, we received IDE approval for CGuard™ Carotid Stent System, CARENET-III.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Affordable Care Act, signed into law in the United States in March 2010, contains certain provisions which are not yet fully implemented and for which it is unclear what the full impact will be from the legislation.

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

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump presidential administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, the president has signed two executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare plans, commonly referred to as the "donut hole." In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment.

The Trump administration has also taken executive actions to undermine or delay implementation of the Affordable Care Act. Since January 2017, the President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. One Executive Order directs federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the Affordable Care Act for plans sold through such marketplaces. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in Affordable Care Act risk corridor payments to third-party payors who argued such payments were owed to them, which the U.S. Supreme Court is reviewing during its current term. The effects of this gap in reimbursement on third-party payors, the viability of the Affordable Care Act marketplace, providers, and potentially our business, are not yet known.

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

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

General Risk Factors

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

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

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our issued patents and pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. Third parties may initiate adversarial proceedings, known as an inter-partes review (IPR) in the U.S. Patent and Trademark Office to challenge the validity of our patent claims in the United States. It is possible that we may be unsuccessful in the proceedings, resulting in a loss of some portion or all of our patent rights in the United States.

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

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

We may not be able to protect our trade secrets adequately. Although we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology, these agreements may be breached and we may not have adequate remedies for such breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

We face risks associated with litigation and claims.

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

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

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

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

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

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

We operate globally and develop and market products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. In addition, we are subject to global events beyond our control, including war, public health crises, such as pandemics and epidemics, trade disputes and other international events. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations.

For example, the COVID-19 pandemic has significantly affected most of the world, including each of our primary markets, resulting in, among other things, government-imposed quarantines and other public health safety measures. At this point, the extent to which the coronavirus may impact our business cannot be estimated; however, procedures with CGuard EPS, which are generally scheduled or non-emergency procedures, have seen extended postponements since the onset of COVID-19 as hospitals shift resources to patients affected by the coronavirus, and it is highly plausible that this trend will continue. 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 the coronavirus, the actions to contain COVID-19 or treat its impact, the efficacy and scale of the various vaccines currently deployed across the world, among others. Moreover, COVID-19 has had 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 continues to harm the global economy generally.

International sales and operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;

- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and
- general economic and political conditions in these foreign markets.

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

Risks Related to Operating in Israel

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock, Preferred Stock and Warrants

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

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

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

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market prices of our common stock and our publicly traded warrants.

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

We intend to effect the Planned Reverse Split (as defined below) with the primary intent of increasing the price of our common stock in order to meet the initial listing requirements of the Nasdaq Capital Market 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 Planned Reverse Split on the market price for our common stock cannot be accurately predicted. In particular, we cannot assure you that the proportionate increase in the price of our common stock immediately after the Planned Reverse Split from the price for shares of our common stock immediately before the Planned Reverse Split will be maintained for us to meet the initial listing requirements of the Nasdaq Capital Market or that the such market prices will be maintained for a substantial period of time. 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 following the Planned Reverse Split, the percentage decline may be greater than would occur in the absence of the Planned Reverse Split. The market price of our common stock may also be affected by other factors which may be unrelated to the Planned Reverse Split or the number of shares outstanding.

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

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

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

Notwithstanding NYSE American's approval of our plan, there is no assurance that we will be able to maintain compliance with Section 1003(a)(iii) of the Company Guide moving forward. Additionally, we will be subject to ongoing review for compliance with NYSE American requirements and there can be no assurance that we will continue to remain in compliance with this standard.

In the event the NYSE American issues a future notice and recommences proceedings against us, delisting from NYSE American would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have additional negative ramifications, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

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

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

If in the future we fall below the continued listing criterion of a minimum average share price of $0.20 over a 30-day trading period, our common stock will be subject to immediate review by NYSE American. There can be no assurance that the market price of our common stock will remain above the levels viewed as abnormally low for a substantial period of time. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock, causing it to fall below the level viewed as a low selling price for a substantial period of time, and lead the NYSE American to immediately suspend trading in our common stock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 will probably 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 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;
- 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;
- 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. You should review carefully the risks and uncertainties described under the heading “Item 1A. Risk Factors” in this Annual Report on Form 10-K for a discussion of these and other risks that relate to our business and investing in shares of our common stock. The forward-looking statements contained in this Annual Report on Form 10-K 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters are located in Tel Aviv, Israel, where we lease a 1,050 square meter office and manufacturing facility that has the capacity to manufacture and assemble 1,200 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Item 3. Legal Proceedings.

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

On July 10, 2019, Bosti Trading Ltd., a former distributor in Russia ("Bosti"), filed suit with the Tel Aviv-Jaffa District Court in Israel, or the Complaint, against InspireMD Ltd., claiming damages for alleged breaches by InspireMD Ltd. under the Distribution Agreement, dated May 26, 2011, between Bosti and InspireMD Ltd., in connection with the voluntary field corrective action of our MGuard Prime EPS we initiated in 2014. Bosti claimed that Bosti and its Russian subsidiary returned 1,830 units of MGuard Prime EPS to InspireMD Ltd. upon initiation of the voluntary filed action, and, since the Russian Ministry of Health prohibited distribution of MGuard Prime EPS on August 28, 2014, and did not approve distribution MGuard Prime EPS until September 20, 2016, Bosti was entitled to recover from InspireMD Ltd. €1,830,000 (which is approximately $2 million), the amount Bosti was due to receive from its Russian subsidiary, or alternatively, €1,024,000 (which is approximately $1.1 million), the amount Bosti paid to InspireMD Ltd., for the MGuard Prime EPS returned to InspireMD Ltd. On January 31, 2020, InspireMD Ltd. filed with court its letter of defense in which it contested this matter vigorously. On January 21, 2021, we executed a Mediation Agreement with Bosti and InspireMD Ltd., pursuant to which Bosti agreed to release the Company from all claims stated in the Complaint in exchange for a payment of $580,000, which we paid on January 25, 2021.

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

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been quoted on the NYSE American since April 11, 2013 under the symbol "NSPR." The last reported sales price of our common stock on the NYSE American on March 5, 2021, was $0.73 per share. As of March 8, 2021, there were approximately 267 holders of record of our common stock.

We plan to effect a reverse split of our common stock, or the Planned Reverse Split, and, accordingly, share amounts, per share data, share prices, exercise prices or conversion rates in this annual report on Form 10-K are subject to change following the effectiveness of the Planned Reverse Split. The Planned Reverse Split will not change the authorized number of shares or the par value of our common stock.

Dividend Policy

In the past, we have not declared or paid cash dividends on our common stock. We do not intend to pay cash dividends in the future, rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

The holders of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis, and without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors. We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

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 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.

Critical Accounting Policies

We prepared our consolidated financial statements in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP"). U.S. GAAP represents a comprehensive set of accounting and disclosure rules and requirements, and applying these rules and requirements requires management judgments and estimates including, in certain circumstances, choices between acceptable U.S. GAAP alternatives. The following is a discussion of our most critical accounting policies, judgments and uncertainties that are inherent in our application of U.S. GAAP.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory valuations, assessing the likelihood of exercise of options to extend the lease term and legal contingencies.

Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash and cash equivalents, which are deposited in major financially sound institutions in the United States, Israel and Germany, and trade accounts receivable. Our trade accounts receivable is derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from customers. We also have a credit insurance policy for some customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount management reasonably believes will be collected, which is netted against "Accounts receivable — Trade".

Inventory

Inventories are stated at the lower of cost (cost is determined on a "first-in, first-out" basis) or net realizable value. Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, based on such evaluation, factors indicate that impairment has occurred, we impair the inventories' carrying value.

Leases

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

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

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

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

Revenue recognition

A contract with a customer exists only when: 1) the parties to the contract have approved it and are committed to perform their respective obligations, 2) we can identify each party's rights regarding the distinct goods or services to be transferred ("Performance Obligations"), 3) we can determine the transaction price for the goods or services to be transferred, 4) the contract has commercial substance and 5) it is probable that we will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Revenues are recorded in the amount of consideration to which we expect to be entitled in exchange for Performance Obligations upon transfer of control to the customer, excluding sales taxes.

Revenue from sales of goods, including sales to distributors, is recognized when the customer obtains control of the product, once we have a present right to payment, legal title, and risk and rewards of ownership are obtained by the customer. This occurs when products are shipped.

We recognize the incremental costs of obtaining contracts as an expense since the amortization period of the assets that we otherwise would have recognized is one year or less. The costs are recorded under selling and marketing expenses.

We recognize revenue net of value added tax (VAT).

Research and development costs

Research and development costs are charged to the statement of operations as incurred.

Share-based compensation

Employee option awards are classified as equity awards and accounted for using the grant-date fair value method. The fair value of share-based awards is estimated using the Black-Scholes valuation model and expensed over the requisite service period, net of estimated forfeitures. We elected to account for forfeitures as they occur.

We elected to recognize compensation expenses for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

Fair value measurement

We measure fair value and disclose fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and consider counterparty credit risk in our assessment of fair value.

Results of Operations

Twelve months ended December 31, 2020 compared to the twelve months ended December 31, 2019

Revenues. For the twelve months ended December 31, 2020, revenue decreased by $1,236,000, or 33.2%, to $2,485,000, from $3,721,000 during the twelve months ended December 31, 2019. Revenues were negatively impacted by 15.6% due to a settlement of litigation with a former distributor in 2014 (see Part I, Item 3. "Legal Proceedings") under which we agreed to pay them $580,000. Under US GAAP we were required to charge that amount against revenues. In addition, there was a 15.3% decrease in sales volume of CGuard EPS from $3,265,000 during the twelve months ended December 31, 2019, to $2,764,000 during the twelve months ended December 31, 2020, mainly due to the postponement of procedures with CGuard EPS, which are generally scheduled or nonemergency procedures, as hospitals shifted resources to patients affected by COVID-19. There was a 34.0% decrease in sales volume of MGuard Prime EPS from $456,000 during the twelve months ended December 31, 2019, to $301,000 during the twelve months ended December 31, 2020, mainly due to the postponement of procedures with MGuard Prime EPS, which are generally scheduled or nonemergency procedures, as hospitals shifted resources to patients affected by COVID-19.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of $985,000 in revenue from sales made in Europe (driven by $580,000 decrease of the settlement with a former distributor and $329,000 decrease of CGuard EPS and $76,000 decrease of MGuard Prime EPS for the reasons discussed in the paragraph above), a decrease of $131,000 in revenue of CGuard from sales made in Asia due to the same COVID-19-related factor, as well as a decrease of $79,000 in revenue from sales made in Latin America (primarily driven by a $68,000 decrease of MGuard Prime EPS sales due to the same COVID-19-related factor).

Gross Profit. For the twelve months ended December 31, 2020, gross profit (revenue less cost of revenues) decreased by 89.0%, or $673,000, to $83,000, compared to a $756,000 for the same period in 2019. This decrease in gross profit resulted from the impact of the $580,000 settlement with our former distributor in 2014 as well as $198,000 decrease in revenues less the related material and labor costs (as mentioned above). This decrease was partially offset by a decrease of $69,000 in expenses related to upgrades made to our production facilities during the year ended December 31, 2019, which did not reoccur during the year ended December 31, 2020 and a decrease of $36,000 in miscellaneous expenses during the year ended December 31, 2020. Gross margin (gross profits as a percentage of revenue) decreased to 3.3% during the year ended December 31, 2020 from 20.3% during the year ended December 31, 2019, driven mainly by a negative effect on gross margin of 18.3% due to the settlement with our former distributor offset by a 1.3% gross margin increase due to the upgrades made to our production facilities and miscellaneous expenses as mentioned above.

Research and Development Expenses. For the twelve months ended December 31, 2020, research and development expenses decreased by 24.4%, or $721,000, to $2,233,000, from $2,954,000 during the twelve months ended December 31, 2020. This decrease resulted primarily from: a decrease of $861,000 in clinical expenses associated with CGuard EPS, mainly related to the IDE approval process, of which an approval from the FDA was received on September 8, 2020, a decrease of $354,000 due to settlement expenses that were paid to a former service provider pursuant to a settlement agreement during the year ended December 31, 2019, which did not reoccur during the year ended December 31, 2020, and a decrease of $136,000 in quality assurance and regulatory expenses related to the development of various projects during the year ended December 31, 2019, which were significantly reduced during the year ended December 31, 2020. These decreases were partially offset by an increase of $531,000 in development expenses related to the CGuard EPS new delivery system and accessory solutions and an increase of $99,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the twelve months ended December 31, 2020, selling and marketing expenses decreased by 12.2%, or $293,000, to $2,103,000, from $2,396,000 during the twelve months ended December 31, 2020. This decrease resulted primarily from: a decrease in travel expenses of $268,000 in light of restrictions imposed by governments worldwide in order to mitigate the spread of COVID-19 during year ended December 31, 2020, a decrease of $129,000 in promotional expenses, primarily related to having already built our social media infrastructure in 2019, and a decrease of $88,000 in miscellaneous expenses. These decreases were partially offset by an increase of $192,000 in compensation expenses.

General and Administrative Expenses. For the twelve months ended December 31, 2020, general and administrative expenses increased by 17.3%, or $905,000, to $6,127,000, from $5,222,000 during the twelve months ended December 31, 2020. This increase resulted primarily from an increase of $400,000 due to expenses for the settlement agreement with the underwriter of our prior offerings paid during the year ended December 31, 2020, an increase in our Directors' and Officers' Liability Insurance expenses of $249,000 partially due to recent economic effects on the insurance industry caused by the COVID-19 pandemic, an increase in regulatory expenses of $177,000 required for new regulatory standards and an increase of $79,000 in miscellaneous expenses.

Financial Expenses. For the twelve months ended December 31, 2020, financial expenses decreased by 20.0%, or $40,000, to $160,000, from $200,000 during the year ended December 31, 2020. The decrease in financial expenses primarily resulted from a decrease of $66,000 in financial expenses related to changes in exchange rates, offset, in part, by an increase of $26,000 in miscellaneous expenses.

Tax Expenses (Income). For the twelve months ended December 31, 2020, tax expenses decreased by $20,000 compared to the twelve months ended December 31, 2019.

Net Loss. Our net loss increased by $504,000, or 5.0%, to $10,544,000, for the twelve months ended December 31, 2020, from $10,040,000 during the twelve months ended December 31, 2019. The increase in net loss resulted primarily from a decrease of $673,000 in gross profit, offset, in part, by a decrease of $109,000 in operating expenses, a decrease of $40,000 in financial expenses and a decrease of $20,000 in tax expenses.

Liquidity and Capital Resources

As of the date of issuance of the consolidated financial statements, we have the ability to fund our planned operations for at least the next 12 months. 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.

Equity Financings

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

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

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

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 8, 2021, we closed an underwritten public offering of 29,032,258 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 $0.62 per unit. The Series G Warrants were immediately exercisable at a price of $0.682 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 4,354,838 shares of common stock and Series G Warrants to purchase 2,177,419 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 1,669,355 shares of common stock with an exercise price of $0.682 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.

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 $0.6708 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.

Twelve months ended December 31, 2020 compared to the twelve months ended December 31, 2019

General. At December 31, 2020, we had cash and cash equivalents of $12,645,000, 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 twelve months ended December 31, 2020, net cash used in our operating activities decreased by $729,000 to $9,081,000, from $9,810,000 during the same period in 2019. The primary reason for the decrease in cash used in our operating activities was a decrease of $1,293,000 in payments for third party related expenses and for professional services (primarily due to production related payments and payments related to IDE application process), offset, in part, by an increase of $408,000 in salary and bonus payments from $5,690,000 in the twelve months ended December 31, 2019 to $6,098,000 during the same period in 2020 and a decrease of $156,000 in payments received from customers to $3,447,000 during the twelve months ended December 31, 2020, from $3,603,000 during the same period in 2019.

Cash used by our investing activities was $187,000 during the twelve months ended December 31, 2020 compared to $387,000 during the twelve months ended December 31, 2019. The primary reasons for the decrease in cash used by our investing activities was a decrease of $218,000 in net payments made for purchase of property, plant and equipment to $66,000 during the twelve months ended December 31, 2020, from $284,000 during the same period in 2019, offset, in part, by an increase of $18,000 in cash deposited to employee funds, to $121,000 during the twelve months ended December 31, 2020, from $103,000 during the same period in 2019.

Cash provided by financing activities for the twelve months December 31, 2020 was $16,395,000, compared to $6,335,000 during the same period in 2019. The principal sources of the cash provided by financing activities during the twelve months ended December 31, 2020 were our June 2020 public offering of common stock, pre-funded warrants and warrants, the subsequent exercise of the pre-funded warrants sold in the offering, as well as exercise of warrants F and Unit Purchase Options, that resulted in approximately $12,169,000 of aggregate net proceeds, and funds received from our ATM Facility that resulted in approximately $ 4,126,000 of aggregate net proceeds. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2019, was the funds received from our December 2019 public offering of common stock, pre-funded warrants and warrants, as well as the subsequent exercise of the pre-funded warrants sold in the offering, that resulted in approximately $4,289,000 of aggregate net proceeds, and funds received from our April 2019 public offering of common stock that resulted in approximately $2,046,000 of aggregate net proceeds.

As of December 31, 2020, our current assets exceeded our current liabilities by a multiple of 4.1. Current assets increased by $7,529,000 during the period and current liabilities increased by $590,000 during the period. As a result, our working capital increased by $6,939,000 to $11,634,000 as of December 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.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology. Under the new guidance, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies will have an effective date for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, we meet the definition of an SRC as of the ASU 2019-10 issuance date and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. We are currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements, but does not believe the adoption of this standard will have a material impact on its consolidated financial statements.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The following financial statements are included as part of this Report (See Item 15):

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of our "disclosure controls and procedures", as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K. The disclosure controls and procedures evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. 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 have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate over time.

Management, including our chief executive officer and our chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework 2013*. Based on its assessment and those criteria, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2020.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth information regarding our executive officers and the members of our board of directors.

Name	Age	Position
Marvin Slosman	57	President, Chief Executive Officer and Director
Craig Shore	59	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
Michael Berman[(1)(2)]	63	Director
Campbell Rogers, M.D.	59	Director
Paul Stuka[(1)(2)(3)]	66	Chairman of the Board of Directors
Thomas J. Kester[(1)(3)]	74	Director
Gary Roubin, M.D.	72	Director

(1) Member of our audit committee

(2) Member of our nominating and corporate governance committee

(3) Member of our compensation committee

Our directors hold office until the earlier of their death, resignation or removal by stockholders or until their successors have been qualified. Our directors are divided into three classes. Paul Stuka and Gary Roubin are our Class 1 directors, with their terms of office to expire at our 2021 annual meeting of stockholders. Michael Berman and Campbell Rogers, M.D. are our Class 2 directors, with their terms of office to expire at our 2022 annual meeting of stockholders. Marvin Slosman and Thomas J. Kester are our Class 3 directors, with their terms of office to expire at our 2023 annual meeting of stockholders. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election, with each director to hold office until his or her successor shall have been duly elected and qualified.

Our officers hold office until the earlier of their death, resignation or removal by our board of directors or until their successors have been selected. They serve at the pleasure of our board of directors.

Marvin Slosman has served as our president, chief executive officer and director since January 1, 2020. Mr. Slosman has served as chief operating officer for MEDCURA Inc. from May 2019 to December 2019. From September 2017 to September 2019, Mr. Slosman served as a Business Consultant, overseeing international commercial strategy and market development, at Integra Life Sciences, a leading innovator in orthopedic extremity surgery, neurosurgery, and reconstructive and general surgery. From 2010 to 2014 Mr. Slosman served as President of Itamar Medical, Inc., a medical technology company focused on cardiovascular and sleep diagnostics. Mr. Slosman also served as chief executive officer of Ovalum Vascular Ltd. from 2008 to 2010. Mr. Slosman's qualifications to serve on the board of directors of the Company include his significant experience in senior management positions of leading medical device companies.

Craig Shore has served as our chief financial officer, secretary and treasurer since March 31, 2011 and as our chief administrative officer since May 3, 2013. In addition, from November 10, 2010 through March 31, 2011, Mr. Shore served as InspireMD Ltd.'s vice president of business development. Mr. Shore has over 30 years of experience in financial management in the United States, Europe and Israel for companies such as Pfizer Pharmaceuticals, Bristol Myers Squibb and General Electric. His experience includes raising capital both in the private and public markets. Mr. Shore graduated with honors and received a B.Sc. in Finance from Pennsylvania State University and an M.B.A. from George Washington University.

Michael Berman has served as our director since February 7, 2013. Mr. Berman is a medical device entrepreneur who works with high-potential development and early-stage commercial companies. From 2005 to 2012, when the company was sold to Boston Scientific, Mr. Berman was a co-founder and the chairman of BridgePoint Medical, Inc., which developed technology to treat coronary and peripheral vascular chronic total occlusions. Mr. Berman was also a member of the board of Lutonix, Inc. from 2007 until 2011, when the company was sold to C.R. Bard, Inc. From 2011 to 2019, Mr. Berman served as a co-founder and director of Rebiotix Inc., a company developing an innovative treatment for C Diff colitis. Rebiotix was sold to Ferring Pharmaceuticals in 2018. From 2014 till 2018 Mr. Berman served as a director Mazor Robotics, a company pioneering Spinal Robotic Surgery. Mr. Berman has served (i) since 2011 as an advisor to, and since 2012 as a director of, Cardiosonic, Inc., a company developing a system for hypertension reduction via renal denervation, (ii) since 2005 as a director of PharmaCentra, LLC, which creates customizable marketing programs that help pharmaceutical companies communicate with physicians and patients, (iii) since 2018 as a Director of STMedical, a medical device company that has developed a temporary stent for the treatment of chronic sinusitis, (iv) since 2019 as a director of CardiacSense Inc, a medical device company that has developed a smart watch vital sign monitor, (v) since 2017 as a Director of Owlytics Healthcare, (vi) since 2013 as a Director of ClearCut Inc., a medical device company that has developed an MRI system for tumor margin assessment, (vii) since 2013 as a director of PulmOne Ltd., a medical device company developing an innovative Pulmonary Function Testing system, (viii) since 2014 as a director of SoniVie, a medical device company, (ix) since 2014 as a venture partner at RiverVest Ventures and (x) since 2017 as a Director of Truleaf Medical. Mr. Berman brings to the board his extensive executive and entrepreneurial experiences in the field of medical devices and vascular intervention, which should assist in strengthening and advancing our strategic focus.

Campbell Rogers, M.D. has served as a director since September 3, 2013. Dr. Rogers is the executive vice president and chief medical officer of HeartFlow, Inc., a cardiovascular diagnostics company, since March 2012. Prior to joining HeartFlow, Inc., he was the chief scientific officer and global head of research and development at Cordis Corporation (currently part of Cardinal Health, Inc.), Johnson & Johnson, where he was responsible for leading investments and research in cardiovascular devices. Prior to that, he was associate professor of medicine at Harvard Medical School and the Harvard-M.I.T. Division of Health Sciences and Technology and director of the cardiac catheterization and experimental cardiovascular interventional laboratories at Brigham and Women's Hospital. He served as principal investigator for numerous interventional cardiology device, diagnostic, and pharmacology trials, is the author of numerous journal articles, chapters, and books in the area of coronary artery and other cardiovascular diseases and was the recipient of research grant awards from the National Institute of Health and the American Heart Association. He received his A.B. from Harvard College and his M.D. from Harvard Medical School. Dr. Rogers' qualifications to serve on the board include his significant experience in cardiovascular devices, as well as his familiarity with the operations of medical device companies.

Paul Stuka has served as a director since August 8, 2011 and has served as our chairman since June 2, 2017. Mr. Stuka has served as the managing member of Osiris Partners, LLC, an investment fund, since 2000. Prior to forming Osiris Partners, LLC, Mr. Stuka, with 40 years of experience in the investment industry, was a managing director of Longwood Partners, managing small cap institutional accounts. In 1995, Mr. Stuka joined State Street Research and Management as manager of its Market Neutral and Mid Cap Growth Funds. From 1986 to 1994, Mr. Stuka served as the general partner of Stuka Associates, where he managed a U.S.-based investment partnership. Mr. Stuka began his career in 1980 as an analyst at Fidelity Management and Research. As an analyst, Mr. Stuka followed a wide array of industries including healthcare, energy, transportation, and lodging and gaming. Early in his career he became the assistant portfolio manager for three Fidelity Funds, including the Select Healthcare Fund which was recognized as the top performing fund in the United States for the five-year period ending December 31, 1985. Mr. Stuka has been serving as a director of Caliber Imaging & Diagnostics, Inc. (formerly Lucid, Inc.) since June 2013. Mr. Stuka's qualifications to serve on the board include his significant strategic and business insight from his years of experience investing in the healthcare industry.

Thomas J. Kester has served as a director since September 6, 2016. Mr. Kester has been serving as the chief financial officer of Kester Search Group, Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies, since October 2014. From 2004 to 2010, Mr. Kester served as a director of Orthofix International, NV (NASDAQ: OFIX), a global medical device company. Mr. Kester's experience includes 28 years at KPMG LLP, including 18 years as an audit partner, advising public and private companies in connection with annual audit and financings. Mr. Kester's qualifications to serve on the board include his significant strategic and business insight from his years of experience auditing global companies and serving on the boards of several public and not-for-profit organizations. Mr. Kester received his B.S. in mechanical engineering from Cornell University and an M.B.A. from Harvard University.

Gary Roubin, M.D. has served as a director since October 13, 2020. Dr. Roubin cofounded Essential Medical Inc., which has had success in bringing a large bore vascular closure device to world markets and was recently acquired by Teleflex Inc. From 2002 to 2003, Dr. Roubin served as Chief Medical Officer of the Medicines Company during the release of its Angiomax product. From 2003 to 2012, Dr. Roubin served as Department Chairman and Chief of Service of the Lenox Hill Hospital Cardiac and Vascular program in New York. From 1989 to 1997, he served as Chief of Interventional Cardiology at the University of Alabama at Birmingham, to which he joined in 1989 as Professor of Medicine and Radiology and Director of the Cardiac Catheterization Laboratories and Interventional Cardiology Section at the University Hospital. In 2001, Dr. Roubin played a pivotal role in the success of Mednova Inc., which was acquired by Abbott Vascular, resulting in the introduction and marketing in the U.S. of the top selling carotid embolic protection system (NAV6) and stent system (XACT). In 1987, he developed and placed the world's first balloon expandable coronary stent. In 1984, Dr. Roubin joined Andreas Gruentzig at Emory University to continue his post-doctoral research. He is also acknowledged for the development of coronary stenting and the first FDA-approved coronary stent. Dr. Roubin received his M.D. from the University of Queensland medical school and his Ph.D. from Sydney University.

Mr. Slosman and Mr. Shore are parties to certain agreements related to their service as executive officers and directors described under "Executive Compensation – Agreements with Executive Officers."

Family Relationships

We have no family relationships amongst our directors and executive officers.

Board Committees

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which has the composition and responsibilities described below.

Audit Committee. Our audit committee is currently comprised of Messrs. Berman, Stuka and Kester, each of whom our board has determined to be financially literate and qualify as an independent director under Section 803(B)(2) of the NYSE American rules. Mr. Kester is the chairman of our audit committee and qualifies as a financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K. The audit committee's duties are to recommend to our board of directors the engagement of independent auditors to audit our financial statements and to review our accounting and auditing principles. The audit committee will review the scope, timing and fees for the annual audit and the results of audit examinations performed by the internal auditors and independent public accountants, including their recommendations to improve the system of accounting and internal controls. The audit committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee is currently comprised of Messrs. Berman and Stuka, each of whom qualify as an independent director under Section 803(A) of the NYSE American rules. Mr. Berman is the chairman of our nominating and corporate governance committee. The nominating and corporate governance committee identifies and recommends to our board of directors individuals qualified to be director nominees. In addition, the nominating and corporate governance committee recommends to our board of directors the members and chairman of each board committee who will periodically review and assess our code of business conduct and ethics and our corporate governance guidelines. The nominating and corporate governance committee also makes recommendations for changes to our code of business conduct and ethics and our corporate governance guidelines to our board of directors, reviews any other matters related to our corporate governance and oversees the evaluation of our board of directors and our management. The nominating and corporate governance committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Compensation Committee. Our compensation committee is currently comprised of Messrs. Stuka and Kester, each of whom qualify as an independent director under Sections 803(A) and 805(c)(1) of the NYSE American rules. Mr. Stuka is the chairman of our compensation committee. The compensation committee reviews and approves our salary and benefits policies, including compensation of executive officers and directors. The compensation committee also administers our stock option plans and recommends and approves grants of stock options under such plans. The compensation committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Code of Ethics

We have adopted a code of ethics and business conduct that applies to our officers, directors and employees, including our principal executive officer, principal financial officer and principal accounting officer, which is posted on our website at *www.inspiremd.com*. We intend to disclose future amendments to certain provisions of the code of ethics, or waivers of such provisions granted to executive officers and directors, on this website within four business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

Summary Compensation Table

The table below sets forth the compensation earned by our named executive officers for the twelve-month period ended December 31, 2020 and 2019.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Restricted Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Marvin Slosman	2020	366,666(2)	150,000(3)	658,981	196,162(7)	10,309(4)	1,382,118
President and Chief Executive Officer							
		(2)	(3)				
Craig Shore	2020	265,004(5)	138,692(5)	264,745	78,955	121,626(6)	869,022
Chief Financial Officer, Secretary and Treasurer	2019	269,758(5)	60,000(5)	57,000	-	114,395(6)	501,153

(1) For awards of stock, the aggregate grant date fair value is computed in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date.

(2) On April 21, 2020, Mr. Slosman and Mr. Shore each signed waivers in connection with the COVID-19 pandemic and certain cost-reduction measures, whereby Mr. Slosman's monthly base salary was reduced from $33,333 to $16,666 and Mr. Shore's monthly base salary was reduced from NIS 80,125 to NIS 40,063. On June 10, 2020, following the closing of our underwritten public offering in June 2020, each of Mr. Slosman's and Mr. Shore's monthly base salaries were reinstated to $33,333 and NIS 80,125, respectively, effective as of June 1, 2020.

(3) Cash bonus awards for the 2020 calendar year were approved by the compensation committee in January 2021.

(4) Mr. Slosman's other compensation for 2020 consisted of benefits related to health insurance.

(5) Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable period, except for bonus amounts which have been converted into U.S. dollars using 3.215 NIS per dollar which was the exchange rate as of December 31, 2020. The average exchange rate for the twelve month period ended December 31, 2020 and 2019 were 3.437 NIS per dollar and 3.564 NIS per dollar, respectively.

(6) Mr. Shore's other compensation consisted solely of benefits in the twelve months ended December 31, 2020 and 2019. In each of the periods reported, Mr. Shore's benefits included our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car or car allowance and cell phone, and a daily food allowance.

(7) 182,381 shares of common stock issuable upon the exercise of Restricted Stock Units outside our 2013 Long-Term Incentive Plan.

Agreements with Executive Officers

Marvin Slosman

On December 9, 2019, we entered into an Employment Agreement with Marvin Slosman, which was subsequently amended on December 31, 2019 (as amended, the "Slosman Employment Agreement"), pursuant to which Mr. Slosman was appointed as our new chief executive officer and president. Mr. Slosman's term of employment commenced on January 1, 2020, which will remain in effect for three years (the "Initial Employment Term"), unless earlier terminated, and to be automatically renewed for successive one-year terms after the Initial Employment Term. Mr. Slosman was also appointed as a Class 3 director, effective January 1, 2020, with a term expiring on the 2020 annual meeting of our stockholders.

As consideration for his services as chief executive officer, Mr. Slosman will be entitled to receive (i) an annual base salary of $400,000, less applicable payroll deductions and tax ("Base Salary"), which will be reviewed by the Board on an annual basis for increase; (ii) reimbursement of up to $50,000 for any reasonable and customary, documented out-of-pocket relocation expenses actually incurred by Mr. Slosman in 2019 or 2020 calendar years, in connection with his relocation to Europe; (iii) annual performance bonuses in an amount up to 50% percent of the Base Salary, as may be in effect from time to time, for each calendar year during his employment with us based on the extent to which performance criteria/financial results for the applicable year have been met; and (iv) equity awards as of the date of the Slosman Employment Agreement that represent, in the aggregate, 5% of the Company's issued and outstanding common stock determined on a fully diluted basis as of the date of grant (the "Equity Awards"), with 75% of the Equity Awards being granted as restricted stock units and with the remaining 25% of the Equity Awards being granted as stock options, all of which Equity Awards shall be outside of the 2013 Long-Term Incentive Plan and subject to terms and conditions of the award agreements entered by Mr. Slosman. In addition, on or before December 31, 2020, Mr. Slosman shall become eligible to receive an additional grant of equity awards under the 2013 Long-Term Incentive Plan and the applicable award agreements up to 5% (including the Equity Awards) of the Company's actual outstanding shares of Common Stock on the date of grant, provided that the actual amount of the grant shall be based on the achievement of certain performance/financial criteria as established by the Board after consultation with Mr. Slosman, in its reasonable discretion. For the purposes of the equity award calculation, "fully diluted basis" is defined as the sum of the total shares of common stock then outstanding, the shares of common stock issuable upon the conversion of our then outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock and the shares of common stock issuable upon the exercise of our then outstanding pre-funded warrant. On January 2, 2020, pursuant to the Slosman Employment Agreement, we granted Mr. Slosman restricted stock units for 182,381 shares and a stock option to purchase 60,794 shares of common stock at $1.10 per share.

In the event Mr. Slosman voluntarily resigns without good reason, we may, in our sole discretion, shorten the notice period and determine the date of termination without any obligation to pay Mr. Slosman any additional compensation other than the accrued obligations and without triggering a termination of Mr. Slosman's employment without cause. In the event the Slosman Employment Agreement expires, or we terminate Mr. Slosman's employment for cause or Mr. Slosman voluntarily resigns without good reason, we shall have no further liability or obligation to Mr. Slosman under the Slosman Employment Agreement. Notwithstanding the foregoing, in the event that this the Slosman Employment Agreement expires as a result of our decision not to renew the Slosman Employment Agreement, we shall, subject to the execution and timely return by Mr. Slosman of a release of claims, pay Mr. Slosman cash payments totaling $100,000 in the aggregate, payable in equal installments on our regular pay dates that occur during the period commencing on 60th day following his employment termination date and ending on the last day of the Restricted Period (as defined below); provided, however, that if, at any time within the period commencing on the date that is 3 months prior to the expiration of the Initial Employment Term or the then current renewal term, as applicable, and ending on the date that is 3 months following the expiration of the Slosman Employment Agreement, we and a third party execute a definitive, written, and binding agreement (a "Sale Agreement") to enter into certain transactions described therein that, if consummated, would constitute a change in control in us, then Mr. Slosman's termination shall be deemed a termination by us without cause or for good reason, as of the date such Sale Agreement is executed, provided further that any amounts payable to Mr. Slosman pursuant to such termination shall be reduced by any amounts previously paid to him upon expiration of the Slosman Employment Agreement, termination by us for cause or voluntary resignation by Mr. Slosman without good reason.

If Mr. Slosman's employment is terminated (i) by us without cause or (ii) by Mr. Slosman for good reason, then we must pay Mr. Slosman, (a) a severance pay in an amount equal to twelve months of his then-current base salary, (b) his entire performance bonus for any calendar year for which Mr. Slosman has already worked the entire year but the bonus has yet to be paid, (c) a pro-rated performance bonus in an amount equal to the target annual performance bonus to which Mr. Slosman may have been entitled for the year in which the termination occurs that he would have received had his employment not been terminated during such year. In addition, 50% of all unvested stock options, shares of restricted stock, restricted stock units, stock appreciation rights, or similar stock-based rights granted to Mr. Slosman shall vest and, if applicable, be immediately exercisable and any risk of forfeiture included in such restricted or other stock grants previously made to Mr. Slosman shall immediately lapse, and Mr. Slosman may exercise any outstanding stock options or stock appreciation rights until the earlier of (x) the last date on which such stock options or stock appreciation rights could have been exercised pursuant to the terms of the applicable award agreement, irrespective of Mr. Slosman's termination of employment; and (y) the date that is two years following his employment termination date.

Craig Shore

We have been a party to an employment agreement with Craig Shore since November 28, 2010. On May 5, 2014, we entered into an amended and restated employment agreement with Mr. Shore, which was amended on January 5, 2015, July 25, 2016, and on March 25, 2019. The employment agreement, as amended, has an initial term that ends on December 31, 2020, and will automatically renew for additional one-year periods on January 1st thereafter unless either party gives the other party written notice of its election not to extend such employment at least six months prior to the next January 1st renewal date. If a change in control occurs when less than two full years remain in the initial term or during any renewal term, the employment agreement will automatically be extended for two years from the change in control date and will terminate on the second anniversary of the change in control date.

Under the terms of the employment agreement, as amended by the third amendment to the amended and restated employment agreement, dated March 25, 2019, Mr. Shore is entitled to an annual base salary of at least $250,000. Such amount may be reduced only as part of an overall cost reduction program that affects all of our senior executives and does not disproportionately affect Mr. Shore, so long as such reduction does not reduce the base salary to a rate that is less than 90% of the amount set forth above (or 90% of the amount to which it has been increased). The base salary will be reviewed annually by our chief executive officer for increase (but not decrease, except as permitted as part of an overall cost reduction program) as part of our annual compensation review. Mr. Shore is also eligible to receive an annual bonus in an amount equal to 60% of his then-annual salary upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with Mr. Shore. Mr. Shore is eligible to receive the percentage of his annual bonus corresponding to the percentage of his achievement of such target objectives and performance goals. The annual bonus will be reviewed annually by our chief executive officer for increase in the amount of the percentage of his then-base salary (but not decrease), as well as the criteria and the goals, as part of our annual compensation review. In addition, Mr. Shore is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion. Mr. Shore will also be considered for grants of equity awards each year as part of the board's annual compensation review, which will be made at the sole discretion of the board of directors. Each grant will, with respect to any awards that are options, have an exercise price equal to the fair market value of our common stock as of the date of grant, and will be subject to a three-year vesting period subject to Mr. Shore's continued service with us, with one-third of each additional grant vesting equally on the first, second, and third anniversary of the date of grant for such awards.

If during the term of the employment agreement, Mr. Shore's employment is terminated upon his death or disability, by us without cause (as such term is defined in Mr. Shore's employment agreement), or upon his resignation for "good reason" (as such term is defined in Mr. Shore's employment agreement), Mr. Shore will be entitled to receive, in addition to any amounts he is entitled to receive under the manager's insurance policy: (i) any unpaid base salary and accrued unpaid vacation or earned incentive compensation and the pro rata amount of any bonus plan incentive compensation for the fiscal year of such termination (based on the number of business days he was actually employed by us during the fiscal year of such termination and based on the percentage of the goals that he actually achieved under the bonus plan) that he would have received had his employment not been terminated; (ii) a one-time lump sum severance payment equal to 100% of his base salary, provided that he executes a release relating to employment matters and the circumstances surrounding his termination in favor of us, our subsidiaries and our officers, directors and related parties and agents, in a form reasonably acceptable to us at the time of such termination; (iii) vesting of all unvested stock options, stock appreciation rights or similar stock-based rights granted to him and immediate lapse of any risk of forfeiture included in restricted or other stock grants previously made to Mr. Shore; (iv) an extension of the exercise period of all vested stock options granted to Mr. Shore until the earlier of (a) two years from the date of termination or (b) the latest date that each stock option would otherwise expire by its original terms; (v) to the fullest extent permitted by our then-current benefit plans, continuation of health, dental, vision and life insurance coverage for the lesser of 12 months after termination or until Mr. Shore obtains coverage from a new employer; and (vi) reimbursement of up to $30,000 for executive outplacement services, subject to certain restrictions. The severance payment described in (ii) of the foregoing sentence upon Mr. Shore's death or disability will be reduced by any payments received by Mr. Shore pursuant to any of our employee welfare benefit plans providing for payments in the event of death or disability. If, during or after the term of his employment agreement, Mr. Shore's employment is terminated by us for cause or by Mr. Shore voluntarily, Mr. Shore will only be entitled to unpaid amounts owed to him (e.g., base salary, accrued vacation and earned incentive compensation through the date of such termination) and whatever rights, if any, are available to him pursuant to our stock-based compensation plan or any award documents related to any stock-based compensation.

Mr. Shore may terminate his employment for good reason by delivering a notice of termination to us 30 days in advance of the date of termination; provided, however, that Mr. Shore agreed to not terminate his employment for good reason until he has given us at least 30 days' notice from which to cure the circumstances set forth in the notice of termination constituting good reason, and if such circumstances are not cured by the 30th day, Mr. Shore's employment shall terminate on such date.

Pursuant to terms contained in Mr. Shore's stock option and restricted stock award agreements, in the event of a change of control of our company, the stock options and restricted stock granted to Mr. Shore that were unvested will vest immediately upon such change of control, in the case of stock options, if such stock options are not assumed or substituted by the surviving company.

If we terminate Mr. Shore's employment without cause, Mr. Shore will be entitled, under Israeli law, to severance payments equal to his last month's salary multiplied by the number of years Mr. Shore has been employed with us. In order to finance this obligation, we make monthly contributions equal to 8.33% of Mr. Shore's salary to a severance payment fund. The total amount accumulated in Mr. Shore's severance payment fund as of December 31, 2020 was $206,000, as adjusted for conversion from New Israeli Shekels to U.S. Dollars. However, if Mr. Shore's employment is terminated without cause, on account of a disability or upon his death, as of December 31, 2020, Mr. Shore would have been entitled to receive $270,000 in severance under Israeli law, thereby requiring us to pay Mr. Shore $64,000, in addition to releasing the $206,000 in Mr. Shore's severance payment fund. On the other hand, pursuant to his employment agreement, Mr. Shore is entitled to the total amount contributed to and accumulated in his severance payment fund in the event of the termination of his employment as a result of his voluntary resignation. In addition, Mr. Shore would be entitled to receive his full severance payment under Israeli law, including the total amount contributed to and accumulated in his severance payment fund, if he retires from our company at or after age 67.

We are entitled to terminate Mr. Shore's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to compensate Mr. Shore.

Also, upon termination of Mr. Shore's employment for any reason, we will compensate him for all unused or previously uncompensated vacation days accrued.

The employment agreement also contains certain standard noncompetition, non-solicitation, confidentiality, and assignment of inventions requirements for Mr. Shore.

Mr. Shore is also entitled to participate in or receive benefits under our social insurance and benefits plans, including but not limited to our manager's insurance policy and education fund, which are customary benefits provided to executive employees in Israel. A management insurance policy is a combination of severance savings (in accordance with Israeli law), defined contribution tax-qualified pension savings and disability pension payments. An education fund is a savings fund of pre-tax contributions to be used after a specified period of time for advanced educational training and other permitted purposes, as set forth in the by-laws of the education fund. We will make periodic contributions to these insurance and social benefits plans based on certain percentages of Mr. Shore's base salary, including (i) 7.5% to the education fund and (ii) 15.83% to the manager's insurance policy, of which 8.33% will be allocated to severance pay, 5.5% to pension fund payments and up to 2.5% to disability pension payments. Upon the termination of Mr. Shore's employment for any reason other than for cause, Mr. Shore will be entitled to receive the total amount contributed to and accumulated in his manager insurance policy fund.

On August 14, 2020, we entered into the fourth amendment to that certain Amended and Restated Employment Agreement dated as of May 5, 2014, as amended on January 5, 2015, July 25, 2016, and on March 25, 2019, in order to, among other things, (i) amend the term of Mr. Shore's employment, so that the initial term of Mr. Shore employment will end on July 31, 2022, which will automatically be renewed for additional one-year periods on August 1, 2022 and on each August 1 thereafter; (ii) increase Mr. Shore's monthly base salary to NIS 86,000; and (iii) amend certain terms related to termination of Mr. Shore's employment without Cause (as defined therein)

Change of Control Agreements

We do not currently have any plans providing for the payment of retirement benefits to our officers or directors, other than as described under "Agreements with Executive Officers" above.

We do not currently have any change-of-control or severance agreements with any of our executive officers or directors, other than as described under "Agreements with Executive Officers" above. In the event of the termination of employment of the named executive officers, any and all unexercised stock options shall expire and no longer be exercisable after a specified time following the date of the termination, other than as described under "Agreements with Executive Officers" above.

Outstanding Equity Awards at December 31, 2020

The following table shows information concerning unexercised options and unvested shares of restricted stock outstanding as of December 31, 2020 for each of our named executive officers.

	Option Awards				Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($)
Marvin Slosman (1)	-	60,794(2)	1.10	1/2/2030		
					182,381(3)	62,010
	-	391,762(4)	0.39	8/31/2030		
					1,175,287(5)	399,598
Craig Shore	11	-	8,312.50	07/25/2026		
					4,000(6)	1,360
	-	226,278(4)	0.39	8/31/2030		
					678,834(7)	230,804

(1) Mr. Slosman was appointed as chief executive officer effective as of January 1, 2020

(2) These options vest annually, with one-third vesting on each of January 2, 2021, January 2, 2022 and January 2, 2023.

(3) These RSU's vest annually, with one-third vesting on each of January 2, 2021, January 2, 2022 and January 2, 2023.

(4) These options vest annually, with one-third vesting on each of August 31, 2021, August 31, 2022 and August 31, 2023.

(5) These RSU's vest annually, with one-third vesting on each of August 31, 2021, August 31, 2022 and August 31, 2023.

(6) These restricted shares vest annually, with one-half vesting on each of February 4, 2021 and February 4, 2022.

(7) These Restricted Stock vest annually, with one-third vesting on each of August 31, 2021, August 31, 2022 and August 31, 2023.

Option Exercises and Stock Vested

There were no stock options exercised by our named executive officers during the twelve months ended December 31, 2020.

2011 UMBRELLA Option Plan

On March 28, 2011, our board of directors and stockholders adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan, which was subsequently amended on October 31, 2011 and December 21, 2012. Under the InspireMD, Inc. 2011 UMBRELLA Option Plan, we have reserved 11 shares of our common stock as awards to the employees, consultants, and service providers to InspireMD, Inc. and its subsidiaries and affiliates worldwide.

The InspireMD, Inc. 2011 UMBRELLA Option Plan currently consists of three components, the primary plan document that governs all awards granted under the InspireMD, Inc. 2011 UMBRELLA Option Plan, and two appendices: (i) Appendix A, designated for the purpose of grants of stock options and restricted stock awards to Israeli employees, consultants, officers and other service providers and other non-U.S. employees, consultants, and service providers, and (ii) Appendix B, which is the 2011 U.S. Equity Incentive Plan, designated for the purpose of grants of stock options and restricted stock awards to U.S. employees, consultants, and service providers who are subject to the U.S. income tax. On December 21, 2012, the stockholders approved the awarding of "incentive stock options" pursuant to the U.S. portion of the plan.

The purpose of the InspireMD, Inc. 2011 UMBRELLA Option Plan is to provide an incentive to attract and retain employees, officers, consultants, directors, and service providers whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial success. The InspireMD, Inc. 2011 UMBRELLA Option Plan is administered by our compensation committee. Unless terminated earlier by the board of directors, the InspireMD, Inc. 2011 UMBRELLA Option Plan will expire on March 27, 2021. We have no shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan.

2013 Long-Term Incentive Plan

On December 16, 2013, our stockholders approved the InspireMD, Inc. 2013 Long-Term Incentive Plan, which was adopted by our board of directors on October 25, 2013.

The purpose of the InspireMD, Inc. 2013 Long-Term Incentive Plan is to provide an incentive to attract and retain employees, officers, consultants, directors, and service providers whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial success. The InspireMD, Inc. 2013 Long-Term Incentive Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem. The InspireMD, Inc. 2013 Long-Term Incentive Plan is administered by our compensation committee.

The InspireMD, Inc. 2013 Long-Term Incentive Plan is intended to serve as an "umbrella" plan for us and our subsidiaries worldwide. Therefore, if so required, appendices may be added to the InspireMD, Inc. 2013 Long-Term Incentive Plan in order to accommodate local regulations that do not correspond to the scope of the InspireMD, Inc. 2013 Long-Term Incentive Plan. Attached as Appendix A to the InspireMD, Inc. 2013 Long-Term Incentive Plan is the InspireMD, Inc. 2013 Employee Stock Incentive Plan, for the purpose of making grants of stock options, restricted stock, and other stock incentive awards pursuant to Sections 102 and 3(i) of the Israeli Income Tax Ordinance (New Version), 1961 to Israeli employees and officers and any other service providers or control holders of us who are subject to Israeli Income Tax.

When the InspireMD, Inc. 2013 Long-Term Incentive Plan was adopted, a total of 11 shares of common stock were reserved for awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan.

On September 9, 2015, our stockholders approved an amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 11 shares of common stock, to a total of 22 shares of common stock.

On May 24, 2016, our stockholders approved the second amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 229 shares of common stock, to a total of 251 shares of common stock.

On September 28, 2016, our stockholders approved the third amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 144 shares of common stock, to a total of 395 shares of common stock.

On October 24, 2018, our stockholders approved the fourth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to (i) increase the number of shares of common stock available for issuance pursuant to awards under such InspireMD, Inc. 2013 Long-Term Incentive Plan by 178,000 shares, to a total of 178,395 shares of common stock, and (ii) remove the cap on the number of shares of common stock with respect to which stock options or stock appreciation rights may be granted to certain executive officers of the Company during any calendar year.

On March 21, 2019, our stockholders approved the fifth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the total number of shares of common stock issuable under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 500,000 shares to a total of 678,395 shares of common stock

On August 31, 2020, our stockholders approved the sixth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the total number of shares of common stock issuable under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 6,500,000 shares to a total of 7,178,395 shares of common stock.

As of December 31, 2020, we had 2,306,956 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

As of March 8, 2021, we had 2,234,642 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

Director Compensation

The following table shows information concerning our directors during the twelve months ended December 31, 2020.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Paul Stuka	47,250	93,191	27,792	-	168,233
Michael Berman	29,750	61,633	18,381	-	109,764
Campbell Rogers, M.D.	21,875	61,633	18,381	-	101,889
Thomas Kester	35,875	61,633	18,381	-	115,889
Gary Roubin, M.D.	5,503	78,854	23,516	-	107,873

For the 2020 calendar year, our board approved the following compensation for our independent directors: (i) a $40,000 stipend, payable quarterly to the chairman of the board; (ii) a $25,000 stipend, payable quarterly to the other directors; (iii) annual committee chair compensation of $12,000 for the chairman of the audit committee, $8,000 for the chairman of the compensation committee and $5,000 for the chairmen of the nominating and corporate governance committee and the research and development committee; and (iv) annual committee membership compensation of $4,000 for members of the audit committee and the compensation committee and $2,000 for members of the nominating and corporate governance committee and the research and development committee for members of the nominating and corporate governance committee and the research and development committee. Notwithstanding the foregoing, 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, and on July 1, 2020, the Board reinstated the original annual cash compensation for non-employee directors.

Directors' and Officers' Liability Insurance

We currently have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, we have entered into indemnification agreements with key officers and directors and such persons shall also have indemnification rights under applicable laws, and our certificate of incorporation and bylaws.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 8, 2021 by:

- each person known by us to beneficially own more than 5.0% of our common stock;
- each of our directors;
- each of the named executive officers; and
- all of our directors and executive officers as a group.

The percentages of common stock beneficially owned are reported on the basis of regulations of the Securities and Exchange Commission (the "SEC") governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security.

Except as indicated in the footnotes to this table, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o InspireMD, Inc., 4 Menorat Hamaor St., Tel Aviv, Israel 6744832. As of March 8, 2021, we had 117,832,226 shares outstanding

Name of Beneficial Owner	Number of Shares Beneficially Owned[1]	Percentage Beneficially Owned[1]
5% Owners		
Armistice Capital, LLC	9,677,415(2)	8.2%
FiveT Capital AG	7,258,050(3)	6.2%
Officers and Directors		
Marvin Slosman	252,638(4)	*
Craig Shore	1,499,251(5)	1.27%
Michael Berman	120,976(6)	*
Campbell Rogers, M.D.	160,650(7)	*
Paul Stuka	243,634(8)	*
Thomas Kester	392,081(9)	*
Gary Roubin, M.D.	1,046,291(10)	*
All directors and executive officers as a group (7 persons)	3,715,521	3.14%

* Represents ownership of less than one percent.

(1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assumes the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 8, 2021. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

(2) Consists of (i) 6,451,610 shares of common stock purchased in connection with the February 2021 Offering, and (ii) warrants to purchase 3,225,805 shares of common stock, at an exercise price of $0.682 per share, purchased in the February 2021 Offering. We are not aware whether this stockholder has sold any of the foregoing securities it purchased in the February 2021 Offering.

(3) Consists of (i) 4,838,700 shares of common stock purchased in the February 2021 Offering, and (ii) warrants to purchase 2,419,350 shares of common stock, at an exercise price of $0.682 per share, purchased in the February 2021 Offering. We are not aware whether this stockholder has sold any of the foregoing securities it purchased in the February 2021 Offering.

(4) Consists of (i) 95,870 shares of common stock, (ii) 60,794 Restricted Stock Units granted outside the plan that are currently exercisable or exercisable within 60 days of March 8, 2021, (iii) options to purchase 20,264 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021, and (iv) 75,710 warrants to purchase shares of common stock that are currently exercisable.

(5) Consists of (i) 4,021 shares of common stock, (ii) options to purchase 11 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021, (iii) 680,828 shares of restricted stock granted under the Israeli Appendix of the InspireMD, Inc. 2013 Long-Term Incentive Plan and (iv) 814,391 shares of restricted stock granted to employees under the Israeli Appendix of the InspireMD, Inc. 2013 Long-Term Incentive Plan held in trust, and with respect to which Mr. Shore was granted a proxy with the right to vote such shares at his discretion.

(6) Consists of (i) 80,642 shares of common stock, (ii) 40,320 warrants to purchase shares of common stock that are currently exercisable, and (iii) options to purchase 14 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021. Excludes 160,633 shares of common stock and restricted stock granted under the Israeli Appendix of InspireMD, Inc. 2013 Long-Term Incentive Plan held in trust, with respect to which the trustee has a proxy with the right to vote such shares at his discretion.

(7) Consists of (i) 1,736 shares of common stock, (ii) 158,899 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) options to purchase 14 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021, and (iv) one warrant to purchase a share of common stock that is currently exercisable or exercisable within 60 days of March 8, 2021.

(8) Paul Stuka is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of (A) (i) 264 shares of common stock, (ii) warrants to purchase 6 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021 in addition to (B) personally holding (i) options to purchase 15 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021, (ii) 240,250 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) warrants to purchase 7 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021, and (iv) 3,092 shares of common stock.

(9) Consists of (i) 172,694 shares of common stock, (ii) 158,899 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 60,480 warrants to purchase shares of common stock that are currently exercisable and (iv) options to purchase 8 shares of common stock that are currently exercisable or exercisable within 60 days of March 8, 2021.

(10) Consists of (i) 464,153 shares of common stock, (ii) 238,950 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, and (iii) 343,188 warrants to purchase shares of common stock that are currently exercisable.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2020, with respect to our equity compensation plans under which our equity securities are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	1,169,665	37.69	2,306,956
Equity compensation plans not approved by security holders	205,615(1)	50.36	-
Total	1,375,280	39.59	2,306,956

(1) Comprised of awards made to individuals outside the InspireMD, Inc. 2011 UMBRELLA Option Plan and 2013 Long Term Incentive Plan, as described below:

- Options issued to former director: In November 2011, we issued options to purchase an aggregate of 3 shares of common stock to Dr. Barer, then chairman of our board of directors who resigned from the board of directors effective as of June 2, 2017. The exercise price of these options is $3,412,500 per share and the options may be exercised at any time prior to the tenth anniversary of the grant date, pursuant to the nonqualified stock option agreement, as amended on June 2, 2017.

- On January, 2020, we issued to Mr. Marvin Slosman, our Chief Executive Officer, President and Director, 182,381 shares of restricted stock and 60,794 shares of common stock, as inducement awards outside the Company's 2013 Long-Term Incentive Plan.

- On October 6, 2020, we issued to Mr. Patrick Jamnik, our Vice President of Business Development and Strategic Initiatives, options to purchase 54,307 shares of our common stock, as inducement awards outside the Company's 2013 Long-Term Incentive Plan.

- On November 3, 2020, we issued to Mr. Andrea Tommasoli, our Senior Vice President of Global Sales and Marketing, options to purchase 90,511 shares of our common stock, as inducement awards outside the Company's 2013 Long-Term Incentive Plan.]

Item 13. Certain Relationships and Related Transactions, and Director Independence.

In accordance with our audit committee charter, the audit committee is required to approve all related party transactions. In general, the audit committee will review any proposed transaction that has been identified as a related party transaction under Item 404 of Regulation S-K. A related party includes (i) a director, director nominee or executive officer of us, (ii) a security holder known to be an owner of more than 5% of our voting securities, (iii) an immediate family member of the foregoing or (iv) a corporation or other entity in which any of the foregoing persons is an executive, principal or similar control person or in which such person has a 5% or greater beneficial ownership interest.

There were no related party transactions that are required to be disclosed pursuant to Regulation S-K promulgated under the Securities Act of 1933, as amended.

Director Independence

The board of directors has determined that Dr. Rogers and Messrs. Stuka, Berman and Kester, satisfy the requirement for independence set out in Section 803 of the NYSE American rules and that each of these directors has no material relationship with us (other than being a director and/or a stockholder). In making its independence determinations, the board of directors sought to identify and analyze all of the facts and circumstances relating to any relationship between a director, his immediate family or affiliates and our company and our affiliates and did not rely on categorical standards other than those contained in the NYSE American rule referenced above.

Item 14. Principal Accountant Fees and Services.

The fees billed for professional services provided to us by Kesselman & Kesselman, Certified Public Accountants ("Kesselman"), a member of PricewaterhouseCoopers International Limited, for the years ended December 31, 2020 and 2019 are described below.

Audit Fees

Kesselman billed us audit fees in the aggregate amount of $160,000 and $160,000 for the years ended December 31, 2020 and 2019, respectively. These fees relate to the audit of our annual financial statements and the review of our interim quarterly financial statements.

Audit-Related Fees

Kesselman billed us audit-related fees in the aggregate amount of $53,900 and $60,000 for the year ended December 31, 2020 and 2019, respectively. The fees for the year ended December 31, 2020 mostly related to registration statement on Form S-1 filed with the SEC in June 2020 and to our prospectus supplements filed with the Securities and Exchange Commission in July 2020.

The fees for the year ended December 31, 2019 mostly related to our prospectus supplements filed with the Securities and Exchange Commission in April 2019 and to our registration statement on Form S-1 filed with the Securities and Exchange Commission in August and September of 2019.

Tax Fees

Kesselman billed us tax fees in the aggregate amount of $39,209 and $38,675 for the year ended December 31, 2020 and 2019, respectively. These fees relate to professional services rendered for tax compliance, tax advice and tax planning.

All Other Fees

Kesselman did not bill us for any other fees for the year ended December 31, 2020 and 2019.

Our audit committee pre-approves all auditing services, internal control-related services and permitted non-audit services (including the fees and terms thereof) to be performed for us by our independent auditor, except for de minimis non-audit services that are approved by the audit committee prior to the completion of the audit. The audit committee may form and delegate authority to subcommittees consisting of one or more members when appropriate, including the authority to grant pre-approvals of audit and permitted non-audit services, provided that decisions of such subcommittee to grant pre-approvals is presented to the full audit committee at its next scheduled meeting. The Audit Committee pre-approved all of the fees set forth above.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

Documents filed as part of report:

1. Financial Statements

The following financial statements are included herein:

- Report of Kesselman & Kesselman, Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2020 and 2019
- Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019
- Consolidated Statements of Changes in Equity for the Years Ended December 31, 2020 and 2019
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019
- Notes to Consolidated Financial Statements

2. Financial Statement Schedules

None

3. Exhibits

See Index to Exhibits

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits [Subject to additional analysis/review]

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (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., dated March 27, 2019 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019)
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 5, 2013)
4.2	Rights Agreement dated as of October 22, 2013 between InspireMD, Inc. and Action Stock transfer Corporation, as Rights Agent, including exhibits thereto (incorporated by reference to an exhibit to the Registration Statement on Form 8-A filed with Securities and Exchange Commission on October 25, 2013)
4.3	Form of Series B Warrant Agent Agreement and Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Amendment No.3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2017)
4.4	Description of Securities (incorporated by reference to Exhibit 4.4 to our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 2020)
10.1+	Amended and Restated 2011 Umbrella Option Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 4, 2011)
10.2+	Form of Stock Option Award Agreement (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
10.3+	Employment Agreement, by and between InspireMD Ltd. and Craig Shore, dated as of November 28, 2010 (incorporated by reference to Exhibit 10.21 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
10.4+	Form of Indemnity Agreement between InspireMD, Inc. and each of the directors and executive officers thereof (incorporated by reference to Exhibit 10.22 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.5	Agreement by and between InspireMD Ltd. and MeKo Laser Material Processing, dated as of April 15, 2010 (incorporated by reference to Exhibit 10.26 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.6	Agreement by and between InspireMD Ltd. and Natec Medical Ltd, dated as of September 23, 2009 (incorporated by reference to Exhibit 10.27 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.7+	InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 20, 2013)
10.8+	Amended and Restated Employment Agreement, dated May 5, 2014, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2014)
10.9+	First Amendment to the InspireMD, Inc. Amended and Restated 2011 UMBRELLA Option Plan (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2014)
10.10+	Form of Incentive Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.2 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.11+	Form of Nonqualified Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.3 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)

10.12+	Form of Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.4 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.13+	Form of Restricted Stock Unit Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.5 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.13+	Form of Section 3(i) Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.6 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.14+	Form of Section 102 Capital Gain Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.7 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.15+	Form of Section 102 Capital Gain Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.8 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.16+	Form of Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (European) (incorporated by reference to Exhibit 99.9 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.17+	Form of Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (European) (incorporated by reference to Exhibit 99.10 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.18+	Form of Stock Option Award Agreement outside the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.11 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.19+	Employment Agreement, dated July 14, 2014, by and between InspireMD, Inc. and James J. Barry, Ph.D. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on July 18, 2014)
10.20+	Amendment to Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.21+	First Amendment to Amended and Restated Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.22+	Amendment Number Two to Employment Agreement, dated February 22, 2015, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2015)
10.23+	First Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 9, 2015)
10.24+	Third Amendment to Employment Agreement, dated March 28, 2016, by and between InspireMD, Inc. and James J. Barry, PhD (incorporated by reference to Exhibit 10.66 to the Annual Report on Form 10-K filed on March 28, 2016)
10.25	Form of $25,812.50 Underwritten Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)

10.26	Form of $32,265.63 Underwriter Warrant (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.27	Form of $25,812.50 Private Placement Warrant (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.28	Form of $32,265.63 Placement Agent Warrant (incorporated by reference to Exhibit 10.7 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2016)
10.29+	Second Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 25, 2016)
10.30+	Fourth Amendment to Employment Agreement, dated June 6, 2016, by and between InspireMD, Inc. and James Barry, Ph.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 7, 2016)
10.31	Warrant Agreement, dated June 13, 2016, by and between InspireMD, Inc. and Hercules Capital, Inc. (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on June 14, 2016)
10.32	Placement Agent Unit Purchase Option, dated June 7, 2016, issued to Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.12 to the Quarterly Report on Form 10-Q filed on August 9, 2016)
10.33	Warrant Agent Agreement and Form of Warrant, dated as of July 7, 2016, between InspireMD, Inc. and Action Stock Transfer Corporation, as Warrant Agent (incorporated by reference to an exhibit to the Registration Statement on Form 8-A filed with Securities and Exchange Commission on July 26, 2016)
10.34+	Second Amendment to Amended and Restated Employment Agreement, dated July 25, 2016, by and between InspireMD, Inc. and Craig Shore agent (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 29, 2016)
10.35+	Third Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 29, 2016)
10.36+	Director Offer Letter, between InspireMD, Inc. and Thomas J. Kester, dated September 6, 2016
10.37+	Fifth Amendment to Employment Agreement, dated September 5, 2017, by and between InspireMD, Inc. and James Barry, Ph.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 7, 2017)
10.38	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 29, 2017)
10.39	Amendment to Securities Purchase Agreement, dated February 21, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 21, 2018)
10.40	Waiver Agreement, dated February 26, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 26, 2018)
10.41	Form of Underwriter Warrant, dated March 1, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 1, 2018)
10.42	Waiver Agreement, dated March 28, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 29, 2018)
10.43	Form of Underwriter Warrant, dated April 2, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 3, 2018)
10.44	Letter Agreement, dated June 28, 2018, by and between InspireMD, Inc. and Sabby Healthcare Master Fund, Ltd. (incorporated by reference to Exhibit 10.67 to the Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))

10.45	Form of Series D Warrant (incorporated by reference to Exhibit A to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
10.46	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
10.47	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
10.48+	Fourth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 26, 2018)
10.49+	Amended and Restated Employment Agreement, dated February 4, 2019, by and between InspireMD, Inc. and James J. Barry, Ph.D. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on February 6, 2019)
10.50+	Fifth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 21, 2019)
10.51+	Third Amendment to Amended and Restated Employment Agreement, dated March 25, 2019, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 28, 2019)
10.52	Form of Underwriter Warrant, dated April 8, 2019 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 8, 2019)
10.53	Form of Series E Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.54	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.55	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.56+	General Release and Severance Agreement, dated December 9, 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 December 10, 2019)
10.57+	Employment Agreement, dated December 9, 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 December 10, 2019).
10.58+	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).
10.59+	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).
10.60+	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 10, 2020)
10.61+	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 10, 2020)

10.62	Form of Series F Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on June 1, 2020 (File No. 333-238247)).
10.63	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on June 1, 2020 (File No. 333-238247))
10.64	Form of Underwriter Warrant (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on June 1, 2020 (File No. 333-238247))
10.65	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)
10.66	Form of Series G Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on February 3, 2021 (File No. 333-238247))
10.67	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on February 3, 2021 (File No. 333-238247))
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
23.1*	Consent of Kesselman & Kesselman, Certified Public Accountants
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from the Company's Annual Report on Form 10-K for the twelve months ended December 31, 2019, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii)Consolidated Statements of Income, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statement of Stockholders' Equity (Capital Deficiency) and (vi) Notes to Consolidated Financial Statements

* Filed herewith.

+ Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: March 8, 2021

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Marvin Slosman Marvin Slosman	President, Chief Executive Officer and Director (principal executive officer)	March 8, 2021
/s/ Craig Shore Craig Shore	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer (principal financial and accounting officer)	March 8, 2021
/s/ Paul Stuka Paul Stuka	Chairman of the Board of Directors	March 8, 2021
/s/ Michael Berman Michael Berman	Director	March 8, 2021
/s/ Thomas J. Kester Thomas J. Kester	Director	March 8, 2021
/s/ Campbell Rogers, M.D. Campbell Rogers, M.D.	Director	March 8, 2021
/s/ Gary Roubin Gary Roubin	Director	March 8, 2021

INSPIREMD, INC.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2020

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Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of InspireMD Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of InspireMD Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, changes in equity and cash flows for the years then ended , including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2(g) to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

/s/ Kesselman&Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 8, 2021

We have served as the Company's auditor since 2010.

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

	December 31,	
	2020	**2019**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 12,645	$ 5,514
Accounts receivable:		
Trade, net	476	823
Other	146	150
Prepaid expenses	334	87
Inventory	1,415	1,236
Receivable for sale of Shares	323	-
TOTAL CURRENT ASSETS	15,339	7,810
NON-CURRENT ASSETS:		
Property, plant and equipment, net	448	547
Operating lease right of use assets	1,265	937
Fund in respect of employee rights upon retirement	725	586
TOTAL NON-CURRENT ASSETS	2,438	2,070
TOTAL ASSETS	$ 17,777	$ 9,880

	December 31,	
	2020	**2019**
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	236	646
Other	3,469	2,469
TOTAL CURRENT LIABILITIES	3,705	3,115
LONG-TERM LIABILITIES:		
Operating lease liabilities	999	653
Liability for employee rights upon retirement	910	729
TOTAL LONG-TERM LIABILITIES	1,909	1,382
COMMITMENTS AND CONTINGENT LIABILITIES (Note 6)		
TOTAL LIABILITIES	5,614	4,497
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2020 and 2019; 49,264,830 and 3,916,134 shares issued and outstanding at December 31, 2020 and 2019, respectively	5	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2020 and 2019; 17,303 shares issued and outstanding at December 31, 2020 and 2019, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2020 and 2019; 2,343 and 34,370 shares issued and outstanding at December 31, 2020 and 2019, respectively	-	-
Additional paid-in capital	180,334	163,015
Accumulated deficit	(168,176)	(157,632)
Total equity	12,163	5,383
Total liabilities and equity	$ 17,777	$ 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)

	Year Ended December 31,	
	2020	**2019**
REVENUES (2020 - net of settlement payment of $580, see note 6)	$ 2,485	$ 3,721
COST OF REVENUES	2,402	2,965
GROSS PROFIT	83	756
OPERATING EXPENSES:		
Research and development	2,233	2,954
Selling and marketing	2,103	2,396
General and administrative	6,127	5,222
Total operating expenses	10,463	10,572
LOSS FROM OPERATIONS	(10,380)	(9,816)
FINANCIAL EXPENSES	(160)	(200)
LOSS BEFORE TAX EXPENSES	(10,540)	(10,016)
TAX EXPENSES	4	24
NET LOSS	$ (10,544)	$ (10,040)
NET LOSS PER SHARE - basic and diluted	(0.46)	(4.80)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	22,686,590	2,089,964

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 as of December 31, 2018	**768,615**	*	**17,303**	*	**61,423**	*	**$ 156,355**	**$ (147,592)**	**$ 8,763**
Net loss								**(10,040)**	**(10,040)**
Issuance of common shares, warrants, pre-funded warrants and exercise of pre-funded warrants, net of $1,177 issuance costs	**3,039,161**	*					**6,335**		**6,335**
Conversion of Series C Convertible Preferred Stock to common shares	**38,614**	*			**(27,053)**	*		*	-
Share-based compensation related to restricted stock , restricted stock units and stock options award, net of forfeitures of 838 shares	**69,744**	*					**325**		**325**
BALANCE as of December 31, 2019	**3,916,134**	*	**17,303**	*	**34,370**	*	**$ 163,015**	**$ (157,632)**	**$ 5,383**

* Represents an amount less than $1

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 as of December 31, 2019	**3,916,134**	*	**17,303**	*	**34,370**	*	**$ 163,015**	**$ (157,632)**	**$ 5,383**
Net loss								**(10,544)**	**(10,544)**
Exercise of pre-funded warrants	**14,856,400**	2					**16**		**18**
Settlement of restricted stock units in shares of common stock	**165,000**	*							*
Issuance of common shares, including at the market offering net of $1,110 issuance costs	**24,108,771**	**3**					**15,197**		**15,200**
Exercise of Warrants F	**2,866,600**	*					**1,418**		**1,418**
Exercise of Unit Purchase Option	**253,587**	*					**82**		**82**
Conversion of Series C Convertible Preferred Stock to common shares	**372,173**	*			**(32,027)**	*			*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 55,755 shares	**2,726,165**	*					**606**		**606**
BALANCE as of December 31, 2020	**49,264,830**	**5**	**17,303**	*	**2,343**	*	**$ 180,334**	**$ (168,176)**	**$ 12,163**

* Represents an amount less than $1

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

	Year ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (10,544)	$ (10,040)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	151	158
Loss from sale of property, plant and equipment	14	-
Change in liability for employees rights upon retirement	181	124
Non cash financial expense (income)	(4)	8
Net change in operating lease assets and liabilities	56	78
Share-based compensation expenses	606	325
Gains on amounts funded in respect of employee rights upon retirement, net	(18)	(35)
Changes in operating asset and liability items:		
Increase in prepaid expenses	(247)	(6)
Decrease (increase) in trade receivables	347	(107)
Decrease (increase) in other receivables	4	(46)
Increase in inventory	(179)	(102)
Decrease in trade payables	(410)	(283)
Increase in other payables	962	116
Net cash used in operating activities	(9,081)	(9,810)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(88)	(284)
Proceeds from sale of property, plant and equipment	22	-
Amounts withdrawn in respect of employee rights upon retirement, net	(121)	(103)
Net cash used in investing activities	(187)	(387)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of $1,110 and $1,177 issuance costs, respectively	16,395	6,335
Net cash provided by financing activities	16,395	6,335
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	4	(8)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,131	(3,870)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	5,514	9,384
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 12,645	$ 5,514
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	619	67
Receivable for Shares	323	-

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.

b. COVID-19 Pandemic

During the year ended December 31, 2020, in an effort to contain and mitigate the spread of COVID-19, many countries have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. As of the beginning of the second quarter of 2020, we began to experience a significant COVID-19 related impact on our financial condition and results of operations, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. To the best of our knowledge, most European countries in which we operate are reinstating elective procedures, but we do not know when the hospitals will resume to normal pre-pandemic levels with such procedures in light of recent increases in COVID-19 cases in the territories we sell into. We anticipate that the continuation of the pandemic and related restrictions and safety measures would likely result in a continued fluctuations in sales of our products for the upcoming periods.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory valuations, assessing the likelihood of exercise of options to extend the lease term and legal contingencies.

b. Functional currency

The currency of the primary economic environment in which the operations of the Company and its subsidiaries are conducted is the U.S. dollar ("$" or "dollar"). Accordingly, the functional currency of the Company and its subsidiaries is the U.S. dollar.

The dollar figures are determined as follows: transactions and balances originally denominated in dollars are presented in their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. The resulting translation gains or losses are recorded as financial income or expense, as appropriate. For transactions reflected in the statements of operations in foreign currencies, the exchange rates at transaction dates are used. Depreciation and changes in inventories and other changes deriving from non-monetary items are based on historical exchange rates.

c. Principles of consolidation

The consolidated financial statements include the accounts of the Company and of its subsidiaries. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash and cash equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit), that are not restricted as to withdrawal or use, to be cash equivalents.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

e. Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, which are deposited in major financially sound institutions in the U.S, Israel and Germany, and trade accounts receivable. The Company's trade accounts receivable is derived from revenues earned from customers from various countries. The Company performs ongoing credit evaluations of its customers' financial condition and, requires no collateral from its customers. The Company also has a credit insurance policy for some of its customers. The Company maintains an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. The Company reviews its allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If the Company determines that a specific customer is unable to meet its financial obligations to the Company, the Company provides an allowance for credit losses to reduce the receivable to the amount management reasonably believes will be collected, which is netted against "Accounts receivable - Trade".

f. Inventory

Inventories are stated at the lower of cost (cost is determined on a "first-in, first-out" basis) or net realizable value. The Company's inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. The Company regularly evaluates the carrying value of its inventory and when, based on such evaluation, factors indicate that impairment has occurred, the Company impairs the inventories' carrying value.

The fair value of the Company's financial instruments approximates their carrying values."

g. Leases

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

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

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

Upon adoption, we recognized additional operating lease liabilities, of approximately $1.2 million based on the present value of the remaining lease payments under current leasing standards for existing operating leases. The Company also recognized corresponding ROU assets of approximately $1.2 million. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the extension option will be exercised or termination option will not be exercised. For Operating Lease expense is recognized on a straight-line basis over the lease term. Our leases may include variable payments based on measures that include changes in price index which are expensed as incurred and presented as operating expense on the condensed consolidated statements of operations in the same line item as expense arising from fixed lease payments.

The new standard also provides practical expedients for an entity's ongoing accounting. See Note 5.

h. Property, plant and equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets: over three years for computers and other electronic equipment, and seven to fifteen years for office furniture and equipment and machinery and equipment (mainly seven years). Leasehold improvements are amortized on a straight-line basis over the term of the lease, which is shorter than the estimated life of the improvements.

i. Impairment in value of long-lived assets

The Company tests long-lived intangible and tangible assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, an impairment would be recognized, and the assets would be written down to their estimated fair values, based on

expected future discounted cash flows.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Revenue recognition

A contract with a customer exists only when: 1) the parties to the contract have approved it and are committed to perform their respective obligations, 2) the Company can identify each party's rights regarding the distinct goods or services to be transferred ("Performance Obligations"), 3) the Company can determine the transaction price for the goods or services to be transferred, 4) the contract has commercial substance and 5) it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for Performance Obligations upon transfer of control to the customer, excluding sales taxes.

Revenue from sales of goods, including sales to distributors, is recognized when the customer obtains control of the product, once the Company has a present right to payment and the customer has legal title, and risk and rewards of ownership are obtained by the customer. This occurs when products are shipped.

The Company recognizes the incremental costs of obtaining contracts as an expense since the amortization period of the assets that the Company otherwise would have recognized is one year or less. The costs are recorded under selling and marketing expenses. Disaggregated revenue is disclosed in Note 10.

The Company recognizes revenue net of value added tax (VAT).

k. Research and development costs

Research and development costs are charged to the statement of operations as incurred.

l. Share-based compensation

The Company has equity incentive plans under which the Company grants equity awards, including stock options, restricted stock and restricted stock units ("RSUs"). Employee equity awards are classified as equity awards and accounted for using the grant-date fair value method. The Company determines compensation expense associated with Restricted Stock and RSUs based on the fair value of our common stock on the date of grant. The fair value of option awards is estimated using the Black-Scholes valuation model and expensed over the requisite service period. The Company elected to account for forfeitures as they occur.

The Company elected to recognize compensation expenses for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

m. Uncertain tax positions

The Company follows a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. If under the first step a tax provision is assessed to be more likely than not of being sustained on audit, the second step is performed, under which the tax benefit is measured as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. The Company's policy is to include interest related to unrecognized tax benefits within "Financial expenses - net".

n. Deferred income taxes

Deferred taxes are determined utilizing the "asset and liability" method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws, and on tax rates anticipated to be in effect when the deferred taxes are expected to be paid or realized. The Company assesses realization of deferred income tax assets and, based on all available evidence, concludes whether it is more likely than not that the net deferred income tax assets will be realized. A valuation allowance is provided for the amount of deferred income tax assets not considered to be realizable.

The Company may incur an additional tax liability in the event of intercompany dividend distributions by its subsidiaries. Such additional tax liability in respect of these foreign subsidiaries has not been provided for in these financial statements as it is the Company's policy to permanently reinvest the subsidiaries' earnings and to consider distributing dividends only in connection with a specific tax opportunity that may arise.

Taxes that would apply in the event of disposal of investments in a foreign subsidiary have not been taken into account in computing the deferred taxes, as it is the Company's intention to hold, and not to realize, these investments.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. Advertising

Costs related to advertising and promotion of products are charged to sales and marketing expense as incurred. Advertising expenses were approximately $163,000 and $262,000 for the years ended December 31, 2020 and 2019, respectively.

p. Net loss per share

Basic and diluted net loss per share is computed by dividing the net loss for the period attributable to common stock by the weighted average number of shares of common stock outstanding during the period, including 922,720 and 151,884 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the years ended December 31, 2020 and 2019, respectively, (since they are convertible based on passage of time) and 72,493 weighted average shares of common stock issuable to holders of unexercised Pre-Funded Warrants for the year ended December 31, 2019.

The total number of shares of common stock related to outstanding options, warrants, restricted stock, restricted stock units, Series C Convertible Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 32,493,268 and 4,707,230 for the years ended December 31, 2020 and 2019, respectively.

q. Segment reporting

The Company has one operating and reportable segment.

r. Fair value measurement

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

s. Issued accounting pronouncements effective in future periods

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. This guidance replaces the current incurred loss impairment methodology. Under the new guidance, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. In November 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two-tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies will have an effective date for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, the Company meets the definition of an SRC and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial statements but does not believe the adoption of this standard will have a material impact on its consolidated financial statements.

NOTE 3 - PROPERTY, PLANT AND EQUIPMENT

a. Composition of assets, grouped by major classifications, is as follows:

	December 31,	
	2020	**2019**
	($ in thousands)	
Cost:		
Computer equipment	$ 289	$ 287
Office furniture and equipment	95	95
Machinery and equipment	1,427	1,414
Leasehold improvements	211	206
	2,022	2,002
Less - accumulated depreciation and amortization	(1,574)	(1,455)
Net carrying amount	$ 448	$ 547

b. Depreciation and amortization expenses totaled approximately $151,000 and $158,000 for the years ended December 31, 2020 and 2019, respectively.

NOTE 4 - LIABILITY FOR EMPLOYEES RIGHT UPON RETIREMENT

Israeli labor law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances.

Pursuant to section 14 of the Israeli Severance Compensation Act, 1963, some of the Company's employees are entitled to have monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with insurance companies. Payments in accordance with section 14 relieve the Company from any future severance payments to these employees.

The severance pay liability of the Company for the rest of its Israeli employees, which reflects the undiscounted amount of the liability, is based upon the number of years of service and the latest monthly salary. The severance pay liability is partly covered by insurance policies and by regular deposits with recognized severance payment funds. The Company may only withdraw funds previously deposited for savings in connection with the payment of severance. The severance pay expenses were approximately $276,000 and $197,000 for the years ended December 31, 2020 and 2019, respectively.

Defined contribution plan expenses were approximately $339,000 and $294,000 for the years ended December 31, 2020 and 2019, respectively.

The Company expects contribution plan expenses in 2021 to be approximately $346,000.

NOTE 5 – 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 company exercised the Option Period as estimated. In addition, the Company amended the agreement mentioned above which include a new option period for two additional years until December 31, 2024 under the terms stipulated in the agreement, the Option Period was taken in consideration when calculating the operating lease right of use assets and liabilities. In addition, the Company entered into another amendment to the lease agreement for a lease of additional space in the facility, the additional space amendment was taken in consideration when calculating the operating lease right of use assets and liabilities.

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

3) Operating lease cost for the year ended December 31, 2020 was comprised of the following:

	Twelve months ended December 31 2020 ($ in thousands)	Twelve months ended December 31 2019 ($ in thousands)
Operating lease expense	370	358
Short-term lease expense	-	8
	370	366

Supplemental information related to leases are as follows:

	December 31 2020 ($ in thousands)	December 31 2019 ($ in thousands)
Operating lease right-of-use assets	1,265	937
Current Operating lease liabilities	(400)	(362)
Non-current operating lease liabilities	(999)	(653)

Other information:

Operating cash flows from operating leases (cash paid in thousands)	(387)	(366)
Weighted Average Remaining Lease Term	1.73	1.33
Weighted Average Discount Rate	8.38%	9.07%

Maturities of lease liabilities are as follows:

	Amount ($ in thousands)
2021	421
2022	389
2023	400
2024	419
Total lease payments	1,629
Less imputed interest	(230)
Total	1,399

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES:

Litigation:

In July 2016, a service provider filed a suit seeking damages from the Company's subsidiary amounting to $1,967,822. The Company's subsidiary and the plaintiff have entered into a confidential settlement agreement in the amount of $600,000, and on April 24, 2019, the parties filed a stipulation of dismissal, dismissing all claims in this action. On April 25, 2019, the court denied as moot all pending motions. The related increase in provision of $354,000 was recorded to "Research and development expense" within the Consolidated Statements of Operations for the year months ended December 31, 2019.

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). In January 2021, we executed a Mediation Agreement with the former distributor, pursuant to which the former distributor agreed to release the Company from all claims stated in the Complaint in exchange for a payment of $580,000. Accordingly, the amount of $580,000 was recorded as a debit to revenue.

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

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

In July 2020, a former senior employee of InspireMD GmbH filed a statement of claim at the Munich Labor Court, seeking confirmation of the court that the notice of termination is not effective. On November 10, 2020, we entered into a settlement agreement. As consideration for the final release, we paid the former senior employee 25,000 Eur (approximately $30,000) which was recorded to "Selling and marketing expense" within the Consolidated Statements of Operations.

NOTE 7 - EQUITY

a. Share capital

The Company's common stock are listed on the NYSE American.

On March 27, 2019, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a one-for-fifty reverse stock split of its common stock, par value $0.0001 per share, effective as of March 29, 2019, which decreased the number of issued and outstanding shares of common stock and restricted stock as of December 31, 2018 from 38.4 million shares to 769 thousand shares.

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

NOTE 7 – EQUITY (continued):

Public Offerings

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

In connection with the offering, the Company issued to the underwriter warrants to purchase up to 34,955 shares of common stock, or 7% of the shares sold in the offering, including the shares issued pursuant to the over-allotment option (the "April 2019 Underwriter Warrants"). The April 2019 Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending on April 4, 2024, at an exercise price of $6.25 per share (125% of the offering price to the public per share).

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

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

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

The Series E Warrants included in the 2019 Common Units and the 2019 Pre-Funded Units are immediately exercisable at a price of $1.80 per share of common stock, subject to adjustment in certain circumstances, and expire five years from the date of issuance.

Each 2019 Pre-Funded Warrant contained in a 2019 Pre-Funded Unit is exercisable for one share of our common stock at an exercise price of $0.01 per share. The 2019 Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the 2019 Pre-Funded Warrants are exercised in full.

In connection with the offering, the Company issued to the underwriter warrants to purchase up to 194,444 shares of common stock, or 7% of the shares sold in the offering, including the number of shares of common stock issuable upon exercise of the 2019 Pre-Funded Warrants sold in the offering (the "September 2019 Underwriter Warrants"). The September 2019 Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending on September 19, 2024, at an exercise price of $2.25 per share (125% of the offering price to the public per 2019 Common Unit).

Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company's Series B Convertible Preferred Stock and Series C Preferred Stock, the conversion price of the outstanding shares of the Series B Convertible Preferred Stock and the Series C Preferred Stock was reduced to $1.80 per share, effective as of the date of the underwriting agreement entered for the September 2019 Offering, and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock had increased as follows:

- an aggregate of 355,288 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of September 19, 2019.
- an aggregate of 84,253 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 37,025 shares of Series C Preferred Stock outstanding as of September 19, 2019.

NOTE 7 – EQUITY (continued):

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

On June 5, 2020, the Company closed an underwritten public offering of (i) 7,635,800 units ("Units"), with each Unit being comprised of one share of the Company's common stock, par value $0.0001 per share, and one Series F warrant (a "Series F Warrant") to purchase one share of common stock, and (ii) 14,586,400 pre-funded units (the "Pre-Funded Units"), with each Pre-Funded Unit being comprised of one pre-funded warrant (a "Pre-Funded Warrant") to purchase one share of common stock and one Series F Warrant. In connection with this public offering, the underwriter exercised its over-allotment option in full and purchased an additional 3,333,300 shares of common stock and 3,333,300 Series F Warrants. The offering price to the public was $0.45 per Unit and $0.449 per Pre-Funded Unit. The net proceeds to the Company from the offering and the exercise of the underwriter's over-allotment option were approximately $10.7 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series F Warrants and the Pre-Funded Warrants sold in the offering. The pre-funded warrants exercisable at a price of $0.001 per share of common stock.

The Series F Warrants included in the Common Units and the Pre-Funded Units are immediately exercisable at a price of $0.495 per share of common stock, subject to adjustment in certain circumstances, and expire June 2, 2025. The shares of common stock, or Pre-Funded Warrants in the case of the Pre-Funded Units, and the Series F Warrants were offered together, but the securities contained in the Common Units and the Pre-Funded Units were issued separately.

During the year ended December 31, 2020, 2,866,600 Series F Warrants were converted into 2,866,600 shares of common stock. The net proceeds to the Company from exercise of the Series F Warrants were approximately $1.4 million.

Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company's Series B Convertible Preferred Stock and Series C Preferred Stock, the conversion price of the outstanding shares of the Series B Convertible Preferred Stock and the Series C Preferred Stock was reduced to $0.45 per share, effective as of the date of the underwriting agreement entered for the June 2020 Offering, and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock had increased as follows:

● An aggregate of 1,665,414 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of June 2, 2020.

● An aggregate of 283,285 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 26,558 shares of Series C Preferred Stock outstanding as of June 2, 2020.

for the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the Pre-funded Warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them. The Company has also concluded that the series F warrants are classified as equity, since the warrants meet all criteria for equity classification.

During the year ended December 31, 2020, the Company issued a total of 14,586,400 shares of common stock in connection with the exercise of all outstanding Pre-Funded Warrants issued in June 2020. In addition, 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 December 31, 2020, there are no outstanding Pre-Funded Warrants.

During the year ended December 31, 2019, the Company issued a total of 2,000,811 shares of its common stock in connection with the exercise of an aggregate of 2,000,811 Pre-Funded Warrants and 2019 Pre-Funded Warrants. The Company received aggregate cash proceeds equal to approximately $35,705 in connection with such exercises.

ATM Offering

During the year ended December 31, 2020, the Company sold 12,917,448 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with A.G.P./Alliance Global Partners. These sales resulted in net proceeds to the Company of approximately $4,447 thousand.

Pursuant to the full ratchet anti-dilution adjustment provisions in the respective certificate of designation for the Company's Series B Convertible Preferred Stock and Series C Preferred Stock, the conversion price of the outstanding shares of the Series B Convertible Preferred Stock and the Series C Preferred Stock was reduced to $0.321 per share, triggered by the ATM Facility, effective as of December 14, 2020 , and the number of shares of common stock issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock had increased as follows:

- an aggregate of 892,371 additional shares of common stock upon conversion of the Series B Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Preferred Stock outstanding as of December 14, 2020.
- an aggregate of 13,392 additional shares of common stock upon conversion of the Series C Preferred Stock, based on 2,343 shares of Series C Preferred Stock outstanding as of December 14, 2020.

As of December 31, 2020, the Number of Preferred shares 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	3,112,923**
Series C Convertible Preferred Stock	2,343	46,714***
Total		3,159,637

* See "Note 11 - Subsequent events" regarding conversion of all remaining Series B Convertible Preferred Stock into common stock.

** On July 7, 2016, we issued 442,424 shares of Series B Preferred Stock in a public offering. Our Series B Preferred Stock has a stated value of $33.00 which currently converted into 3,112,923 reflecting a conversion price equal to $ 0.321. The holders of Series B 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.

*** On March 14, 2017, we issued 1,069,822 shares of Series C Preferred Stock in a public offering. Our Series C Preferred Stock has a stated value of $6.40 which currently converted into 46,714 reflecting a conversion price equal to $ 0.321.

As of December 31, 2020, the Company has outstanding warrants to purchase an aggregate of 26,705,502 shares of common stock as follows:

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

As of December 31, 2020, the Company has 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 the event of our liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock are entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Preferred Stock if such shares had been converted to common stock immediately prior to such event.

NOTE 7 – EQUITY (continued):

b. Share-Based Compensation

1) Pursuant to the current Section 102 of the Israeli Tax Ordinance, which came into effect on January 1, 2003, options may be granted through a trustee (i.e., Approved 102 Options) or not through a trustee (i.e., Unapproved 102 Options). As a result of an election made by the Company under Section 102 of the Income Tax Ordinance, the Company will not be allowed to claim as an expense for tax purposes in Israel the amounts credited to the employee as capital gains to the grantees, although it will generally be entitled to do so in respect of the salary income component (if any) of such awards when the related tax is paid by the employee.

2) During the year ended December 31, 2020, the Company granted stock options to the CEO, employees and directors to purchase a total of 1,379,856 shares of the Company's common stock. The options have exercise prices ranging from $0.33-$1.10 per share, respectively, which were the fair market value of the company's common stock on the date of each respective grant. As of December 31, 2020, the fair value of the above options, using the Black-Scholes pricing models, was approximately $509,000. The options are subject to a three-year vesting period with one-third of such awards vesting each year.

3) During the years ended December 31, 2020 and 2019, the Company granted to the then CEO, employees and directors 2,781,920 and 70,582 restricted stock, respectively. The fair value of these restricted stock was approximately $1,051,604 and $668,000, respectively. The restricted stock are subject to a three-year vesting period, with one-third of such awards vesting each year.

4) During the years ended December 31, 2020 and 2019, the Company granted CEO and former CEO 1,357,668 and 165,000 Restricted Stock Units, respectively. The fair value of these restricted stock units was approximately $658,981 and $141,900, respectively. The restricted stock units granted during the years ended December 31, 2020 are subject to a three-year vesting period, with one-third of such awards vesting each year. The restricted stock units granted during the year ended December 31, 2019 were fully vested upon grant.

5) The following table summarizes information about stock options granted to employees:

	Year ended December 31			
	2020		2019	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding - beginning of period	160	$ 189,161.99	164	$ 184,656
Granted	1,379,856	0.41	-	-
Forfeited	(4,751)	343.51	(4)	4,423
Outstanding -end of period	1,375,265	$ 21.24	160	$ 189,162
Exercisable at the end of the period	115	$ 249,006	160	$ 189,162

NOTE 7 – EQUITY (continued):

6) The following table summarizes information about stock options granted to non-employees:

	Year ended December 31			
	2020		2019	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding - beginning of period	16	$ 1,711,975	20	$ 1,693,174
Granted	-	-	-	-
Forfeited	(1)	2,156,208	(4)	1,617,338
Exercised	-	-	-	-
Outstanding - end of period	15	1,682,385	16	1,711,975
Exercisable at the end of the period	15	1,682,385	16	1,711,975

7) The following table summarizes information about restricted stock granted to employees:

	Year ended December 31	
	2020	2019
	Number of restricted stock	
Outstanding - beginning of period	69,631	19
Reverse Split Adjustments	-	(127)
Granted	2,781,920	70,582
Forfeited	(55,755)	(838)
Vested	(9,915)	(5)
Outstanding - end of period	2,785,881	69,631

8) The following table summarizes information about Restricted Stock Unit granted to employees:

	Year ended December 31	
	2020	2019
	Number of restricted stock	
Outstanding - beginning of period	165,000	-
Granted	1,357,668	165,000
Forfeited	-	-
Vested	(165,000)	-
Outstanding - end of period	1,357,668	165,000

9) The following table provides additional information about all options outstanding and exercisable:

	Outstanding as of December 31, 2020		
Exercise price	Options outstanding	Weighted average remaining contractual life (years)	Options exercisable
$0.175	2	1.39	2
$0.33-0.39	1,314,356	9.69	-
$1.10	60,794	9.01	-
$175 and above	128	4.71	128
	1,375,280	9.66	130

The weighted average of the remaining contractual life of total vested and exercisable options as of December 31, 2020 was 4.66 years.

The aggregate intrinsic value of the total exercisable options as of December 31, 2020 was approximately $1.

NOTE 7 – EQUITY (continued):

The weighted average fair value of options granted was $0.37 for the year ended December 31, 2020. The weighted average fair value of options granted was estimated using the Black-Scholes option-pricing model.

10) The following table sets forth the assumptions that were used in determining the fair value of options granted to employees for the year December 31, 2020:

	Year ended December 31
	2020
Expected life	5.5-6.5 years
Risk-free interest rates	0.32%-0.42%
Volatility	124.53%-136.66%
Dividend yield	0%

The Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. Accordingly, as to ordinary course options granted, the expected term was determined using the simplified method, which takes into consideration the option's contractual life and the vesting periods (for non-employees, the expected term is equal to the option's contractual life).

The annual risk-free rates are based on the yield rates of zero coupon non-index linked U.S. Federal Reserve treasury bonds as both the exercise price and the share price are in dollar terms. The Company's expected volatility is derived from its historical data.

11) As of December 31, 2020, the total unrecognized compensation cost on employee and non-employee stock options and restricted stock, related to unvested stock-based compensation, amounted to approximately $1.7 million. This cost is expected to be recognized over a weighted-average period of approximately 0.95 years. This expected cost does not include the impact of any future stock-based compensation awards.

12) The following table summarizes the allocation of total share-based compensation expense in the consolidated statements of operations:

	Year ended December 31	
	2020	2019
	($ in thousands)	
Cost of revenues	$ 22	$ 14
Research and development	29	10
Sales and marketing	32	29
General and administrative	523	272
	$ 606	$ 325

NOTE 8 - TAXES ON INCOME:

a. Tax laws applicable to the Company and its subsidiaries

Taxation in the United States

InspireMD, Inc. is taxed under U.S. tax laws. Accordingly, the applicable federal corporate tax rate in 2020 is 21%. State tax may also apply .

Taxation in Israel

The corporate tax rate was 23% in 2020 and will be 23% thereafter.

Taxation in Germany

InspireMD GmbH is taxed according to the tax laws in Germany. Accordingly, the applicable tax rates are corporate tax rate of 15.825% and trade tax rate of 17.15%.

b. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Law"):

InspireMD Ltd. has been granted a "Beneficiary Enterprises" status under the Investment Law including Amendment No. 60 thereof, which became effective in April 2005. The tax benefits derived from any such Beneficiary Enterprise relate only to taxable profits attributable to the specific program of investment to which the status was granted.

The main benefit, to which InspireMD Ltd. is entitled, conditional upon the fulfilling of certain conditions stipulated by the above law, is a two-year exemption and five to eight years of a reduced tax rate of 10% to 23% from tax on income derived from beneficiary activities in facilities in Israel. The two-year exemption starts only when the Company starts to pay taxes after using all tax offsetting losses. The tax benefit period is twelve years from the year of election, which means that after a year of election, the two-year exemption and eight years of reduced tax rate can only be used within the next twelve years. The Company elected the year 2011 as a year of election.

NOTE 8 - TAXES ON INCOME (continued):

In the event of a distribution of tax-exempt income attributable to "Beneficiary Enterprises" as a cash dividend, the Company will be required to pay tax at a rate of 10% to 23% on the amount distributed, subject to certain conditions. In addition, dividends originating from income attributable to the "Beneficiary Enterprises" will be subject to a 20% withholding tax.

Should InspireMD Ltd. derive income from sources other than the "Beneficiary Enterprises" during the period of benefits, such income shall be taxable at the regular corporate tax rate.

1) Conditions for entitlement to the benefits

The entitlement to the above benefits is conditional upon InspireMD Ltd. fulfilling the conditions stipulated by the law, regulations published thereunder and the instruments of approval for the specific investments in approved assets. In the event of failure to comply with these conditions, the benefits may be cancelled, and InspireMD Ltd. may be required to refund the amount of the benefits, in whole or in part, with the addition of interest and linkage.

The Company opted not to apply for Preferred Enterprise status (as defined in the Amendment of the Law for the Encouragement of Capital Investments, 1959).

c. Carry forward tax losses

As of December 31, 2020, the Company had a net carry forward tax loss of approximately $44 million, of which approximately $35 million (arising before January 1, 2018), expires until 2037, and approximately $9 million, which does not expire, but is limited to offset 80% of the net income in the year it is utilized.

Under the U.S. tax laws, for net operating losses (NOLs) arising after December 31, 2017, the Tax Cuts and Jobs Act enacted on December 22, 2017 (the "2017 Act") limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income.

In addition, NOLs arising after 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018, will not be subject to the foregoing taxable income limitation and will continue to have a two-year carryback and twenty-year carryforward period.

Further to COVID-19 CARES act of the U.S. Treasury, the business tax provision temporarily removes the current law taxable income 80% limitation to allow an NOL to fully offset income in tax years 2018, 2019 and 2020. The provision also allows an NOL from tax years beginning in 2018, 2019, or 2020 to be carried back for five years.

As of December 31, 2020, InspireMD Ltd., an Israeli subsidiary, had a net carry forward tax loss of approximately $98 million. Under Israeli tax laws, the carry forward tax losses can be utilized indefinitely.

d. Loss before income taxes

The components of loss before income taxes are as follows:

	Year ended December 31	
	2020	**2019**
	($ in thousands)	
Loss before taxes on income:		
InspireMD, Inc.	$ (3,897)	$ (3,687)
Subsidiaries	(6,643)	(6,329)
	$ (10,540)	$ (10,016)

NOTE 8 - TAXES ON INCOME (continued):

e. Current taxes on income

The main reconciling items between the statutory tax rate of the Company and the effective tax rate are the change in subsidiary tax rates and the change in valuation allowance in respect of tax benefits from carried forward tax losses due to uncertainty of the realization of such tax benefits and changes in tax rates following the 2017 Act.

The changes in the valuation allowance for the year ended December 31, 2020 and 2019 were as follows:

	Year ended December 31	
	2020	2019
	($ in thousands)	
Balance at the beginning of the year	$ 31,181	$ 27,640
Changes during the year:		
Losses during the year (including foreign exchange rate effect)	3,964	3,541
Balance at the end of the year	$ 35,145	$ 31,181

f. Accounting for Uncertain Tax position

Following is a reconciliation of the total amounts of the Company's uncertain tax positions during the year ended December 31, 2020 and 2019 were as follows:

	Year ended December 31,	
	2020	2019
	($ in thousands)	
Balance at beginning of period	$ 44	$ 28
Increase in uncertain tax positions because of tax positions taken during the year	8	16
Balance at end of period	$ 52	$ 44

A summary of open tax years by major jurisdiction is presented below:

Jurisdiction	Years
U.S.	2017-2020
Israel	2015-2020
Germany	2017-2020
United Kingdom	2014-2015

NOTE 8 - TAXES ON INCOME (continued):

g. Deferred income tax:

	December 31,	
	2020	**2019**
	($ in thousands)	
Long-term:		
Allowance for bonus	2	57
Provision for vacation and recreation pay	63	35
R&D expenses	578	589
Operating lease right of use assets	(291)	(215)
Operating lease liabilities	322	233
Share-based compensation	2,669	2,596
Carry forward tax losses	31,759	27,854
Accrued severance pay, net	43	32
	35,145	31,181
Less-valuation allowance	(35,145)	(31,181)
	-	-

NOTE 9 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

Inventory:

	December 31,	
	2020	**2019**
	($ in thousands)	
Finished goods	$ 350	$ 173
Work in process	376	81
Raw materials and supplies	689	982
	$ 1,415	$ 1,236

NOTE 9 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):

a. Accounts payable and accruals-other:

	December 31,	
	2020	**2019**
	($ in thousands)	
Employees and employee institutions	$ 1,236	$ 1,238
Accrued vacation and recreation pay	278	188
Accrued expenses	886	604
Accrual for settlement payment (see note 6)	580	-
Current Operating lease liabilities	400	362
Other	89	77
	$ 3,469	$ 2,469

NOTE 10 – DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:

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

	Year ended December 31,	
	2020	**2019**
	($ in thousands)	
Germany	$ 708	$ 727
Italy	596	686
Poland	219	370
Other (2020 - net of settlement payment of $580, see note 6)	962	1,938
	$ 2,485	$ 3,721

By product:

	Year ended December 31,	
	2020	**2019**
	($ in thousands)	
CGuard™ EPS	$ 2,764	$ 3,265
MGuard Prime™ EPS (2020 - net of settlement payment of $580, see note 6)	(279)	456
	$ 2,485	$ 3,721

By principal customers (2020 - before of settlement payment of $580 see note 6):

	Year ended December 31,	
	2020	**2019**
Customer A	21%	18%
Customer B	11%	8%
Customer C	8%	10%
Customer D	7%	10%

All tangible long lived assets are located in Israel.

NOTE 11 - SUBSEQUENT EVENTS:

Subsequent to December 31, 2020 the Company had several stock transactions as follows (U.S. dollars in thousands, except share data):

	Common Stock	Gross amount
BALANCE as of December 31, 2020	49,264,830	
Issuance of shares to Chinese distributor	1,341,682	900(a)
ATM sales	12,277,844	5,659(b)
February 2021 public offering	33,387,096	20,700(c)
Series F and Series G warrants exercise	18,381,177	9,469(d)
Conversion of Series B Convertible Preferred Stock to common shares	3,112,923	-(e)

a. 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 shares of the Company's common stock at a purchase price of $0.6708 per share.

b. Subsequent to year-end, the Company sold an aggregate of 12,277,844 shares of common stock for aggregate gross proceeds of $5,659,000 under the ATM Sales Agreement. In addition, in January 2021 we received $323,000 for shares of common stock sold on December 2020 and recorded to "Receivable for sale of Shares" in current assets of the Consolidated Balance Sheet as of December 31, 2020.

c. On February 3, 2021, the Company entered into an underwriting agreement with A.G.P./Alliance Global Partners, relating to an underwritten public offering (the "Offering") of 29,032,258 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. The offering price to the public was $0.62 per Unit. The Series G Warrants are immediately exercisable at a price of $0.682 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance. The Offering closed on February 8, 2021.

The Company granted the Underwriter a 45-day option to purchase up to an additional 4,354,838 Units consisting of 4,354,838 shares of Common Stock and Series G Warrants to purchase 2,177,419 shares of common stock in the Offering, which the Underwriter exercised in full on February 4, 2021.

The Company granted the Underwriter a compensation warrant to purchase up to 1,669,355 shares of Common Stock. The Underwriter Warrants have an exercise price of $0.682 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.

d. Subsequent to year-end, Series F and Series G warrants to purchase shares of common stock were exercised by investors at an exercise price of $0.495 and $0.682 per share, resulting in the issuance of 18,381,177 shares of common stock for proceeds of approximately $9,469,000.

e. On February 3, 2021, 17,303 shares of Series B Convertible Preferred Stock were converted into 3,112,923 shares of common stock.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-238247, 333-252199 and 333-252710), Form S-3 333-223530 and Form S-8 (Nos. 333-248837, 333-249320, 333-232348, 333-218499, 333-196533 and 333-188839), of InspireMD, Inc. of our report dated March 8, 2021 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
March 8, 2021

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)

I, Marvin Slosman, certify that:

1. I have reviewed this Annual Report on Form 10-K of InspireMD, Inc. (the "registrant");

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 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 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: March 8, 2021

By: */s/ Marvin Slosman*

Name: Marvin Slosman
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)

I, Craig Shore, certify that:

1. I have reviewed this Annual Report on Form 10-K of InspireMD, Inc. (the "registrant");

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 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 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: March 8, 2021

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

Exhibit 32.1

CERTIFICATION FURNISHED 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 Annual Report on Form 10-K (the "Form 10-K") for the fiscal year ended December 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-K 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-K 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: March 8, 2021

By: */s/ Marvin Slosman*
Name: Marvin Slosman
Title: President and Chief Executive Officer (Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K 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-K 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 FURNISHED 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 Annual Report on Form 10-K (the "Form 10-K") for the fiscal year ended December 31, 2020 of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K 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-K 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: March 8, 2021

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

The foregoing certification is being furnished as an exhibit to the Form 10-K 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-K 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.