InspireMD, Inc.
Form 10-K
February 19, 2019

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, 2018

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
(Address of principal executive offices)

6744832
(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	Name of each exchange on which registered
Common Stock, $0.0001 par value	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes [X] No [ ]

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

Large accelerated filer [ ] Accelerated filer [ ]

Non-accelerated filer [X] Smaller reporting company [X]

Emerging growth company [ ]

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

Indicate by check mark whether the registrant is a shell company (as defined 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, 2018, based on the price at which the common equity was last sold on the NYSE American on such date, was $1,603,155. 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 February 18, 2019**
Common Stock, $0.0001 par value	41,888,895

Documents incorporated by reference:

None

TABLE OF CONTENTS

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 we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately $1.0 billion in 2017. (source: *Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets*).

In April 2017, we had a pre-investigational device exemption ("IDE") submission meeting with the U.S. Food and Drug Administration 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. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States. We intend to make an IDE submission seeking

approval to conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, 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. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever. 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 and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

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

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

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

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

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

Recent Developments

NYSE American Notification

On August 17, 2017, we received a notice from NYSE American indicating that we do not meet the continued listing standards of the NYSE American as set forth in Part 10 of the NYSE American Company Guide (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, 2017, and net losses in our five most recent fiscal years ended December 31, 2016. As a result, we became subject to the procedures and requirements of Section 1009 of the Company Guide. On October 19, 2017, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by February 19, 2019. We are subject to periodic review by the NYSE American staff during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NYSE American.

On November 22, 2017, we received an additional letter from the NYSE American indicating that we are not in compliance with the stockholders' equity and net income continued listing standards set forth in Section 1003(a)(ii) of the Company Guide because we reported stockholders' equity of less than $4 million as of September 30, 2017. We have until February 17, 2019, to regain compliance with the continued listing requirements.

On January 16, 2018, we received notification from the NYSE American that we are not in compliance with certain NYSE American continued listing standards. The deficiency letter states 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 staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 16, 2018.

Effective as of 5:00 p.m. Eastern Time on February 7, 2018, we amended our amended and restated certificate of incorporation in order to effectuate a 1-for-35 reverse stock split of our outstanding shares of common stock.

On July 16, 2018, we received notification from the NYSE American that we have resolved the continued listing deficiency with respect to low selling price pursuant to Section 1003(f)(v) of the Company Guide. We remain below compliance with Sections 1003(a)(ii) and (iii) of the Company Guide.

However, on January 7, 2019, we again received notification from the NYSE American that we are not in compliance with the NYSE American continued listing standards because our shares of common stock 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 staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 7, 2019.

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 Heart Federation (*http://www.world-heart-federation.org/cardiovascular-health/stroke/*, last visited on Mar. 11, 2016), 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*). At an average price of $1,650 per stent, the addressable market is more than $1 billion. 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 value of coronary products is estimated at $5.9 billion, of which $4.2 billion is for stable angina and $1.7 billion is for acute myocardial infarctions according to Health Research International (June 2011). According to the 2014 MEDTECH OUTLOOK produced in December 2013 by BMO Capital Markets ("MEDTECH OUTLOOK"), revenues from the global coronary stent market are predicted to slightly decline, although in volume of stents the market is predicted to continue to grow. We believe the growth in volume is due to the appeal for less invasive percutaneous coronary intervention ("PCI") procedures and advances in technology coupled with the increase in the elderly population, obesity rates and advances in technology.

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 current global market for the aneurysm flow modulating devices is estimated at $550 million, and the current market value of the flow diversion market segment is estimated to be $125 million. 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.

The global market value of PVDs is estimated at $1.6 billion by 2017 (*source: Global Data 2011*). The overall peripheral vascular devices market consists of nine different product segments: peripheral vascular stents, chronic total occlusion devices, peripheral transluminal angioplasty balloon catheters, atherectomy devices, percutaneous transluminal angioplasty guidewires, aortic stents, embolic protection devices, synthetic surgical grafts and inferior vena cava filters *(source: Grand View Research 2014).* Treatment modalities and methods have considerably improved during the last several years, and this trend is expected to continue (*source: Global Data 2011*). Stents and balloons hold the majority of the share in the peripheral vascular devices market. 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. The expansion of the elderly population is contributing to increasing incidence rates of PVD. The percentage of the global population above the age of 50 is expected to reach 17% by 2030. As the risk of developing PVD increases with age, a growing elderly population translates into a growing incidence of PVD (*source: Global Data 2011*). The growing global geriatric population base also triggers increasing demand for minimally invasive endovascular procedures on account of their shorter recovery time, lesser scaring and lesser chances of post-surgery infections. In addition, a growing prevalence of disease-causing lifestyle factors and eating habits such as high consumption of alcohol and tobacco products is expected to boost peripheral vascular devices market demand by triggering the incidence rates of cardiac arrest, blood clotting and other vascular diseases *(source: Grand View Research 2014).*

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 April 2017, we had a pre-IDE submission meeting with the U.S. Food and Drug Administration 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. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, 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. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever. 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 and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

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. Flow diversion is a growing market segment within the neurovascular medical device field. Current commercial flow diverters are highly flexible dense metal mesh tubes that go across most types of cerebral aneurysms and divert the blood flow away from the aneurysm with the desired end result of sealing the aneurysm. The challenges with the current flow diverters are that they (i) are difficult to place given the high metal content in the device, which makes it more difficult to move the device through the delivery system due to resistance from the metal, and to subsequently accurately place it, (ii) need to be accurately placed to avoid crossing and blocking other cerebral vessels, which could cause additional damage by cutting off blood flow to sections of the brain, (iii) require chronic use of anti-thrombotic medications due to the amount of metal in the cerebral vasculature, which could cause thrombotic complications, and (iv) do not allow a physician to re-access the aneurysm if the aneurysm does not seal, in which event the aneurysm may need to be treated with another therapy such as aneurysm coils, due to the tight metal mesh that will not allow other devices to pass through the flow diverter.

Our flow diverter prototype will include our MicroNet that has been employed in CGuard EPS and MGuard Prime EPS. MicroNet has already demonstrated the ability to effectively seal aneurysms in human coronary arteries using the MGuard Prime EPS and aneurysms in the carotid arteries using CGuard EPS in human clinical situations without the need for additional devices or procedures (coils or a second stent) (*source: Journal of Medical Case Reports http://www.jmedicalcasereports.com/content/4/1/238*). For our flow diverter, we plan to utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We believe our flow diverter could be more accurately delivered due to a lower metal content scaffold than current commercial flow diverters. Lower metal content in our flow diverter may reduce the need for long-term anticoagulation; the open cell metal scaffold combined with the MicroNet may allow passage of other devices through the MicroNet mesh without compromising the MicroNet, thus allowing a physician to reaccess the aneurysm, if needed; and our flow diverter should be capable of being delivered through a state-of-the-art microcatheter for accurate placement without constant repositioning. 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 MGuard Prime EPS and, provided that we have sufficient resources, the development of CGuard EPS with a smaller delivery catheter (5 French gauge) 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 cm^3. 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	**30 days**
	n=27	**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 MicroNetcovered 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).

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 U.S. Food and Drug Administration, 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 transition current users of conventional carotid stents to use CGuard EPS and to convince vascular surgeons to use CGuard EPS in filter protected carotid artery stenting instead of vascular surgery in appropriate patients. We publish and present our clinical data and support investigator-initiated clinical registries, which we plan to continue and expand. We have partnered and will continue to seek out partnerships with appropriate societies 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 widening 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 will continue 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 we are planning to launch there in 2019. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, the Middle East, Asia and Latin America. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

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.

Continue to protect and expand our portfolio of patents. Our MicroNet technology and the use of patents to protect it are critical to our success. We own numerous patents for our MicroNet technology. Seventeen patent applications have been filed (seven of which are now pending) in the United States, some of which have corresponding patent applications and/or issued patents in Canada, China, Europe, Israel, India, and South Africa. We believe these patents and patent applications collectively cover all of our existing products and may be useful for protecting our future technological developments. We intend to aggressively continue patenting new technology, and to actively pursue any infringement covered by any of our patents. We believe that our patents, and patent applications once allowed, are important for maintaining the competitive differentiation of our products and maximizing our return on research and development investments.

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.

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

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.

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. Pursuant to this strategy, we completed our transition away from a single distributor covering 18 European countries to a direct distribution model. Through our former distributor in Europe, CGuard EPS was largely sold to interventional neuroradiologists. Our current strategy is intended 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. We have expanded our clinical support team to support new customers and accelerate growth. 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

Product Positioning

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.

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 2019 as more and more positive clinical data is presented. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval within three calendar quarters of receiving such proceeds. Based on the level of interest in this product that we have observed in our clinical trials, we believe that CGuard EPS with a smaller profile delivery catheter will enable us to meet the market demand for minimally invasive devices, which, we believe, may have broader and easier usage, and for a lower profile system used in procedures in which predilation could be problematic. We also believe that CGuard EPS with a smaller profile delivery catheter will enable us to have a competitive advantage in penetrating the Asia Pacific market, since its population is generally smaller than in Western countries. In addition, we believe that CGuard EPS with a smaller profile delivery catheter will enable us to offer CGuard EPS for use in transradial catheterization, which, we believe, is gaining favor among interventionalists. 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.

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 MGuard coronary products and CGuard 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 twenty-nine pending patent applications, seven of which are pending in the United States, many of which cover aspects of our MGuard and CGuard technology. Some of the corresponding patent applications outside the U.S. are filed in Canada, China, Europe, Israel, India and South Africa. We hold an aggregate total of over 80 patents and pending applications including twelve issued U.S. patents. These patent rights are directed to cover various patent families, including the following seven (7) patent families:

Base Title of Patent Family	Country Pending	Country/Patent No.	Issue Date
		Israel 198,188	5/1/2014
Bifurcated Stent Assemblies			
		China ZL200780046676.2	9/26/2012
	US	—	—
Deformable Tip for Stent Delivery and Methods of Use			
	Brazil	—	—
	Canada	—	—
	China	—	—
	EPO	—	—
	Israel	—	—
	India	—	—
	Japan	—	—
	Mexico	—	—
	Russia	—	—

In Vivo Filter Assembly	India	Canada 2,666,712	
		Canada 2,881,557	3/31/2015
		US 8,043,323	10/11/2016
		US 9,132,261	10/25/2011
		Israel 198,189	9/15/2015
		China ZL200780046659.9	2/1/2014
		China ZL201210119132.7	6/13/2012
			6/24/2015
		EP 07827228.3 (Germany, France, & UK)	8/30/2017
Knitted Stent Jackets	India	Canada 2,666,728	
		Canada 2,887,189	6/23/2015
		China ZL200780046697.4	5/1/2018
		China ZL201210320950.3	10/10/2012
		Israel 198,190	12/2/2015
		EP 07827229.1 (Germany, France, & UK)	2/1/2014
			3/29/2017
			11/27/2018
Optimized Stent Jacket	Canada EPO Israel US	US 10,137,015 Canada 2,670,724 China ZL201210454357.8 China ZL200780043259.2 India 297,257	12/11/2018 12/9/2015 1/2/2013 5/30/2018 5/28/2014

		Israel 198,665	9/15/2015
		US 9,132,003	12/27/2016
		US 9,526,644	10/10/2017
		US 9,782,281	10/11/2017
		EP 07827415.6 (10 EP countries)	
		South Africa 2007/10751	10/27/2010
Stent Apparatuses for Treatment Via Body Lumens and Methods of Use	US	Canada 2609687	4/22/2015
	Israel	Canada 2,843,097	10/27/2015
	Europe (EPO)	US 8,961,586	2/24/2015
		US 10,058,440	8/28/2018
	Australia	US 10,070,977	9/11/2018
	Canada		
Stent Thermoforming Apparatus and Methods	Europe (EPO)	US 9,527,234	12/27/2016
	India	US 9,782,278	10/10/2017
	Japan		
	US		

In lay terms, these patent applications generally cover three aspects of our products: the mesh sleeve with and without a drug, the product and the delivery mechanism of the stent. We also believe that one or more additional pending patent applications, upon issuance, will cover our existing products. We also believe that the patent applications we have filed, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, if issued as patents with claims substantially in their present form, would likely create a significant barrier for another company seeking to use similar technology.

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 this, we rely on non-disclosure and confidentiality agreements

with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology.

Trademarks

We use the InspireMD®, MGuard®, CGuard®, and MGuard Prime® trademarks in connection with our products. We have registered these trademarks in the European Union. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have registrations for Carenet®, NGuard®, PVGuard® and the MNP Micronet Protection Logo in the European Union and a supplemental registration for Micronet® in the United States. We have also applied to register the names PVGuard™ as a trademark in the European Union, as well as Carenet™, CGuard™ InspireMD™, SmartFit™, PVGuard™, NGuard™, AGuard™, and MGuard Prime™ as trademarks in the United States. 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 U.S. Food and Drug Administration 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 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.

As noted below, we have or had regulatory approval and made sales of MGuard Prime EPS, CGuard 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, 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	MGuard Prime EPS Approval	MGuard Prime EPS Sales	CGuard EPS Approval	CGuard EPS Sales
Argentina	Y	Y	Y	Y
Australia	N	Y	(1) Y	Y
Austria	Y	Y	Y	Y
Belarus	Y	Y	Y	Y
Belgium	Y	Y	Y	Y
Brazil	Y	Y	N	N
Bulgaria	Y	Y	Y	Y
Chile	N	Y	(2) Y	Y
Colombia	Y	Y	Y	Y
Croatia	Y	Y	Y	N
Cyprus	Y	Y	Y	Y
Czech Republic	Y	Y	Y	Y
Denmark	Y	N	Y	Y
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	N	Y	Y
Holland (Netherlands)	Y	Y	Y	Y
Hong Kong	N	N	Y	Y
Hungary	Y	Y	Y	Y
Iceland	Y	N	Y	N
India	Y	N	Y	Y
Ireland	Y	Y	Y	N
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	Y	Y	N
Malaysia	Y	Y	Y	N
Malta	Y	Y	Y	N

Mexico	Y	Y	Y	Y
Norway	Y	Y	Y	N
Peru	Y	N	Y	Y
Poland	Y	Y	Y	Y
Portugal	Y	N	Y	Y
Romania	Y	Y	Y	Y
Russia	Y	Y	Y	Y
Saudi Arabia	N	Y	(3) N	N
Serbia	Y	N	Y	Y
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y	(4) Y	Y	N
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	Y
Switzerland	Y	Y	Y	Y
Turkey	Y	Y	Y	Y
Venezuela	Y	Y	Y	Y
Vietnam	Y	Y	Y	Y
United Kingdom	Y	Y	Y	Y

21

(1) We have lost our approval due to administrative issues but are now in the process of renewing the approval.

(2) We have made sales to distributors in this country, but based upon information from such distributors, we believe that the product has not been sold to customers in this country.

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

(4) 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.

U.S. Food and Drug Administration Government Regulation of Medical Devices for Human Subjects

Many of our activities are subject to regulatory oversight by the U.S. Food and Drug Administration 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.

U.S. Food and Drug Administration Approval/Clearance Requirements

In the United States, Class II or III medical devices must be cleared or approved by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration to market, distribute, and sell in the United States. Medical devices that obtain a premarket approval by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration’s general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the U.S. Food and Drug Administration’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 U.S. Food and Drug Administration through the 510(k) process described below.

Class II devices are subject to the U.S. Food and Drug Administration's General Controls, and any other special controls as deemed necessary by the U.S. Food and Drug Administration to ensure the safety and effectiveness of the device. Premarket review and clearance by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration.

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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration to market, distribute, and sell in the United States. Medical devices that obtain a premarket approval by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration'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 U.S. Food and Drug Administration, to human health, the U.S. Food and Drug Administration requires the device sponsor to file an IDE application with the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration will accept the application and begin an in-depth review of the submitted information. By statute, the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the U.S. Food and Drug Administration may be convened to review and evaluate the application and provide recommendations to the U.S. Food and Drug Administration as to the approvability of the device. The preapproval inspections conducted by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration has not yet called for the submission of 510(k). U.S. Food and Drug Administration's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases, the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a premarket approval, but the U.S. Food and Drug Administration can review any such decision and can disagree with a manufacturer's determination. If the U.S. Food and Drug Administration disagrees with a manufacturer's determination, the U.S. Food and Drug

Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration specified types of adverse events involving their products), labeling regulations, and the U.S. Food and Drug Administration'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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration’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 U.S. Food and Drug Administration. 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 U.S. Food and Drug Administration. As such, we and our manufacturing facilities will be subject to U.S. Food and Drug Administration inspections for compliance with the U.S. Food and Drug Administration’s Quality System Regulation. Additionally, some of our subcontractors may also be subject to U.S. Food and Drug Administration announced and unannounced inspections for compliance with the U.S. Food and Drug Administration’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 U.S. Food and Drug Administration 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. U.S. Food and Drug Administration 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 U.S. Food and Drug Administration. Class III medical devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control by the U.S. Food and Drug Administration, since the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration will either approve or deny a premarket approval application and we cannot market a device unless or until the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 U.S. Food and Drug Administration 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 Germany, and then back to Israel for final packaging and distribution.

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.

Employees

As of February 18, 2019, we had 43 full-time employees. Except for three 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 consider our relations with our employees to be good. We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel.

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.

Risks Related to Our Business

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

We have yet to establish any history of profitable operations. We reported a net loss of $7.2 million for the fiscal year ended December 31, 2018, and had a net loss of approximately $8.4 million during the fiscal year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of $148 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

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

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

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

Without materially curtailing our operations, we estimate that we have sufficient capital to fund operations through the end of the third quarter of 2019. As such, in order for us to pursue our business objectives, we will need to raise additional capital, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- development of our current and future products, including CGuard EPS with a smaller delivery catheter;
- furthering our efforts to obtain an IDE approval for CGuard EPS, to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States;
- 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. See "*Risk Factors—Risks Related to Our Common Stock, Preferred Stock and Warrants— The respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of these shares will dilute the interests of other security holders and may depress the price of our common stock.*"

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

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

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

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

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

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

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

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

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

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

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications

relating to, our stent technologies. In the event that a third party has also filed a U.S. patent application covering our stents or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. It is possible that we may be unsuccessful in the interference, resulting in a loss of some portion or all of our position in the United States.

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

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

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

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

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

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

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

Pre-clinical and clinical trials will be lengthy and expensive, and any delay or failure of clinical trials could prevent us from commercializing our MicroNet products, which would materially and adversely affect our results of operations and the value of our business.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including, if we seek in the future to sell our products in the

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

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

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, 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. None of our current coronary products is a drug-eluting stent, 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. Our MGuard Prime EPS is a bare-metal stent product and has experienced no growth in sales over the past three years. Such sales may never grow and we do not currently have the resources to develop a drug-eluting stent product. Our failure to

provide industry standard devices could adversely affect our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

on behalf of the U.S. government under the False Claims Act as well, as under the false claims laws of several states.

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

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

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

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

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

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our current products and products under development. We face intense competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Abbott Laboratories, Boston Scientific Corporation, 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. 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 seeking to invalidate our intellectual property or our rights thereto.

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

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

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

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

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

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

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

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

We face risks associated with litigation and claims.

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

We are subject to a lawsuit filed by Medpace Inc. in July 2016, seeking $1,967,822 in damages plus interest, costs, attorneys' fees and expenses. See "Business — Legal Proceedings" for more information. While we believe that the claims in this suit are without merit, due to the uncertainties of litigation, however, we can give no assurance that we will prevail on the claims made against us in such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results. Adverse outcomes in some or all of these claims may result in significant monetary damages that could adversely affect our ability to conduct our business.

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

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

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

We depend on the skills, experience and performance of our senior management and research personnel. The efforts of each of these persons will be critical to us as we continue to further develop our products, increase sales and broaden our product offerings. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due

to the intense competition for qualified personnel among life science businesses. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the intense competition among medical device, biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced management, scientists, researchers, sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our operations, and our results of operations may be materially and adversely affected.

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

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

foreign currency exchange rate fluctuations;

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

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

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

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

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

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

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

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

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

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

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework governing medical devices in the European Union. These proposals are currently being reviewed by the European Parliament and the Council and may undergo significant amendments as part of the legislative process. If adopted by the European Parliament and the Council in their present form, these proposed revisions would, among other things, impose stricter requirements on medical device manufacturers and strengthen the supervising competences of the competent authorities of European Union Member States and the notified bodies. As a result, if and when adopted, the proposed new legislation could prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis. The regulation of advanced therapy medicinal products is also in continued development in the European Union, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis. Any of these regulatory changes and events could limit our ability to form collaborations and our ability to continue to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

Risks Related to Operating in Israel

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

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

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

Our executive office, sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. A

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

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

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

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

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

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

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

A significant portion of our intellectual property has been developed by our Israeli employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Israeli Patent Law"), inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Israeli Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "C&R Committee"), a body

constituted under the Israeli Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. The C&R Committee (decisions of which have been upheld by the Israeli Supreme Court) has held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. We generally enter into intellectual property assignment agreements with our employees pursuant to which such employees assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

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

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

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

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

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

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

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

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

reduction, and the amount of any taxable income that we may earn in the future.

Risks Related to Our Common Stock, Preferred Stock and Warrants

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

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

technological innovations or new products and services by us or our competitors;

additions or departures of key personnel;

our ability to execute our business plan;

operating results that fall below expectations;

loss of any strategic relationship;

industry developments;

economic, political and other external factors; and

period-to-period fluctuations in our financial results.

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

Our common stock could be delisted from the NYSE American if we fail to regain compliance with the NYSE American's stockholders' equity continued listing standards on the schedule required by the NYSE American. 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 17, 2017, 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, 2017, and had net losses in our five most recent fiscal years ended December 31, 2016. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide. The notice also included an early warning of our potential noncompliance with Section 1003(a)(iv) of the Company Guide because the uncertainty regarding our ability to generate sufficient cash flows and liquidity to fund operations raises substantial doubt about its ability to continue as a going concern. In order to maintain our listing on NYSE American, we submitted a plan of compliance to NYSE American addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide, which was accepted by NYSE American on October 19, 2017. On November 22, 2017, we received an additional letter from the NYSE that we are not in compliance with Section 1003(a)(ii) of the Company Guide indicating that we are not in compliance with the stockholders' equity and net income continued listing standards. We have until February 19, 2019, to regain compliance with the continued listing requirements.

We believe, based on our stockholder's equity as of December 31, 2018, that we will be able to regain compliance with Sections 1003(a)(ii)-(iii) of the Company Guide and demonstrate to NYSE American that our estimated stockholder's equity will be at least $6 million as of February 19, 2019 (which should also make us in compliance with Section(a)(ii) by having stockholders' equity of greater than $4 million). However, even if we demonstrate that we would have sufficient stockholders' equity to regain compliance with Sections 1003(a)(ii)-(iii) of the Company Guide by February 19, 2019, 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. If we do not regain compliance by February 19, 2019, or fail to remain in compliance as of February 19, 2019, or anytime thereafter, with Sections 1003(a)(ii)-(iii) of the Company Guide, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE American will initiate delisting proceedings.

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

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

In addition to our non-compliance with Sections 1003(a)(ii)-(iii) of the Company Guide, 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 has 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. Pursuant to Section 1003(f)(v) of the Company Guide, the NYSE American staff determined that our continued listing is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be until July 7, 2019. We had previously received a notification of non-compliance of the same kind on January 16, 2018, effected a 1-for-35 reverse stock split of our common stock on February 7, 2018, and regained compliance on July 16, 2018.

One of the primary intents for the reverse stock split effected on February 7, 2018, was that the anticipated increase in the price of our common stock immediately following and resulting from a reverse stock split due to the reduction in the number of issued and outstanding shares of common stock would help us meet the price criteria for continued listing on NYSE American. However, the increase in the price of our common stock from the reverse stock split effected on February 7, 2018, was not maintained, and our common stock again traded for a low price per share for a substantial period of time: our stock has traded at prices less than $0.20 for much of the past month. If the market price of our common stock continues to remain below the levels viewed as low selling price for a substantial period of time, we may have to effect another reverse stock split of our common stock to regain or remain compliance with the price criteria for continued listing on NYSE American. There can be no assurance that the market price of our new common stock after another reverse stock split will remain above the levels viewed as abnormally low 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 reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock to fall below the levels viewed as low selling price for a substantial period of time and lead the NYSE American to immediately suspend trading in our common stock.

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

The respective certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock contains anti-dilution provisions that may result in the reduction of the conversion price in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of these shares will dilute the interests of other security holders and may depress the price of our common stock.

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

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

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

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

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

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

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

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

There is no public market for our preferred stock, pre-funded warrants or the Series D Warrants.

There is no established trading market for our preferred stock, the pre-funded warrants or the Series D warrants to purchase common stock issued in the July 2018 public offering. A trading market for these securities is not expected to develop, and even if a market develops for these securities, it may not provide meaningful liquidity. The absence of a trading market or liquidity for our preferred stock, pre-funded warrants or the Series D Warrants may adversely affect their value.

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

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

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

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

potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

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

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

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

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

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

No industry analyst publishes research about our business.

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. Because no industry analyst publishes research about us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to 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," "p "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 history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- our ability to regain compliance with NYSE American listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- market acceptance of our products;
- negative clinical trial results or lengthy product delays in key markets;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;

inability to carry out research, development and commercialization plans;

loss of a key customer or supplier;

technical problems with our research and products and potential product liability claims;

product malfunctions;

price increases for supplies and components;

adverse economic conditions;

insufficient or inadequate reimbursement by governmental and other third-party payors 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 1,000 square meter office and manufacturing facility that has the capacity to manufacture and assemble 4,800 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 12, 2016, Medpace Inc., a former service provider, filed suit with the Court of Common Pleas, Hamilton County, Ohio, against us asserting that we breached a master services agreement with Medpace Inc. by failing to pay Medpace Inc. certain fees purportedly owed to it in connection with Medpace Inc.’s provision of certain clinical development program services to Inspire Ltd. We have removed the suit to the U.S. District Court for the Southern District of Ohio. Since removal, Medpace Inc. has amended its complaint to name InspireMD Ltd., our wholly owned subsidiary, as the only defendant. Medpace Inc. is seeking $1,967,822 in damages plus interest, costs, attorneys’ fees and expenses against InspireMD Ltd. InspireMD Ltd. filed a motion to dismiss all claims on February 10, 2017. On May 17, 2017, the district court denied InspireMD’s motion to dismiss, but ordered Medpace Inc. to file a second amended complaint by June 5, 2017. Medpace Inc. filed a second amended complaint on June 5, 2017, and InspireMD

Ltd. again moved to dismiss all claims on June 19, 2017. The district court denied our second motion to dismiss on August 11, 2017. Thereafter, we answered the complaint and asserted several counterclaims. Specifically, we brought counterclaims for fraudulent inducement, negligent misrepresentation, and violation of Ohio's Deceptive Trade Practices Act arising from Medpace's false marketing of its purported abilities to manage the clinical trial, and brings a counterclaim for breach of contract, alleging that Medpace breached the master services agreement by, among other things, failing to assign personnel to the clinical trial who were qualified and professionally capable of performing the services called for by the master services agreement and the related Task Order in accordance with the agreed-upon schedule and budget. We are seeking damages believed to be in excess of $3 million, as well as punitive damages and attorney's fees. Medpace Inc. has denied our allegations. On February 21, 2018, InspireMD Ltd. filed a motion for summary judgment, seeking to dismiss Medpace's affirmative claims in their entirety, or in the alternative to limit those claims to invoice payments totaling $468,586. On March 21, 2018, Medpace responded to InspireMD Ltd.'s motion for summary judgment, and also filed two additional motions: (1) a motion under Federal Rule of Civil Procedure 56(d), seeking to deny or delay summary judgment pending completion of additional discovery; and (2) a motion seeking to strike the Declaration of Jonathan Pressment, submitted in support of InspireMD Ltd.'s motion for summary judgment. InspireMD Ltd.'s motion for summary judgment remains pending before the Court. Medpace's motion under Federal Rule of Civil Procedure 56(d) and motion to strike also remain pending before the Court. Pursuant to InspireMD Ltd.'s motion to stay discovery pending the Court's resolution of InspireMD Ltd.'s motion for summary judgment and the completion of Court-ordered mediation, discovery is stayed until the earlier of (1) three days after the entry of an order adjudicating Inspire Ltd.'s motion for summary judgment or (2) August 13, 2018. On August 9, 2018, InspireMD Ltd. filed an unopposed motion to further extend the stay of discovery pending the court's resolution of InspireMD Ltd.'s motion for summary judgment. The court granted this motion on August 9, 2018, and stayed discovery until three days after the entry of an order adjudicating InspireMD Ltd.'s motion for summary judgment. On January 24, 2019, the court held oral argument on (1) InspireMD Ltd.'s motion for summary judgment, (2) Medpace's motion under Federal Rule of Civil Procedure 56(d), and (3) Medpace's motion to strike the Declaration of Jonathan Pressment. On January 29, 2019, the court ordered that the pending motions are taken under submission. InspireMD Ltd. intends to contest this matter vigorously. InspireMD Ltd. intends to contest this matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that InspireMD Ltd. will prevail on any claims made against InspireMD Ltd. in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity or operating results.

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

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 February 15, 2019, was $0.20 per share. As of February 15, 2019, there were approximately 264 holders of record 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.

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 EPS combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS received CE mark approval in the European Union in March 2013, and we launched its release on a limited basis in October 2014. In January 2015, a new version of CGuard, with a rapid exchange delivery system, received CE mark approval in Europe and in September 2015, we announced the full market launch of CGuard EPS in Europe. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. We consider the addressable market for our CGuard EPS consists of individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom an intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS was approximately $1.0 billion in 2017. (source: *Health Research International 2017 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets*).

In April 2017, we had a pre-IDE submission meeting with the U.S. Food and Drug Administration 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. We are currently in the process of obtaining an IDE approval for CGuard EPS, and we intend to ultimately seek the U.S. Food and Drug Administration approval for commercial sales in the United States. We intend to make an IDE submission seeking approval to conduct a human clinical trial in the United States in mid-2019.

While entering the U.S. market remains our top development priority and therefore we are focusing on, as our highest priority, completing the testing required for an IDE submission seeking approval to conduct a human clinical trial in the United States using CGuard EPS, 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. Among other delivery system improvements, we continue to evaluate the development of a smaller delivery catheter (5 French gauge) CGuard EPS product. If we receive sufficient proceeds from future financings, we plan to develop CGuard EPS with a smaller delivery catheter (5 French gauge), which we intend to submit for CE mark approval. We cannot give any assurance that we will receive sufficient (or any) proceeds from future financings or the timing of such financings, if ever. 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 and a smaller delivery system may allow us to reduce cost of goods, increase penetration in our existing geographies and better position us for entry into the Asia Pacific market and for transradial catheterization, which, we believe, is gaining favor among interventionalists.

Our MGuard Prime EPS is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery). MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. However, as a result of a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents,

in 2014 we decided to curtail further development of this product in order to focus on the development of a drug-eluting stent product, MGuard DES. Due to limited resources, though, our efforts have been limited to testing drug-eluting stents manufactured by potential partners for compatibility with MicroNet and seeking to incorporate MicroNet onto a drug-eluting stent manufactured by a potential partner. The FDA has clarified that the primary mode of action for drug-eluting cardiovascular stents, which are regulated as combination products, is that of the device component and has assigned the FDA Center for Devices and Radiological Health (CDRH) primary responsibility for premarket review and regulation, providing some clarity about what to expect regarding the regulatory framework related to the development of MGuard DES.

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

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

Effective as of 5:00 p.m. Eastern Time on February 7, 2018, we amended our certificate of incorporation in order to effectuate a 1-for-35 reverse stock split of our outstanding shares of common stock.

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

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, classification and fair value of financial instruments, and legal contingencies.

Functional currency

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

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 are 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.

Revenue recognition

Revenue recognition following the adoption of the New Revenue Recognition Standard on January 1, 2018

Under the new revenue recognition standard effective as of January 1, 2018, 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, 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.

Revenue recognition prior to the adoption of the New Revenue Recognition Standard on January 1, 2018

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title, fixed or determinable and risks and rewards for the products are transferred to the customer and collection is reasonably assured.

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.

In addition, certain of our share-based awards are market- and performance-based and dependent upon achieving certain goals. With respect to performance-based awards, we estimate the expected pre-vesting award probability that the performance conditions will be achieved. We only recognize expense for those shares that are expected to vest.

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, 2018 compared to the twelve months ended December 31, 2017

Revenues. For the twelve months ended December 31, 2018, revenue increased by $840,000, or 30.4%, to $3,601,000, from $2,761,000 during the twelve months ended December 31, 2017. This increase was predominantly driven by a 54.5% increase in sales of CGuard EPS from $1,922,000 in the twelve months ended December 31, 2017, to $2,970,000 in the twelve months ended December 31, 2018, as a result of our transition from our prior exclusive distribution partner for most of Europe to local distributors, continued focus on expanding existing markets such as Russia, Spain and Italy, and expansion into new geographies such as India. This increase in sales of CGuard EPS was partially offset by a 24.8% decrease in sales of MGuard Prime EPS from $839,000 in the twelve months ended December 31, 2017, to $631,000 in the twelve months ended December 31, 2018, largely driven by the predominant industry preferences favoring drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI

patients.

55

With respect to regions, the increase in revenue was primarily attributable to an increase of $821,000 in revenue from sales made in Europe (driven by $856,000 growth of CGuard EPS for reasons mentioned above), as well as an increase of $196,000 in revenue from sales made in Asia (driven by $171,000 growth of CGuard EPS for reasons mentioned above). These increases in Europe and Asia were partially offset by a decrease of $164,000 in sales made in Latin America (driven by a decrease of $172,000 in revenues of MGuard Prime EPS for reasons mentioned above).

Gross Profit. For the twelve months ended December 31, 2018, gross profit (revenue less cost of revenues) increased by 70.1%, or $410,000, to $995,000, compared to $585,000 during the same period in 2017. This increase resulted primarily from an increase of $388,000 due to the increase in revenues (as mentioned above), less the related material and labor costs, and a decrease of $46,000 in expenses related to the underutilization of our manufacturing resources. These increases in gross profit were partially offset by an increase of $24,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 27.6% in the twelve months ended December 31, 2018 from 21.2% in the twelve months ended December 31, 2017, driven mainly by more efficient utilization of our fixed manufacturing resources.

Research and Development Expenses. For the twelve months ended December 31, 2018, research and development expenses increased by 20.3%, or $259,000, to $1,535,000, from $1,276,000 during the twelve months ended December 31, 2017. This increase resulted primarily from an increase of $247,000 in quality assurance and regulatory expenses related to annual audit activities which included validation reviews required every two years and an increase of $198,000 in clinical expenses associated with CGuard EPS, mainly related to IDE efforts in 2018. These increases in expenses were partially offset by a decrease of $108,000 in compensation expenses due to a reduced headcount and a decrease of $78,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the twelve months ended December 31, 2018, selling and marketing expenses decreased by 4.9%, or $116,000, to $2,241,000, from $2,357,000 during the twelve months ended December 31, 2017. This decrease resulted primarily from a decrease of $121,000 due to a salary accrual in 2017, a decrease of $80,000 in share-based compensation expenses primarily due to the forfeiture of the unvested options caused by the expiration of the employment agreement with our former chief commercial officer, a decrease of $80,000 in consulting expenses and a decrease of $40,000 in miscellaneous expenses. The decrease in expenses related to consulting and miscellaneous expenditures is primarily due to the Company not incurring during the twelve months ended December 31, 2018, the expenditures to support the newly launched CGuard EPS-related sales and marketing activities in connection with the transition from our prior exclusive distribution partner for most of Europe to local distributors incurred during the twelve months ended December 31, 2017. These decreases in expenses were partially offset by an increase of $205,000 in other salary expenses due primarily to an increase in our headcount to further support the new local distributors in Europe.

General and Administrative Expenses. For the twelve months ended December 31, 2018, general and administrative expenses decreased by 6.8%, or $354,000, to 4,830,000, from 5,184,000 during the twelve months ended December 31, 2017. This decrease resulted primarily from a decrease of $486,000 in share-based compensation expenses

primarily due to the Company incurring a large expense in the twelve months ended December 31, 2017, resulting from an equity grant made to our chief executive officer in 2016, which vested over one year, in contrast to the Company incurring no similar expense in the twelve months ended December 31, 2018, and from a decrease of $222,000 due to a salary accrual in 2017. These decreases in general and administrative expenses were partially offset by an increase of $228,000 in legal expenses, an increase of $97,000 in other salary expenses and an increase of $29,000 in miscellaneous expenses.

Financial Expenses (Income). For the twelve months ended December 31, 2018, financial income increased by $550,000, to $371,000 of financial income, from $179,000 of financial expenses during the twelve months ended December 31, 2017. The increase in financial income primarily resulted from an increase of $438,000 in financial income related to the revaluation of the embedded derivative of the Series C Preferred Stock and a decrease in interest expenses of $119,000 due to the repayment of the remaining balance of our outstanding indebtedness in 2017. These decreases in financial expenses were partially offset by an increase of $7,000 in miscellaneous expenses.

Tax Expenses (Income). For the twelve months ended December 31, 2018, tax expenses decreased by $27,000 to $0, from $27,000 in the twelve months ended December 31, 2017.

Net Loss. Our net loss decreased by $1,198,000, or 14.2%, to $7,240,000, for the twelve months ended December 31, 2018, from $8,438,000 during the twelve months ended December 31, 2017. The decrease in net loss resulted primarily from an increase of $550,000 in financial income, an increase of $410,000 in gross profit, a decrease of $211,000 in operating expenses and a decrease of $27,000 in tax expenses.

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2018 of $148 million, as well as a net loss of 7,240,000 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our products (primarily CGuard EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we only have sufficient resources to fund operations through the end of the third quarter of 2019. Therefore, there is substantial doubt about our ability to continue as a going concern.

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

On October 23, 2013, we entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. (“Hercules”), which was subsequently amended on November 19, 2013, July 23, 2014, and June 13, 2016, pursuant to which we received a loan of $10 million, before deduction of issuance costs. Interest on the loan was determined on a daily basis at a variable rate equal to the greater of either (i) 10.5%, or (ii) the sum of (A) 10.5% plus (B) the prime rate minus 5.5%. In connection with the loan and security agreement, on October 23, 2013, we issued the lender a five year warrant to purchase 20 shares of our common stock at a per share exercise price of $25,987.50. The amendment

to the loan and security agreement entered into on June 13, 2016, provides that, among other things, the principal payment otherwise due and payable would be suspended for a four month period beginning May 1, 2016, provided that we receive unrestricted and unencumbered net cash proceeds in an amount of at least $10 million from the sale of our equity securities with investors acceptable to the lender on or prior to June 30, 2016. In addition, we agreed to increase the end of term charge from $500,000 to $520,000 on the earliest to occur of February 1, 2017, or when the loan is paid in full or matures. Our obligations under the loan and security agreement were secured by a grant of a security interest in substantially all of our assets. The principal payments due on May 1, 2016, and June 1, 2016, were suspended, and although the public offering that closed in July 2016 had not closed prior to June 30, 2016, the lender agreed to waive the July 1, 2016, principal payment. Additionally, on July 6, 2016, the lender agreed to waive the August 1, 2016 principal payment, as well. We were required to make monthly payments of interest and principal in the amount of approximately $380,000 per month, with the loan maturing on June 1, 2017. In connection with the third amendment to the loan and security agreement, we entered into a warrant agreement with the lender, pursuant to which we issued on June 13, 2016, a five year warrant to purchase up to 1,106 shares of common stock. On March 21, 2017, we paid down the remaining $1.2 million balance, and all liens and other security interests granted to Hercules by us and our subsidiaries were terminated upon such payment.

Equity Financings and Recapitalization

On March 14, 2017, we closed a public offering of 1,069,822 shares of Series C Preferred Stock, Series B warrants to purchase 122,269 shares of common stock and Series C warrants to purchase 122,269 shares of common stock. Each share of Series C Preferred Stock is initially convertible into 0.114 shares of common stock at a conversion price equal to $56.00 per share. The Series B warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $70.00 per share of common stock. The Series C Warrants expired on September 14, 2017. We received gross proceeds of approximately $6.8 million from the offering, before deducting placement agent fees and offering expenses. The Series B warrants sold in this offering commenced trading on the NYSE American under the ticker symbol “NSPR.WSB” on April 10, 2017.

On December 1, 2017, as part of a planned recapitalization, we sold 750 shares of Series D Convertible Preferred Stock (the “Series D Preferred Stock”) to an institutional accredited investor (the “Series D Investor”) in a private placement (the “Series D Private Placement”) pursuant to a securities purchase agreement (the “Series D Purchase Agreement”), dated November 28, 2017, for aggregate gross proceeds of $750,000. The stated value of each share of Series D Preferred Stock was $1,000, and the Series D Preferred Stock was initially convertible, at the option of the holder, into shares of our common stock (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series D Preferred Stock (“Series D Certificate of Designation”)), at a conversion price of $7.00 per share, subject to adjustment as provided in the Series D Certificate of Designation. Pursuant to the Series D Purchase Agreement and the Series D Certificate of Designation, the purchasers of Series D Preferred Stock had the option, subject to certain limitations, to exchange their Series D Preferred Stock into the securities issued in a subsequent offering (the “Series D Exchange Right”) or into the securities we sell in an offering of our common stock or common stock equivalents for gross proceeds of at least $8 million (a “Qualified Offering”) upon consummation of a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis. In addition, in accordance with the Series D Purchase Agreement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Preferred Stock would be automatically exchanged into the securities we sell in a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis. As a result of the issuance and sale of the Series D Preferred Stock, the conversion price of our outstanding shares of Series B Preferred Stock was reduced to $7.00 pursuant to the anti-dilution adjustment provisions of the Series B Preferred Stock. There was no change to the conversion price of our outstanding Series C Preferred Stock as a result of an amendment made to the terms of the Series C Preferred Stock exempting the issuance of the Series D Preferred Stock from the anti-dilution adjustment provisions of the Series C Preferred Stock. The conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred was subsequently reduced to $3.00 per share in connection with the March 2018 offering, to $1.75 per share in connection with the April 2018 offering, and to $0.30 per share in connection with the July 2018 offering, as described below.

During January and February 2018, the placement agent from the public offering that closed in July 2016 exercised its unit purchase option to purchase 13,508 units and received 13,508 shares of Series B Preferred Stock and Series A warrants to purchase 1,545 shares of common stock. The placement agent subsequently converted its Series B Preferred Stock and received an aggregate of 111,442 shares of common stock. We received an aggregate of $557,205 from the placement agent for the exercise of the unit purchase option.

On February 21, 2018, the Series D Purchase Agreement was amended to require us (i) to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock, and (ii) upon closing of any subsequent offering that is a Qualified Offering, to exchange all remaining outstanding shares of Series C Preferred Stock held by the Series D Investor for any securities issued in such Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series C Preferred Stock). In the event that we fail, or are unable, to issue securities issued in the Qualified Offering to the Series D Investor in exchange for such investor's remaining Series C Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, we were required to offer to purchase from such investor those shares of Series C Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Preferred Stock.

On February 26, 2018, we and the Series D Investor entered into a waiver agreement which provided that (i) the Series D Exchange Right would not be applicable to an offering of up to $7,000,000 which occurred no later than March 9, 2018, (ii) we shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock in such offering, (iii) instead of using 15% of the proceeds from such offering to redeem shares of Series C Preferred Stock held by the Series D Investor, we shall use 15% of the proceeds from such offering to redeem a portion of the outstanding shares of Series D Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series D Preferred Stock, and (iv) we shall file a registration statement with the Securities and Exchange Commission under the Securities Act of 1933, as amended, in order to register the resale of the shares of common stock issuable upon the conversion of the Series D Preferred Stock as soon as practicable following the closing of such offering, but in no event later than seven days following such closing and to cause such registration statement to become effective as soon as practical after its filing.

On March 1, 2018, we closed an underwritten public offering of 1,000,000 shares of our common stock at a price to the public of $3.00 per share, thus triggering the rights under the above described February 26, 2018 agreement. We received gross proceeds of approximately $3.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, we used $450,000 of the proceeds from the offering to redeem 450 shares of Series D Preferred Stock. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to $3.00 per share.

On March 28, 2018, we and the Series D Investor entered into the second waiver agreement which provided that (i) the Series D Exchange Right would not be applicable to a subsequent financing consisting solely of shares of common stock, which shall be publicly registered on Form S-3 for gross proceeds to us of up to $5,000,000, to be consummated by not later than April 3, 2018 (the “Planned April 2018 Offering”), (ii) our obligation to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Preferred Stock held by the Series D Investor would not be applicable to the Planned April 2018 Offering, (iii) we shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock sold in the Planned April 2018 Offering, and (iv) we shall use $300,000 of the proceeds from the Planned April 2018 Offering to redeem outstanding shares of Series C Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Preferred Stock.

On April 2, 2018, we closed an underwritten public offering of 2,857,143 shares of our common stock at a price to the public of $1.75 per share, thus triggering the rights under the above described March 28, 2018 second waiver agreement. We received gross proceeds of approximately $5.0 million from the offering, before deducting underwriter discounts and commissions and offering expenses payable by us. Upon closing of the offering, as required by the second waiver agreement with the Series D Investor, dated March 28, 2018, we used $300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to $1.75 per share.

On June 28, 2018, we and the Series D Investor entered into a letter agreement (the "Letter Agreement") which further amended the Series D Purchase Agreement to provide that, notwithstanding anything to the contrary in the prior agreements, in the event we consummate a Qualified Offering in which the Series D Investor and its affiliates invest at least $3 million, (i) instead of an automatic exchange of all outstanding shares of Series C Preferred Stock held by the Series D Investor into securities issued in a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis, all outstanding shares of Series C Preferred Stock held by the Series D Investor will be redeemed at a per share purchase price equal to the stated value of Series C Preferred Stock, and (ii) all outstanding shares of Series D Preferred Stock will be redeemed at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On July 3, 2018, we closed an underwritten public offering of (i) 10,851,417 common units ("Common Units"), with each Common Unit being comprised of one share of our common stock, and one Series D warrant (collectively, the "Series D Warrants") to purchase one share of common stock and (ii) 22,481,916 pre-funded units ("Pre-Funded Units"), with each Pre-Funded Unit being comprised of one pre-funded warrant (collectively, the "Pre-Funded Warrants") to purchase one share of common stock and one Series D Warrant. We granted the underwriter a 30-day option to purchase up to an additional 4,999,999 shares of common stock at a purchase price of $0.29 per share and/or up to 4,999,999 additional Series D Warrants to purchase 4,999,999 shares of common stock at a purchase price of $0.01 per Series D Warrant, less the underwriting discounts and commissions of $0.0203 per share and $0.0007 per Series D Warrant. The underwriter exercised its option to purchase an additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common stock. The Series D Warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $0.30 per share of common stock. Each Pre-Funded Warrant contained in a Pre-Funded Unit is exercisable for one share of our common stock at an exercise price of $0.01 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. We received net proceeds from the offering and the exercise of the underwriter's option to purchase additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common stock of approximately $8.7 million, excluding the proceeds, if any, from the exercise of the Series D Warrants and the Pre-Funded Warrants sold in the offering, and after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering that are payable by us. 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 Preferred Stock and the Series C Preferred Stock was reduced to $0.30 per share, effective as of June 29, 2018.

Anti-Dilution Provisions

Our outstanding shares of Series B Preferred Stock and Series C Preferred Stock contain anti-dilution provisions that may result in the reduction of the conversion price thereof in the future. This feature may result in an indeterminate number of shares of common stock being issued upon conversion of the Series B Preferred Stock or the Series C Preferred Stock. Sales of additional shares of common stock issuable upon conversion of the Series B Preferred Stock or Series C Preferred Stock as a result of anti-dilution adjustments will dilute the interests of other security holders and may depress the price of our common stock. Accordingly, we may find it more difficult to raise additional equity capital while any of our Series B Preferred Stock or Series C Preferred Stock is outstanding. As of February 18, 2019, 17,303 shares of Series B Preferred Stock and 59,423 shares of Series C Preferred Stock were outstanding.

Twelve months ended December 31, 2018 compared to the twelve months ended December 31, 2017

General. At December 31, 2018, we had cash and cash equivalents of $9,384,000, as compared to $3,710,000 as of December 31, 2017. 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, 2018, net cash used in our operating activities decreased by $525,000 to $7,606,000, from $8,131,000 in the same period in 2017. The primary reason for the decrease in cash used in our operating activities was an increase $1,024,000 in payments received from customers from $2,495,000 in the twelve months ended December 31, 2017 to $3,519,000 in the same period in 2018 and a decrease in payments for third party related expenses and for professional services of $292,000, from $6,444,000 to $6,152,000 (primarily due to the end of term charge of $520,000 paid to Hercules in the twelve months ended December 31, 2017, compared to no such payment made in 2018). These increases in cash used in operating activities was partially offset by an increase of $791,000 in salary payments from $4,182,000 in the twelve months ended December 31, 2017 to $4,973,000 during the same period in 2018.

Cash used by our investing activities was $44,000 during the twelve months ended December 31, 2018 compared to $318,000 during the same period in 2017, resulting primarily from the purchase of production equipment.

Cash provided by financing activities for the twelve months ended December 31, 2018 was $13,370,000, compared to $4,633,000 during the same period in 2017. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2018, were the funds received from our July 2018 public offering of Common Units and Pre-Funded Units, as well as the subsequent exercise of the Pre-Funded Warrants included in the

Pre-Funded Units, that resulted in approximately $8,885,000 of aggregate net proceeds; funds received from our April 2018 public offering of common stock that resulted in approximately $4,439,000 of aggregate net proceeds; and the funds received from our March 2018 public offering of common stock that resulted in approximately $3,060,000 of aggregate net proceeds. Cash provided from such equity financings were offset by a redemption of shares of Series C and Series D Preferred Stock held by the Series D Investor with the proceeds of such offerings in an aggregate amount of $3,014,000. The principal source of cash provided by financing activities during the twelve months ended December 31, 2017, was the funds received from our March 2017 offering of Series C Preferred Stock and warrants that resulted in approximately $6,072,000 of aggregate net proceeds, as well as funds received from the November 2017 Series D Private Placement that resulted in approximately $750,000 of aggregate net proceeds, offset by loan repayments of $2,179,000.

As of December 31, 2018, our current assets exceeded our current liabilities by a multiple of 3.9. Current assets increased by $6,264,000 during the period and current liabilities increased by $438,000 during the period. As a result, our working capital increased by $5,826,000 to $8,499,000 at December 31, 2018.

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 July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. We have determined the adoption will not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02 Leases. The guidance establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance will become effective for interim and annual periods beginning on January 1, 2019. a modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We

expect to adopt the new standard on January 1, 2019 and use the effective date as its date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We expect that this standard will have a material effect on our financial statements. The most significant effect relates to the recognition of new ROU assets and lease liabilities on the balance sheet for our operating leases of real estate and vehicles; and (2) providing significant new disclosures about our leasing activities. We, however, do not expect a material impact to our consolidated statements of income and consolidated statements of cash flow. On adoption, we currently expect to recognize additional operating liabilities of approximately $1.1 million, with corresponding ROU assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. The new standard also provides practical expedients for an entity’s ongoing accounting. We currently expect to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases, 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. We also currently expect to elect the practical expedient to not separate lease and non-lease components for all of our leases.

In August 2018, the FASB issued ASU 2018-13—Fair value measurement (Topic 820)—Disclosure framework—Changes to the disclosure requirements for fair value measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance will need to be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. We are currently evaluating this guidance to determine the impact it may have on our consolidated financial statements.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 (ASU 2016-13) “Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. We will adopt ASU 2016-13 effective January 1, 2020. We are currently evaluating the effect of the adoption of ASU 2016-13 on our 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):

Report of Kesselman & Kesselman, Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of December 31, 2018 and 2017
Consolidated Statements of Operations for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018 and 2017
Notes to Consolidated Financial Statements

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, 2018, 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, 2018.

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, 2018. 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, 2018.

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, 2018 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
James Barry, Ph.D.	59	President, Chief Executive Officer and Director
Craig Shore	57	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
Michael Berman[(1)(2)]	61	Director
Campbell Rogers, M.D.	57	Director
Paul Stuka[(1)(2)(3)]	64	Chairman of the Board of Directors
Thomas J. Kester[(1)(3)]	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 is our Class 1 director, with his term of office to expire at our 2018 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 2019 annual meeting of stockholders. James Barry, Ph.D. and Thomas J. Kester are our Class 3 directors, with their terms of office to expire at our 2020 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.

James Barry, Ph.D. has served as our president and chief executive officer since June 6, 2016, and as a director since January 30, 2012. Prior to becoming our president and chief executive officer, Dr. Barry served as our executive vice president and chief operating officer from July 14, 2014. Dr. Barry served as president and chief executive officer and executive vice president and chief operating officer at Arsenal Medical Inc., a medical device company focused on local therapy, from September 2011 to December 2013. Dr. Barry also heads his own consulting firm, Convergent Biomedical Group LLC, advising medtech companies on product development, strategy, regulatory compliance and fund raising. Until June 2010, he was senior vice president, corporate technology development at Boston Scientific Corporation, where he was in charge of the corporate research and development and pre-clinical science functions and was also a member of the operating committee and corporate portfolio committee. Dr. Barry joined Boston Scientific in 1992 and oversaw its efforts in the identification and development of drug device combinations for both implantable and catheter-based delivery systems. He currently serves on a number of advisory boards including the College of Biomedical Engineering at Yale University, the College of Sciences at University of Massachusetts-Lowell where he is chairman emeritus and the Massachusetts Life Science Center.). Dr. Barry received his Ph.D. in Biochemistry from the University of Massachusetts-Lowell and holds a B.A. degree in Chemistry from Saint Anselm College. Dr. Barry brings to the board over 25 years of experience in leadership roles in the medical device industry and significant medical technology experience, in particular with respect to interventional cardiology products, and as chief executive officer, Dr. Barry's position on the board ensures a unity of vision between the broader goals of our company and our day-to-day operations.

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 2018, 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. 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 2011 as a director of AngioSlide Ltd., a medical device company that has developed an embolic capture angioplasty device, (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 Mazor Robotics, Inc., a publicly held company that has developed and markets an innovative system for robotic surgery, (ix) since 2014 as a director of SoniVie, a medical device company, (x) since 2014 as a venture partner at RiverVest Ventures and (xi) 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 35 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.

Dr. Barry, Mr. Shore and Mr. Gago 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and officers, and persons who own more than ten percent of our common stock, to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock. Directors, officers and persons who own more than ten percent of our common stock are required by Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us, during the twelve months ended December 31, 2018, each of our directors, officers and greater than ten percent stockholders complied with all Section 16(a) filing requirements applicable to our directors, officers and greater than ten percent stockholders.

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, 2018 and 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)	All Other Compensation ($)	Total ($)
James Barry, Ph.D.	2018	391,250	195,626 (2)	62,654 (3)	649,530
President and Chief Executive Officer	2017	365,000	25,000 (4)	50,319 (3)	440,319
Craig Shore	2018	267,306 (5)	76,961 (5)	119,104 (5)(6)	463,371 (5)
Chief Financial Officer, Secretary and Treasurer	2017	267,106 (5)	25,000 (4)(5)	104,681 (5)(6)	396,787 (5)
Agustin Gago(1)	2018	257,954 (7)	-	171,758 (8)	429,712
	2017	275,000	75,000 (9)	28,334 (3)	353,334

Former Executive Vice President and Chief Commercial Officer

67

(1) Mr. Gago's employment with the Company ceased as of September 30, 2018. Mr. Gago served as our Executive Vice President and Chief Commercial Officer until the termination of his employment effective as of September 30, 2018.

(2) Cash bonus awards for the 2018 calendar year were approved by the compensation committee in January 2019.

(3) Dr. Barry's and Mr. Gago's other compensation consisted solely of benefits related to health insurance.

(4) Bonuses for the 2017 calendar year were approved by the compensation committee in July 2018.

(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 3.748 NIS per dollar which was the exchange rate as of December 31, 2018. The average exchange rate for the twelve month period ended December 31, 2018 and 2017 were 3.597 NIS per dollar and 3.5997 NIS per dollar, respectively.

(6) Mr. Shore's other compensation consisted solely of benefits in the twelve months ended December 31, 2018 and 2017. 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) Mr. Gago's salary for 2018 includes cash paid in lieu of accrued vacation of $32,954.

(8) Mr. Gago's other compensation for 2018 consisted of severance benefits of $144,231 following his resignation in September 2018 and benefits related to health insurance of $27,527.

(9) $50,000 of cash bonus earned by Mr. Gago in the 2017 calendar year was approved by the compensation committee in May 2017. $25,000 of cash bonus earned by Mr. Gago in the 2017 calendar year was approved by the compensation committee in July 2018.

Agreements with Executive Officers

James Barry, Ph.D.

On July 14, 2014, we entered into an employment agreement with James Barry to serve as our executive vice president and chief operating officer, which was first amended on January 5, 2015, and further amended on February 22, 2015, and March 28, 2016, and on June 6, 2016, our board of directors appointed Dr. Barry as our president and chief executive officer and further amended the employment agreement. On September 5, 2017, we entered into the Fifth Amendment to Dr. Barry's employment agreement (as amended by the Fifth Amendment, the "Prior Employment Agreement"), and on February 4, 2019, we entered into an amended and restated employment agreement (the "A&R Employment Agreement") with Dr. Barry, which amended, restated and superseded Dr. Barry's Prior Employment Agreement. Dr. Barry was previously a director and continues his role as a director. The A&R Employment Agreement has an initial term that ends on December 31, 2020 unless earlier terminated.

Under the A&R Employment Agreement, Dr. Barry is entitled to an annual base salary of $400,000. Such amount may be reduced only as part of an overall cost reduction program that affects all senior executives of the company and does not disproportionately affect Dr. Barry, so long as such reductions do not reduce the base salary to less than 90% of the amount set forth above (or 90% of the amount to which it has been subsequently increased). The base salary will be reviewed annually by our board of directors as part of our annual compensation review.

Under the Prior Employment Agreement, as amended, Dr. Barry was entitled to an annual base salary of at least $365,000, which amount, in the event of the closing of a transaction or series of related transactions with investors where we raise an aggregate of $7 million from such investors, would increase to $400,000. Dr. Barry's annual base salary was increased to $400,000, as the March 2018 and the April 2018 offerings raised more than $7 million, effective as of April 1, 2018, payment beginning as of the first November 2018 pay period.

Dr. Barry is also eligible to receive an annual bonus in the amount equal to 100% of his base salary upon the achievement of reasonable target objectives and performance goals, to be determined by the Board in consultation with Dr. Barry. In the event that Dr. Barry's actual performance exceeds the goals, the Board may, in its sole discretion, pay Dr. Barry bonus compensation of more than 100% of his base salary. In each case, the annual bonus shall be payable in accordance with our annual bonus plan, and the amounts payable under the annual bonus plan shall be determined by the Board and shall be payable following such fiscal year and no later than two and one-half months after the end of such fiscal year.

In addition, as provided by the A&R Employment Agreement, we agreed to pay for Dr. Barry's accrued but unused vacation time through the calendar year 2018 on our next regular payroll date, which amount will be $32,000.

In accordance with the A&R Employment Agreement, on February 4, 2019, we granted Dr. Barry 2,000,000 shares of restricted stock, made pursuant to a Restricted Stock Award Agreement. The restricted stock is subject to a three-year vesting period subject to Dr. Barry's continued service us, with one-third (1/3rd) of such awards vesting on the first, second and third anniversary of the grant date. Additionally, upon achievement of certain criteria, Dr. Barry will be eligible to receive an equity bonus relating to the number of shares of our common stock equal to 5% of our shares outstanding on the date of the grant (inclusive of, rather than in addition to, the shares granted as part of the restricted stock grant made on February 4, 2019), subject to the board of director's approval, which shall be comprised of as close as is practicable to 50% stock options and 50% shares of restricted stock. Dr. Barry is also eligible to receive additional stock-based compensation at the sole discretion of the Board.

The A&R Employment Agreement also contains certain noncompetition, no solicitation, confidentiality, and assignment of inventions requirements for Dr. Barry.

If, during the term of the A&R Employment Agreement, Dr. Barry's employment is terminated upon his death or disability, by Dr. Barry for good reason, or by us without cause, Dr. Barry will be entitled to receive, in addition to other unpaid amounts owed to him (e.g., for base salary and accrued vacation): (i) the pro rata amount of any bonus for the fiscal year of such termination (assuming full achievement of all applicable goals 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 $850,000, provided that he executes a release relating to employment matters and the circumstances surrounding his termination in favor of us, its subsidiaries and their officers, directors and related parties and agents, in a form reasonably acceptable to us at the time of such termination; (iii) vesting of 100% of all unvested stock options, restricted stock shares, restricted stock units, stock appreciation rights or similar stock based rights granted to Dr. Barry, and lapse of any forfeiture included in such restricted or other stock grants; (iv) an extension of the term of any outstanding stock options or stock appreciation rights for two years from the date of termination; (v) to the fullest extent permitted by our then-current benefit plans, continuation of health, dental, vision and life insurance coverage for up to 18 months unless Dr. Barry secures coverage from a new employer; and (vi) a cash payment of $25,000, which Dr. Barry may use for executive outplacement services or an education program. The payment described in (ii) above will be reduced by any payments received by Dr. Barry pursuant to any of our employee welfare benefit plans providing for payments in the event of death or disability. If Dr. Barry continues to be employed by us after the term of the Employment Agreement, unless otherwise agreed by the parties in writing, and Dr. Barry's employment is terminated upon his death or disability, by Dr. Barry for good reason, or by us without cause, Dr. Barry will be entitled to receive, in addition to other unpaid amounts owed to him, the payments set forth in (i), (ii) and (iii) above. If we do not extend the term of the A&R Employment Agreement and/or Dr. Barry's employment is not extended beyond December 31, 2020, Dr. Barry will be entitled to the payments and benefits set forth in (i)-(vi) above; however, if we have offered to extend the A&R Employment Agreement beyond December 31, 2020 on terms no less favorable than the terms of the A&R Employment Agreement and Dr. Barry does not agree to such extension, the one-time lump sum severance payment set forth in (ii) above shall be in the amount of $600,000.

If, during the term of the A&R Employment Agreement, we terminate Dr. Barry's employment for cause or Dr. Barry terminates his employment by voluntary termination, Dr. Barry will only be entitled to unpaid and accrued amounts owed to him through the date of termination and whatever rights, if any, are available to him pursuant to our stock-based compensation plans or any award documents related to any stock-based compensation.

Dr. Barry has no specific right to terminate the A&R Employment Agreement or right to any severance payments or other benefits solely because of a change in control. However, if within 24 months following a change in control (the "Change in Control Period"), (a) Dr. Barry terminates his employment for good reason, or (b) we terminate his employment without cause, Dr. Barry will be entitled to the payments and benefits set forth in (i)-(vi) above. Notwithstanding the foregoing, if we terminate Dr. Barry's employment with us prior to the date on which a change in control occurs, and it is reasonably demonstrated that Dr. Barry's (i) employment was terminated at the request of an unaffiliated third party who has taken steps reasonably calculated to effect a change in control or (ii) termination of employment otherwise arose in connection with or in anticipation of the change in control, then the "Change in Control Period" shall mean the 24 month period beginning on the date immediately prior to the date of Dr. Barry's termination of employment with the Company.

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 and on July 25, 2016. The employment agreement, as amended, has an initial term that ends on April 20, 2020 and will automatically renew for additional one-year periods on April 21, 2020 and on each April 21st 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 April 21st 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 second amendment to the amended and restated employment agreement, dated July 25, 2016, 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, 2018 was

$136,000, 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, 2018, Mr. Shore would have been entitled to receive $178,000 in severance under Israeli law, thereby requiring us to pay Mr. Shore $42,000, in addition to releasing the $136,000 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% to pension fund payments and 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.

Agustin V. Gago

On October 24, 2016, we entered into an employment agreement with Agustin V. Gago to serve as our executive vice president and chief commercial officer. The initial term of Mr. Gago's employment was to end on October 23, 2018, unless earlier terminated or extended for additional one-year periods on October 23, 2018. On September 24, 2018, we entered into a general release and severance agreement with Mr. Gago, pursuant to which Mr. Gago's employment ceased for all positions, offices and authority with us, effective as of September 30, 2018.

Pursuant to Mr. Gago's employment agreement, Mr. Gago was entitled to an annual base salary of $275,000, which was automatically increased to $300,000, effective as of January 1, 2018. Mr. Gago was eligible to receive an annual bonus in an amount up to 50% of his then-base salary, commencing in 2017, based upon the achievement of reasonable target objectives and performance goals as may be determined by our president and chief executive officer and subject to approval of the board of directors after consultation with Mr. Gago. The target objectives were based 60% on revenue achievement, 20% on marketing objectives, and 20% on corporate objectives. In addition, in the event that Mr. Gago and his team shall exceed quarterly revenue targets determined by our president and chief executive officer and subject to approval of the board of directors after consultation with Mr. Gago, Mr. Gago was to receive additional escalating amounts included as part of the annual bonus based upon the payment scales determined by our president and chief executive officer and approved by the board of directors after consultation with Mr. Gago. Mr. Gago was entitled to a one-time bonus of $25,000, which was paid on October 31, 2016. In addition, pursuant to

Mr. Gago's employment agreement, on October 24, 2016, Mr. Gago was granted (i) a stock option to purchase 385 shares of our common stock at an exercise price of $65.10, vesting on the first anniversary of the date of grant (subject to forfeiture upon termination of employment); and (ii) a stock option to purchase 915 shares of our common stock at an exercise price of $65.10, vesting in equal installments on the first and second anniversary of the date of grant, each subject to the terms and conditions of the InspireMD, Inc. 2013 Long-Term Incentive Plan, and our form of option award agreement. Mr. Gago was also eligible to receive certain stock options or similar stock-based rights as set forth separately in those certain agreements and subject to the terms and conditions of the InspireMD, Inc. 2013 Long-Term Incentive Plan.

Under Mr. Gago's employment agreement, if we had terminated Mr. Gago's employment without cause or Mr. Gago's death, Mr. Gago would be entitled to (A) any unpaid base salary accrued through the termination date, any accrued and unpaid vacation pay and any unreimbursed expenses properly incurred prior to the termination date; (B) a severance pay equal to Mr. Gago's base salary for 12 months; (C) any earned but unpaid annual bonus relating to the calendar year prior to the calendar year in which the termination date occurs; and (D) to the fullest extent permitted by our then-current benefit plans, continuation of certain insurance benefits for the lesser of 12 months after termination of employment or until Mr. Gago secures coverage from new employment.

Pursuant to the general release and severance agreement with Mr. Gago, we agreed to pay severance payments, in an amount equal to Mr. Gago's base salary Mr. Gago would have earned if he had remained employed from the September 30, 2018, through October 23, 2018, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with our standard payroll practices; and (ii) additional severance payments, in an amount equal to $125,000, less applicable payroll deductions and tax withholdings, to be paid in equal installments in accordance with our standard payroll practices, commencing on the first payroll date following October 23, 2018 through March 23, 2019.

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, 2018

The following table shows information concerning unexercised options and unvested shares of restricted stock outstanding as of December 31, 2018 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 ($)
James Barry, Ph.D.	2,015	-		166.25	07/25/2026	-	$ -
Craig Shore							$
						168 (1)	$ 27
	336	168	(2)	166.25	07/25/2026		
Agustin V. Gago(3)	-	-		-			
	-	-		-			

(1) These shares of restricted stock will vest on July 25, 2019.
(2) These options will vest on July 25, 2019.
(3) Mr. Gago served as our executive vice president and chief commercial officer, which employment was terminated as of September 30, 2018.

Option Exercises and Stock Vested

There were no stock options exercised by our named executive officers during the twelve months ended December 31, 2018.

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 571 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 310 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 571 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 537 shares of common stock, to a total of 1,108 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 11,429 shares of common stock, to a total of 12,537 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 7,200 shares of common stock, to a total of 19,737 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 8,900,000 shares, to a total of 8,919,737 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.

As of December 31, 2018, we had 8,910,610 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

As of February 18, 2019, we had 5,473,335 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, other than James Barry, Ph.D., during the twelve months ended December 31, 2018.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Paul Stuka	44,934	-	-	-	44,934
Michael Berman	34,000	-	-	-	34,000
Campbell Rogers, M.D.	25,000	-	-	-	25,000
Thomas Kester	41,000	-	-	-	41,000

For the 2018 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 (effective April 1, 2014) 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 (effective April 1, 2014) 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. The chairman of the board's annual stipend was increased in August 2018.

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 February 18, 2019 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 governing the determination of beneficial ownership of securities. Under the rules of the Securities and Exchange Commission, 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 February 18, 2019, we had 41,888,895 shares outstanding.

Name of Beneficial Owner	Number of Shares Beneficially Owned[1]		Percentage Beneficially Owned[1]	
5% Owners				
Sol J. Barer, Ph.D.	3,469,899	(2)	7.67	%
Officers and Directors				
Craig Shore	803,402	(3)	*	
James Barry, Ph.D.	2,003,397	(4)	4.78	%
Michael Berman	392	(5)	*	
Campbell Rogers, M.D.	130,380	(6)	*	
Paul Stuka	233,830	(7)	*	
Thomas Kester	130,239	(8)	*	
Agustin V. Gago	-	(9)	*	
All directors and executive officers as a group (7 persons)	3,301,640		7.88	%

* 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 February 18, 2019. 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) Includes (i) options to purchase 818 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, (ii) warrants to purchase 4,581 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, (iii) 133,672 shares of common stock and (iv) includes 3,330,828 shares of common stock issuable upon conversion of Series B Preferred Stock that are currently convertible within 60 days of February 18, 2019.

(3) Consists of (i) 355 shares of common stock, (ii) options to purchase 336 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, (iii) 300,168 shares of restricted stock granted under the Israeli Appendix of the InspireMD, Inc. 2013 Long-Term Incentive Plan and (iv) 502,543 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.

(4) Consists of (i) 1,382 shares of common stock, (ii) 2,000,000 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan and (iii) options to purchase 2,015 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019.

(5) Includes options to purchase 387 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019. Excludes 130,000 shares of 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.

(6) Consists of (i) 130,000 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (ii) options to purchase 364 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, and (iii) warrants to purchase 5 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019.

(7) Paul Stuka is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of (A) (i) 12,811 shares of common stock, (ii) warrants to purchase 319 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019 in addition to (B) personally holding (i) options to purchase 419 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, (ii) 195,000 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) warrants to purchase 347 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019, and (iv) 24,934 shares of common stock.

(8) Consists of 130,000 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, and (ii) options to purchase 239 shares of common stock that are currently exercisable or exercisable within 60 days of February 18, 2019.

(9) Mr. Gago served as our executive vice president and chief commercial officer and resigned as of September 30, 2018.

77

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2018, 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	6,305		407.65	8,910,921
Equity compensation plans not approved by security holders	84	(1)	68,250	—
Total	6,389		1,299.62	—

(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 84 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 $68,250 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.

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

On March 21, 2016, we closed a private placement of 1,183 shares of our common stock and warrants to purchase up to 592 shares of our common stock with certain of our officers and directors. The purchasers in the private placement included: Dr. Barer, the then chairman of our board of directors, who purchased 969 shares of common stock and warrants to purchase 485 shares of common stock, for a purchase price of $500,000, Osiris Investment Partners, L.P.,

of which Mr. Stuka, the chairman of our board of directors, is the principal and managing member, which purchased 146 shares of common stock and warrants to purchase 73 shares of common stock, for a purchase price of $75,000, Mr. Loughlin, who served as our director until May 24, 2016, purchased 58 shares of common stock and warrants to purchase 29 shares of common stock, for a purchase price of $29,500 and Dr. Rogers, our director, who purchased 10 shares of common stock and warrants to purchase 5 shares of common stock, for a purchase price of $5,000.

On July 7, 2016, we closed a public offering of 442,424 shares of Series B Preferred Stock and accompanying warrants to purchase up to 50,620 shares of common stock at a price of $33.00 per share of Series B Preferred Stock and the accompanying warrant, for gross proceeds of approximately $14.6 million, before deducting placement agent fees and offering expenses payable by us. Each share of Series B Preferred Stock was convertible into 0.114 shares of common stock reflecting a conversion price equal to $288.75 per share. In accordance with the anti-dilution price protection contained in the certificate of designation for the Series B Preferred Stock, the conversion price for the Series B Preferred Stock was adjusted several times when the Company conducted subsequent equity financings, and as of December 31, 2018, each share of Series B Convertible Preferred Stock is convertible into 110 shares of common stock at $0.30 per share. The holders of Series B Preferred Stock are entitled to receive 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 our discretion. The warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $175.00 per share of common stock. The purchasers in the offering included: Dr. Barer, the then chairman of our board of directors, who purchased 33,333 shares of Series B Preferred Stock and warrants to purchase 3,810 shares of common stock, for a purchase price of $1,099,989, Osiris Investment Partners, L.P., of which Mr. Stuka, the chairman of our board of directors, is the principal and managing member, which purchased 1,515 shares of Series B Preferred Stock and warrants to purchase 174 shares of common stock, for a purchase price of $49,995 and Mr. Stuka, who purchased 3,030 shares of Series B Preferred Stock and warrants to purchase 347 shares of common stock, for a purchase price of $99,990.

On December 1, 2017, as part of a planned recapitalization, we sold 750 shares of Series D Preferred Stock to the Series D Investor, Sabby Healthcare Master Fund, Ltd., who was then a beneficial owner of more than 5% of our common stock, in the Series D Private Placement pursuant to the Series D Purchase Agreement, for aggregate gross proceeds of $750,000. See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.—Liquidity and Capital Resources—Equity Financings and Recapitalization*."

On February 21, 2018, the Series D Purchase Agreement was amended. See "See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.—Liquidity and Capital Resources—Equity Financings and Recapitalization*."

On February 26, 2018, we and the Series D Investor entered into a waiver agreement. See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.—Liquidity and Capital Resources—Equity Financings and Recapitalization*."

On March 1, 2018, we closed an underwritten public offering of 1,000,000 shares of our common stock at a price to the public of $3.00 per share, thus triggering the rights under the above described February 26, 2018 agreement. Upon closing of the offering, we used 450,000 of the proceeds from the offering to redeem 450 shares of Series D Preferred Stock from the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to $3.00 per share.

On March 28, 2018, we and the Series D Investor entered into the second waiver agreement. See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.—Liquidity and Capital Resources—Equity Financings and Recapitalization*."

On April 2, 2018, we closed an underwritten public offering of 2,857,143 shares of our common stock at a price to the public of $1.75 per share, thus triggering the rights under the above described March 28, 2018 second waiver agreement. Upon closing of the offering, we used $300,000 of the proceeds from the offering to redeem 46,875 shares of our Series C Preferred Stock held by the Series D Investor. As a result of such offering, the conversion price for each of our Series B Preferred Stock, our Series C Preferred Stock and our Series D Preferred Stock was reduced to $1.75 per share.

On June 28, 2018, we and the Series D Investor entered into a Letter Agreement amending the Series D Purchase Agreement and the two waiver agreements. See "*Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.—Liquidity and Capital Resources—Equity Financings and Recapitalization*."

Pursuant to the Letter Agreement, on July 3, 2018, upon closing of the July 2018 public offering, we used $2,264,269 of the net proceeds of the July 2018 public offering to redeem 306,917 shares of Series C Preferred Stock and 300 shares of Series D Preferred Stock held by the Series D Investor.

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, which means a transaction, arrangement or relationship in which we and any related party are participants in which the amount involved exceeds $120,000. 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.

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, 2018 and 2017 are described below.

Audit Fees

Kesselman billed us audit fees in the aggregate amount of $161,500 and $119,000 for the years ended December 31, 2018 and 2017, 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 $89,300 and $52,000 for the year ended December 31, 2018 and 2017, respectively. The fees for the year ended December 31, 2018 mostly related to our prospectus supplements filed with the Securities and Exchange Commission in March, April and July of 2018.

The fees for the year ended December 31, 2017 mostly related to our prospectus supplements filed with the Securities and Exchange Commission on March 10, 2017.

Tax Fees

Kesselman billed us tax fees in the aggregate amount of $39,200 and $38,675 for the year ended December 31, 2018 and 2017, 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, 2018 and 2017.

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, 2018 and 2017
Consolidated Statements of Operations for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018 and 2017
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

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)
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)
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)
10.4+	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)
10.5+	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)
10.6	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)
10.7	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)
10.13+	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)
10.14+	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)
10.15+	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)
10.16+	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)
10.17+	

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)

10.18+	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)
10.19+	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)
10.20+	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)
10.21+	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)
10.22+	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)
10.23+	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)
10.24+	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)
10.25+	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)
10.26+	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)
10.28+	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)
10.29+	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)

10.30+	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)
10.31	Form of $4,812.5 Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
10.32+	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)

10.33+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Sol J. Barer (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 28, 2016)
10.34+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and James Barry (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 28, 2016)
10.35+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Michael Berman (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on January 28, 2016)
10.36+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Paul Stuka (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on January 28, 2016)
10.37+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Campbell Rogers (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on January 28, 2016)
10.38+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed on January 28, 2016)
10.39+	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)
10.40	Form of $516.25 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)
10.41	Form of $645.40 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)
10.42	Form of $516.25 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)
10.43	Form of $645.40 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)
10.44+	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)
10.45+	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)

10.46	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)
10.47	Amendment to Securities Purchase Agreement, dated June 17, 2016, by and among InspireMD, Inc. and the Purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.76 to the Registration Statement on Form S-1/A filed on June 17, 2016)

10.48	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)
10.49	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)
10.50+	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)
10.51+	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)
10.52+	Employment Agreement, dated October24, 2016, by and between InspireMD, Inc. and Agustin Gago (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 27, 2016)
10.53+	Director Offer Letter, between InspireMD, Inc. and Thomas J. Kester, dated September 6, 2016
10.54+	First Amendment to Nonqualified Stock Option Agreement dated November 16, 2011, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on June 2, 2017)
10.55+	First Amendment to Nonqualified Stock Option Agreement dated March 31, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on June 2, 2017)
10.56+	First Amendment to Nonqualified Stock Option Agreement dated June 30, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on June 2, 2017)
10.57+	First Amendment to Nonqualified Stock Option Agreement dated September 30, 2015, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on June 2, 2017)
10.58+	First Amendment to Nonqualified Stock Option Agreement dated June 30, 2016, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on June 2, 2017)
10.59+	First Amendment to Nonqualified Stock Option Agreement dated December 7, 2016, by and between InspireMD, Inc. and Sol Barer, dated as of June 2, 2017 (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on June 2, 2017)
10.60+	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)

10.61	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on November 29, 2017)
10.62	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)

10.63	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)
10.64	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)
10.65	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)
10.66	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)
10.67	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))
10.68	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))
10.69	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))
10.70	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))
10.71+	General Release and Severance Agreement, dated September 24, 2018, by and between InspireMD, Inc. and Agustin Gago (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 28, 2018)
10.72+	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)
10.73+	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)
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, 2018, 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: February 19, 2019 By: */s/ James Barry*
James Barry, Ph.D.
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/ James Barry James Barry, Ph.D.	President, Chief Executive Officer and Director (principal executive officer)	February 19, 2019
/s/ Craig Shore Craig Shore	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer (principal financial and accounting officer)	February 19, 2019
/s/ Paul Stuka Paul Stuka	Chairman of the Board of Directors	February 19, 2019
/s/ Michael Berman Michael Berman	Director	February 19, 2019
/s/ Thomas J. Kester Thomas J. Kester	Director	February 19, 2019
/s/ Campbell Rogers, M.D. Campbell Rogers, M.D.	Director	February 19, 2019

INSPIREMD, INC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2018

F-1

INSPIREMD, INC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2018

TABLE OF CONTENTS

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, 2018 and 2017, and the related consolidated statements of operations, changes in equity and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has suffered recurring losses from operations and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Tel-Aviv, Israel Kesselman & Kesselman
February 19, 2019 Certified Public Accountants (lsr.)
A member of PricewaterhouseCoopers International Limited

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

INSPIREMD, INC.

CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

	December 31,	
	2018	2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$9,384	$3,710
Accounts receivable:		
Trade, net	716	643
Other	104	207
Prepaid expenses	81	62
Inventory	1,134	533
TOTAL CURRENT ASSETS	11,419	5,155
NON-CURRENT ASSETS:		
Property, plant and equipment, net	421	476
Fund in respect of employee rights upon retirement	448	476
TOTAL NON-CURRENT ASSETS	869	952
TOTAL ASSETS	$12,288	$6,107

INSPIREMD, INC.

CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands other than share and per share data)

	December 31,	
	2018	2017
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	929	328
Other	1,966	2,134
Contract liability	25	20
TOTAL CURRENT LIABILITIES	2,920	2,482
LONG-TERM LIABILITIES-		
Liability for employees rights upon retirement	605	624
TOTAL LONG-TERM LIABILITIES	605	624
COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)		
TOTAL LIABILITIES	3,525	3,106
REDEEMABLE PREFERRED SHARES	-	274
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2018 and 2017; 38,408,953 and 1,483,556 shares issued and outstanding at December 31, 2018 and 2017, respectively	4	-
Preferred B shares, par value $0.0001 per share; 500,000 shares authorized at December 31, 2018 and 2017; 17,303 and 27,075 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2018 and 2017; 61,423 and 741,651 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Preferred D shares, par value $0.0001 per share; 750 shares authorized at December 31, 2018 and 2017; 0 and 750 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Additional paid-in capital	156,351	143,079
Accumulated deficit	(147,592)	(140,352)
Total equity	8,763	2,727
Total liabilities, redeemable preferred shares and equity	$12,288	$6,107

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,	
	2018	2017
REVENUES	$3,601	$2,761
COST OF REVENUES	2,606	2,176
GROSS PROFIT	995	585
OPERATING EXPENSES:		
Research and development	1,535	1,276
Selling and marketing	2,241	2,357
General and administrative	4,830	5,184
Total operating expenses	8,606	8,817
LOSS FROM OPERATIONS	(7,611)	(8,232)
FINANCIAL EXPENSES, net:		
Interest expenses		119
Other financial expenses (income)	(371)	60
Total financial expenses (income)	(371)	179
LOSS BEFORE TAX EXPENSES	(7,240)	(8,411)
TAX EXPENSES	-	27
NET LOSS	$(7,240)	$(8,438)
BASIC AND DILUTED LOSS PER SHARE:		
Beneficial conversion feature of Series C Convertible Preferred shares	$	$(633)
Extinguishment and accretion of preferred shares	(456)	(3,957)
NET LOSS APPLICABLE TO ORDINARY SHARES	$(7,696)	$(13,028)
NET LOSS PER SHARE - basic and diluted	(0.33)	(34.98)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	23,076,944	372,460

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		Series D Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity (capital deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT JANUARY 1, 2017	42,401	*	311,521	*					$135,959	$(131,914)	$4,045
Net loss										(8,438)	(8,438)
Issuance of preferred shares and warrants, net of $776 issuance costs					1,069,822	*			6,072		6,072
Issuance of preferred shares, net of $90 issuance costs							750	*	660		660
Conversion of preferred B shares to common shares	1,404,424	*	(284,446)	*					660		660
Conversion of preferred C shares to common shares	37,506	*			(328,171)	*					*
Classification of Redemption Obligation of preferred shares holder to Mezzanine									(934)		(934)
Share-based compensation related to restricted stock award, net of forfeitures of 202 shares	(118)	*							333		333

Share-based compensation related to stock options award									339			339	
Taxes withheld in respect of share issuance	(657	)	*						(10	)		(10	)
BALANCE AT DECEMBER 31, 2017	1,483,556	*	27,075	*	741,651	*	750	*	$143,079	$(140,352)		$2,727	

F-7

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		Series D Preferred Stock		Additional paid-in	Accumulated	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
BALANCE AT DECEMBER 31, 2017	1,483,556	*	27,075	*	741,651	*	750	*	$143,079	$(140,352)	$2,727
Net loss										$(7,240)	$(7,240)
Issuance of common shares, warrants, Pre-funded warrants and exercise of pre-funded warrants, net of $2,206 issuance costs	35,588,810	4							15,823		15,827
Redemption of Series D Preferred Stock							(750)	*	(750)		(750)
Conversion of Series B Convertible Preferred Stock to common shares	80,620	*	(9,772)	*					274		274
Classification of Series C Convertible Preferred Stock					(353,792)	*			(3,200)		(3,200)
Conversion of Series C Convertible Preferred Stock to common shares	1,144,726	*			(326,436)	*			936		936
	111,442	*							557		557

Exercise of Unit Purchase Option											
Accretion of redeemable preferred shares									(438)		(438)
Share-based compensation related to restricted stock and stock options award, net of forfeitures of 201 shares	(201)	*							70		70
BALANCE AT December 31, 2018	38,408,953	4	17,303	*	61,423	*	-	*	$156,351	$(147,592)	$8,763

* Represents an amount less than $1 thousand

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

INSPIREMD, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

	Year ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(7,240)	$(8,438)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	152	178
Loss from sale of property, plant and equipment	-	8
Change in liability for employees rights upon retirement	(19)	(37)
Financial income and interest paid	(392)	(511)
Share-based compensation expenses	70	672
Loss (gains) on amounts funded in respect of employee rights upon retirement, net	5	(17)
Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses	(19)	3
Increase in trade receivables	(73)	(287)
Decrease (increase) in other receivables	90	(37)
Increase in inventory	(601)	(33)
(Decrease) increase in trade payables	584	(290)
(Decrease) increase in other payables and contract liability	(163)	584
Net cash used in operating activities	(7,606)	(8,131)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(67)	(258)
Amounts funded (withdrawn) in respect of employee rights upon retirement, net	23	(60)
Net cash used in investing activities	(44)	(318)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of $2,206 and $776 issuance costs, respectively	16,384	6,822
Redemption of series C and D preferred stock	(3,014)	-
Repayment of long-term loan		(2,179)
Taxes withheld in respect of share issuance		(10)
Net cash provided by financing activities	13,370	4,633
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(46)	10
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	5,674	(3,806)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	3,710	7,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$9,384	$3,710
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Income taxes	$-	$-
Interest paid	$-	$583
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Issuance Costs	$-	90

Classification of Redemption Obligation of Preferred Shares to Mezzanine and Embedded Derivative, see Note 10a	$164	274

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

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

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

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

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

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

b. Liquidity

The Company has an accumulated deficit as of December 31, 2018, as well as a history of net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its products (primarily CGuard™ EPS) reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company has sufficient resources to fund operations through the end of the third quarter of 2019. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

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

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

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 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, classification and fair value of financial instruments 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

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 inventories and when, based on such evaluation, factors indicate that impairment has occurred, the Company impairs the inventories' carrying value.

g. 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.

h. 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.

i. Revenue recognition

Revenue recognition following the adoption of the New Revenue Standard on January 1, 2018

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers, and all the related amendments (the "New Revenue Standard") to all contracts using the modified retrospective method. The standard did not have any effect upon its initial application.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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, 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 13.

Revenue recognition prior to the adoption of the New Revenue Standard on January 1, 2018

Revenue is recognized when delivery has occurred, evidence of an arrangement exists, title, fixed or determinable and risks and rewards for the products are transferred to the customer and collection is reasonably assured.

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

j. Research and development costs

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

k. 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. 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.

In addition, certain share-based awards of the Company are market and performance based and dependent upon achieving certain goals. With respect to performance-based awards, the Company estimates the expected pre-vesting award probability that the performance conditions will be achieved. The Company only recognizes expense for those shares that are expected to vest.

l. 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".

m. 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

n. Advertising

Costs related to advertising and promotion of products are charged to sales and marketing expense as incurred. Advertising expenses were approximately $157,000 and $193,000 for the years ended December 31, 2018 and 2017, respectively.

o. 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 (after adding the beneficial conversion feature included in the Series C Convertible Preferred Stock and the extinguishment of Series B Convertible Preferred Stock and the extinguishment and accretion of Series D and Series C Convertible Preferred shares) by the weighted average number of shares of common stock outstanding during the period, including 1,081,581 and 23,481 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the years ended December 31, 2018 and 2017, respectively (since they are convertible based on passage of time).

The calculation of diluted net loss per share excludes potential share issuances of common stock upon the exercise of share options, warrants, restricted stocks, preferred stock and placement agent unit as their effect is anti-dilutive.

p. Segment reporting

The Company has one operating and reportable segment.

q. 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

r. Issued accounting pronouncements

1) In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company has determined the adoption will not have a material impact on its consolidated financial statements.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2) In February 2016, the FASB issued ASU 2016-02 Leases. The guidance establishes a right-of-use model (“ROU”) that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The guidance will become effective for interim and annual periods beginning on January 1, 2019. a modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company expects to adopt the new standard on January 1, 2019 and use the effective date as its date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The Company expects that this standard will have a material effect on its’s financial statements. The most significant effect relates to the recognition of new ROU assets and lease liabilities on the balance sheet for its operating leases of real estate and vehicles; and (2) providing significant new disclosures about the Company’s leasing activities. The Company, however, does not expect a material impact to its consolidated statements of income and consolidated statements of cash flow.

On adoption, the Company currently expects to recognize additional operating liabilities of approximately $1.1 million, with corresponding ROU assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

The new standard also provides practical expedients for an entity’s ongoing accounting. The Company currently expects to elect the short-term lease recognition exemption for all leases that qualify. This means, for those leases, 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. The Company also currently expects to elect the practical expedient to not separate lease and non-lease components for all of the Company’s leases.

3) Fair Value Measurement (Topic 820)

In August 2018, the FASB issued ASU 2018-13—Fair value measurement (Topic 820)—Disclosure framework—Changes to the disclosure requirements for fair value measurement. This guidance removes certain disclosure requirements related to the fair value hierarchy, modifies existing disclosure requirements related to measurement uncertainty and adds new disclosure requirements. The new disclosure requirements include disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Certain disclosures required by this guidance will need to be applied on a retrospective basis and others on a prospective basis. The guidance will be effective for fiscal years beginning after December 15, 2019, although early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

4) Financial Instruments-Credit Losses (Topic 326)

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 (ASU 2016-13) “Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model which requires the use of forward-looking information to calculate credit loss estimates. We will adopt ASU 2016-13 effective January 1, 2020. We are currently evaluating the effect of the adoption of ASU 2016-13 on our consolidated financial statements.

NOTE 3 - FAIR VALUE MEASURMENT

The following tables summarize the activity for those financial liabilities where fair value measurements are estimated utilizing Level 3 inputs:

	Derivative Liability ($ in thousands)
Balance as of January 1, 2017	$ -
Classification of Redemption Obligation of preferred shares holder to Mezzanine	66
Conversion of Series B Convertible Preferred Stock to common shares	(66)
Balance as of December 31, 2017	-
Classification of Redemption Obligation of preferred shares holder to Mezzanine	620
Conversion of Series C Convertible Preferred Stock to common shares	(182)
Revaluation of embedded derivative- financial income	(438)

Balance as of December 31, 2018	$ -

Level 3 liabilities include Derivative Liability related to the Company Series B Convertible Preferred Stock and Series C Convertible Preferred Stock, as described in Note 10. The Company values the Level 3 Derivative Liability using multi-period Binomial model, whose inputs include probability of completing fund raising and the related fund raise amounts, volatility of stock prices, stock prices, term to extinguish the Series C Convertible Preferred shares held by the Series D investor (se defined in Note 10).

In calculating the fair value of Derivative Liability related to the Series C Convertible Preferred Stock, the Company used the following assumptions: stock price of $4.20 for the transaction date, and Volatility of 140.95% -166.60% for the transaction date.

Regarding the derivative embedded in Series B redeemable preferred stock, which is a Level 3 measurement, see Note 10a.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 4 - PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2018	2017
	($ in thousands)	
Cost:		
Computer equipment	$241	$214
Office furniture and equipment	73	75
Machinery and equipment	1,262	1,209
Leasehold improvements	144	143
	1,720	1,641
Less - accumulated depreciation and amortization	(1,299)	(1,165)
Net carrying amount	$421	$476

b. Depreciation and amortization expenses totaled approximately $139,000 and $153,000 for the years ended December 31, 2018 and 2017, respectively.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 5 - 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 $186,000 and $154,000 for the years ended December 31, 2018 and 2017, respectively.

Defined contribution plan expenses were approximately $244,000 and $223,000 for the years ended December 31, 2018 and 2017, respectively.

The Company expects contribution plan expenses in 2019 to be approximately $241,000.

NOTE 6 - loan

During the year ended 2017, the Company paid the remaining interest and principal balances under a Loan and Security Agreement from October 23, 2013, in consideration of $2,684,000. Principal payments of $2,179,000 were classified as financing cash outflows in the consolidated statement of cash flows, with the remaining interest payment classified within operating cash flows. All liens and other security interests granted by the Company and its

subsidiaries in connection with the Loan and Security Agreement were terminated upon such payment.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 7 - RELATED PARTIES TRANSACTIONS

a. Chief Executive Officer ("CEO")

On September 5, 2017 the Company and the Company's CEO entered into a fifth amendment (the "Fifth Amendment") to the CEO's employment agreement, in order to, among other things (i) modify the term of the CEO's employment to (a) continue until July 31, 2018, and (b) provide that in the event that the term is not extended beyond July 31, 2018, by mutual agreement of the parties and the Company does not offer the CEO a position as CEO on the same or more favorable terms with an annual base salary of at least $400,000, the CEO's termination will be deemed a termination without cause; and (ii) amend the terms and conditions of the CEO's compensation, as described below.

Pursuant to the Fifth Amendment, the CEO was to be paid a base salary of no less than $30,416.67 per month ($365,000 on an annualized basis) while he was employed by the Company during the term; such amount may be reduced only as part of an overall cost reduction program that affects all of the senior executives of the Company and does not disproportionately affect the CEO, so long as such reductions do 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). Notwithstanding the foregoing, in the event of the closing of a transaction or series of related transactions with investors where Company raises an aggregate of $7 million from such investors, the CEO's annual base salary would increase to $400,000. The CEO's annual base salary was increased to $400,000, as the March 2018 and the April 2018 offerings raised more than $7 million, effective as of April 1, 2018 with payment beginning as of the first November 2018 pay period. During the year ended 2018, including after the expiration of the term on July 31, 2018, the CEO's compensation was paid pursuant to the prior employment agreement, as amended by the fifth amendment, until, on February 4, 2019, the Company entered into an amended and restated employment agreement (the "A&R Employment Agreement") with the CEO, which amended, restated and superseded the CEO's prior employment agreement.

Pursuant to the prior employment agreement, as amended by the Fifth Amendment, the CEO was eligible to receive, subject to the CEO's continued employment through the applicable grant date, (i) a nonqualified stock option relating to the number of shares of the Company's common stock equal to 2% of the Company's outstanding common stock on the date of the closing of the Financing (the "Financing Option") and (ii) an award of a number of restricted shares of the Company's common stock equal to 2% of our outstanding common stock on the date of the closing of the Financing (the "Financing Restricted Stock Award" and together with the Financing Option, the "Financing Equity Grant"), in each case, subject to the availability of shares for grant under the InspireMD, Inc. 2013 Long-Term Incentive Plan (the "2013 Plan").

The CEO has an option to deliver a number of shares with an aggregate fair market value that equals or exceeds (to avoid issuance of fractional shares) the required tax withholding payment resulted from the vesting of the restricted stock or from the exercise of the options. As of December 31, 2018 and 2017, 0 and 657 shares were withheld by the Company to satisfy tax withholding obligations, respectively. The payment, amounting to $0 and $10,000,

respectively, was deducted from equity.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 7 - RELATED PARTIES TRANSACTIONS (continued):

b. On June 2, 2017 the Company's then chairman of the board resigned from his position. In connection with his resignation, the Company amended certain stock option agreement the Company entered with him, to accelerate the vesting of unvested options in a negligible amount as of resignation date. In connection with the Company's former chairman's resignation, the Company announced the appointment of a new chairman of the board, who has been a director of the Company since August 2011.

c. On June 29, 2017, one of the Company's directors was not nominated for re-election at the Company's 2017 annual meeting of stockholders.

d. During the years ended December 31, 2018 and 2017, the Company did not grant any stock options to directors and executive officers.

e. Balances with related parties:

	December 31, 2018	2017
	($ in thousands)	
Current liabilities:		
Other accounts payable	$ 44	$ 47

f**. Transactions with related parties:**

	Year ended December 31, 2018	2017

	($ in thousands)	
Compensation expenses (including share-based compensation)	$830	$1,208

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 8 - NET LOSS PER SHARE:

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

	December 31,	
	2018	2017
	($ in thousands expect share and share data)	
Net Loss	$(7,240)	$(8,438)
Beneficial conversion feature of Series C Convertible Preferred shares		(633)
Extinguishment and accretion of Series D and Series C Convertible Preferred shares	(456)	
Extinguishment of Series B Convertible Preferred shares		(3,957)
Adjusted Loss	$(7,696)	$(13,028)
Weighted average of Ordinary Shares outstanding during the period	23,076,944	372,460
Basic and diluted loss per share (dollars)	$(0.33)	$(34.98)

The total number of shares of common stock related to outstanding options, warrants, restricted stock, Series C Convertible Preferred Stock, Series D Convertible Preferred Stock and placement agent units excluded from the calculations of diluted loss per share were 44,045,612 and 510,823 for the years ended December 31, 2018 and 2017, respectively.

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES

a. Lease commitments:

1)

The 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.

Rent expense included in the consolidated statements of operations totaled approximately $330,000 and $379,000 for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the aggregate future minimum lease obligations for office rent under non-cancelable operating lease agreements are as follows:

	($ in thousands)
Year Ended December 31:	
2019	$ 300
2020	300
	$ 600

2) The Company leases its motor vehicles under operating lease agreements. As of December 31, 2018, the aggregate non-cancelable future minimum lease obligations for motor vehicles were approximately $7,000.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES (continued):

b. Litigation:

The Company received written communication from a distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action (from April 2014). After considering the views of its legal counsel as well as other factors, the Company's management believes that there is a reasonably possible likelihood of a loss from any related future proceedings would range from a minimal amount up to 1,075,000 Euros.

On April 26, 2016 the Company received a suit seeking damages from the Company amounting to $2.2 million in cash and unspecified compensation in equity in connection with certain finders' fees. By Order dated February 23, 2017, the U.S. District Court for the Southern District of New York granted our motion to dismiss the suit in its entirety. On January 23, 2018, the clerk entered judgment dismissing the complaint consistent with the District court's order. The Claimants have not appealed the District Court's judgement, and the time in which to do so has expired. Accordingly, this matter is now closed.

In July 2016, a service provider filed a suit seeking damages from the Company's subsidiary amounting to $1,967,822. The Company's management, after considering the views of its legal counsel as well as other factors, is of the opinion that a loss to the Company is neither probable nor in an amount or range of loss that is estimable.

NOTE 10 - EQUITY

a. Share capital

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

On February 7, 2018, 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-thirty-five reverse stock split of its

common stock, par value $0.0001 per share, effective as of February 7, 2018, which decreased the number of issued and outstanding shares of common stock and restricted shares of common stock as of December 31, 2017 from 51.9 million shares to 1.5 million shares.

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

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

Status of Share Capital as of December 31, 2018

During 2018 and 2017, the Company made multiple transactions related to the capital structure. Following either redemption or conversion of the company's preferred stock, as of December 31, 2018, the Company has 17,303 shares of Series B Convertible Preferred Stock outstanding (convertible into 3,330,828 shares of common stock) out of 442,424 shares originally issued, 61,423 shares of Series C Convertible Preferred Stock (convertible into 1,310,357 shares of common stock) out of 1,069,822 shares originally issued and no Series D Convertible Preferred Stock. The respective certificate of designation for our Series B Convertible Preferred Stock and Series C Convertible Preferred Stock contains a full ratchet anti-dilution price protection to be triggered upon issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price in effect, so the number of shares of common stock issuable upon conversion of the Series B or C Convertible Preferred Stock could increase if another equity financing is completed at a price lower than the current conversion price of $0.30 per share.

Series B Convertible Preferred Stock – The July 2016 Offering

On July 7, 2016, the Company closed a public offering of 442,424 shares of Series B Convertible Preferred Stock and accompanying warrants (which is referred to as the "Series A Warrants") to purchase up to 50,620 shares of common stock (the "July 2016 Offering"). Each share of Series B Convertible Preferred Stock and the accompanying Series A Warrants were sold at a price of $33.00. Each share of Series B Convertible Preferred Stock was initially convertible into 0.114 shares of common stock, reflecting a conversion price equal to $288.75 per share. The Series B Convertible Preferred Stock has certain anti-dilution provisions, and as further described below, in accordance with such provisions, the conversion price for the Series B Convertible Preferred Stock was adjusted several times when the Company conducted subsequent equity financings, and as of December 31, 2018, each share of Series B Convertible Preferred Stock is convertible into 110 shares of common stock at $0.30 per share. The holders of Series B Convertible Preferred Stock are entitled to receive 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.

The Series B Convertible Preferred Stock will automatically convert into shares of common stock after five years from issuance. Additionally, holders of the Series B Convertible Preferred Stock may elect to convert at any time. As further described below, the certificate of designation for the Series B Convertible Preferred Stock was amended in

December 2017 to provide for an automatic exchange of each share of Series B Convertible Preferred Stock upon consummation of an offering of our common stock or common stock equivalents for gross proceeds of at least $8 million (a "Qualified Offering") subject to the beneficial ownership limitation. The Series B Convertible Preferred Stock is subject to provisions providing for make-whole payments, pursuant to which, if the Series B Convertible Preferred Stock is converted into shares of common stock at any time prior to the fifth anniversary of the date of issuance, the holders will receive all of the dividends that, but for the early conversion, would have otherwise accrued on the applicable shares of Series B Convertible Preferred Stock being converted for the period commencing on the conversion date and ending on the fifth anniversary of the date of issuance, less the amount of all prior dividends paid on such converted Series B Convertible Preferred Stock before the date of conversion. The Series A Warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $175.00 per share of common stock.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

The Company received gross proceeds of approximately $14.6 million from the July 2016 Offering, before deducting placement agent fees and offering expenses payable by the Company. In connection with the closing of the offering of the Series B Convertible Preferred Stock and Series A Warrants, the Company issued to the placement agent a unit purchase option to purchase a number of our securities equal to an aggregate of 3.5% of the securities sold in the July 2016 Offering. The placement agent unit purchase option has an exercise price equal to 125% of the public offering price.

For accounting purposes, the Company analyzed the classification of the Series B Convertible Preferred Stock, including whether the embedded conversion options should be bifurcated. As the Series B Convertible Preferred Stock is not redeemable, and the host contract was determined to be akin to equity, the entire instrument was classified as equity.

The Company has also concluded that the warrants accompanying Series B Convertible Preferred Stock are classified as equity, since the warrants meet all criteria for equity classification.

Series C Convertible Preferred Stock – The March 2017 Offering

On March 14, 2017, the Company closed a public offering of 1,069,822 shares of Series C Convertible Preferred Stock, Series B warrants to purchase up to 122,269 shares of common stock and Series C warrants to purchase up to 122,269 shares of common stock (the “March 2017 Offering”). Each share of Series C Convertible Preferred Stock and the accompanying warrants were sold at a price of $6.40. Each share of Series C Convertible Preferred Stock was initially convertible into 0.114 shares of common stock reflecting a conversion price equal to $56.00 per share. The Series C Convertible Preferred Stock has certain anti-dilution provisions, and as further described below, in accordance with such provisions, the conversion price for the Series C Convertible Preferred Stock was adjusted several times when the Company conducted subsequent equity financings, and as of December 31, 2018, the outstanding shares of Series C Convertible Preferred Stock are convertible into an aggregate of 1,310,357 shares of common stock at $0.30 per share.

The Company received gross proceeds of approximately $6.8 million from the March 2017 Offering, before deducting placement agent fees payable by the Company equal to 8.0% of the gross proceeds of the offering and a solicitation fee equal to 3.0% of the proceeds from the exercise of the Series C Warrants and offering expenses payable by the Company.

The holders of Series C Convertible Preferred Stock may elect to convert at any time. The Series C Convertible Preferred Stock has certain anti-dilution provisions which provisions require the lowering of the applicable conversion price, as then in effect, to the purchase price of equity or equity-linked securities issued in subsequent offerings which will result in a greater number of shares of common stock being required to be issued to the holders of Series C Convertible Preferred Stock

The Series B warrants are exercisable immediately and have a term of exercise of five years from the date of issuance and have an exercise price of $70.00 per share of common stock.

The Series C warrants expired on September 14, 2017, and none were exercised prior to their expiration.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

For accounting purposes, the Company analyzed the classification of the Series C Convertible Preferred Stock, including whether the embedded conversion options should be bifurcated. As the Series C Convertible Preferred Stock is not redeemable, and the host contract was determined to be akin to equity, the entire instrument was classified as equity.

The Company has also concluded that the warrants accompanying Series C Convertible Preferred Stock are classified as equity, since the warrants meet all criteria for equity classification.

Pursuant to the terms of the July 2016 Offering that provided the holders of the Series B Convertible Preferred Stock with certain anti-dilution provisions, which provisions require the lowering of the applicable conversion price, as then in effect, to match the purchase price of equity or equity-linked securities issued in subsequent offerings, upon closing of the March 2017 Offering, the conversion price of the Series B Convertible Preferred Stock was adjusted to $56.00 per share of common stock, and each share of Series B Convertible Preferred Stock became convertible into 0.589 shares of common stock. As a result of such adjustment, the Company was required to issue to the holders of the Series B Convertible Preferred Stock an aggregate of 258,952 additional shares of common stock upon conversion of the Series B Convertible Preferred Stock and as payment of the dividends thereunder in common stock, based on 311,521 shares of Series B Convertible Preferred Stock outstanding as of March 8, 2017.

Series D Convertible Preferred Stock and amendments to existing preferred stock through December 31, 2017 in connection with the Series D Private Placement

On December 1, 2017, as part of a planned recapitalization, the Company sold 750 shares of Series D Convertible Preferred Stock (“Series D Preferred Stock”) to an institutional investor (“Series D Investor”) in a private placement pursuant to a securities purchase agreement (the “SPA”), dated November 28, 2017, for aggregate gross proceeds of $750,000. The stated value of each share of Series D Preferred Stock was $1,000, and each share of Series D Preferred Stock was initially convertible into 142.86 shares of common stock at $7.00 per share. The Series D Preferred Stock did not contain any substantive features that differ materially from common stock other than a mechanism that would prevent the Company from issuing, upon conversion of the Series D Preferred Stock into common stock, a number of shares of common stock which would exceed 42,677 shares (19.99% of the number of shares of common stock outstanding on the trading day immediately preceding the date of the SPA) of the Company common stock, unless the

Company obtains shareholders' approval required by the NYSE American. In addition, the SPA contained a "most favored nation" provision, which provided that, until the Company consummates a "Qualified Offering", in the event the Company undertakes, or enter into any agreement to undertake, the issuance and sale of common stock and/or common stock equivalents to third party investors for cash (a "Subsequent Financing"), the Series D Investor may elect, in its sole discretion, to exchange all or some of the Series D Preferred Stock then held by such investor for any securities or units issued in such Subsequent Financing on a $1.00 per stated value for $1.00 new subscription amount basis (the "Series D Exchange Right") . The surrender of Series D Preferred Stock was to be in lieu of any cash subscription amount required for the participation in such Subsequent Financing. The Series D Investor also had the option to exchange their Series D Preferred Stock into the securities issued in a Qualified Offering upon consummation of a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

As a result of the issuance and sale of the Series D Preferred Stock, the conversion price of the outstanding shares of Series B Convertible Preferred Stock was reduced to $7.00 pursuant to the anti-dilution adjustment provisions of the Series B Convertible Preferred Stock, and the number of shares the Company would be required to issue to the holders of the Series B Convertible Preferred Stock upon conversion of the Series B Convertible Preferred Stock and as payment of the dividends thereunder in common stock was increased by an aggregate of 1,306,536 shares of common stock, based on 180,992 shares of Series B Convertible Preferred Stock outstanding as of November 28, 2017. There was no change to the conversion price of our outstanding Series C Convertible Preferred Stock as a result of an amendment made to the terms of the Series C Convertible Preferred Stock exempting the issuance of the Series D Preferred Stock from the anti-dilution adjustment provisions of the Series C Convertible Preferred Stock

The Company also agreed to use 12.5% of the proceeds from any subsequent offering of the Company's securities to redeem the outstanding shares of Series B Convertible Preferred Stock owned by the Series D Investor until such time that the Company has redeemed, in the aggregate, at least $1 million of Series B Convertible Preferred Stock, up to $1.5 million of stated value of Series B Convertible Preferred Stock ("Redemption Obligation of Series B").

In addition, in accordance with the original SPA, the certificate of designation for the Series B Convertible Preferred Stock was amended in December 2017 to provide for an automatic exchange of each share of Series B Convertible Preferred Stock upon the consummation of a Qualified Offering subject to the beneficial ownership limitation.

Furthermore, the original SPA provided that, upon the consummation of a Qualified Offering, the shares of Series C Convertible Preferred Stock owned by the Series D Investor would be automatically exchanged into the securities sold by the Company in a Qualified Offering upon the terms set forth in the Agreement. However, under the rules of the NYSE American, the Company was required to obtain shareholder approval for the exchange by such purchaser of any securities in the Qualified Offering that represent 20% or more of the Company's total shares of common stock outstanding immediately prior to such offering.

For accounting purposes, the Company analyzed the classification of the Series D Preferred Stock, including whether the embedded conversion options should be bifurcated. As the Series D Preferred Stock is not redeemable, and the host contract was determined to be akin to equity, the entire instrument was classified as equity.

As of the date of the SPA, the Company analyzed the classification of the Redemption Obligation of Series B of the Company regarding the Series B Convertible Preferred Stock as agreed upon in the SPA. Based on ASC 480-10-S99 the Company determined that, as of the date of the SPA, since the Redemption Obligation of Series B was outside of its control, the Series B Convertible Preferred Stock was considered as contingently redeemable upon the occurrence of an event that is outside of its control and should be classified as a mezzanine equity. The Company determined that, as of the date of the SPA, Subsequent Financing and the related payment of Redemption Obligation of Series B was considered to be outside of the Company's control. Accordingly, as of the date of the SPA, the redemption amount net of the embedded derivative (as described below), which amounts to $934,000, was classified as "Redeemable Preferred Shares" in the Consolidated Balance Sheet.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

In addition, as of the date of the SPA, the Company analyzed whether the conversion feature embedded in the shares of the Series B Convertible Preferred Stock subject to the Redemption Obligation of Series B should be bifurcated. As certain shares of the Series B Convertible Preferred Stock was contingently redeemable as of the date of the SPA, the host contract was determined to be akin to debt, and the other criteria under ASC 815-15-25-1 were met, an embedded derivative was separated from the host contract and accounted for as a derivative instrument pursuant to Subtopic 815-10. As of the date of the SPA, the embedded derivative was valued at $66,000.

Furthermore, as of the date of the SPA, the Company analyzed whether the change in the conversion price of the Series B Convertible Preferred Stock constituted an extinguishment for accounting purpose, by comparing the fair value of such preferred stock immediately before and after such change in terms. Since the fair value increased substantially, i.e by more than 10%, the change in terms was accounted for as an extinguishment.

As a result, the difference between the fair value of the preferred stock immediately after the change in term and the carrying amount immediately before such change, in the amount of approximately $3.9 million, was added to the basic loss per share attributable to the Company’s ordinary stockholders in the year ended December 31, 2017.

Conversion of Series B Convertible Preferred Stock held by Series D Investor

Of the 284,446 shares of Series B Convertible Preferred Stock that were converted during the year ended December 31, 2017, 206,105 shares were converted by the Series D Investor, and as of December 31, 2017, the Series D Investor held 8,295 shares Series B Convertible Preferred Stock with a stated value of $274,000. Accordingly, the maximum Redemption Obligation of Series B amount as of December 31, 2017, was $274,000. In addition, following the conversions of Series B Convertible Preferred Stock during the year ended December 31, 2017, the value of the embedded derivative as of December 31, 2017, was $0. On January 8, 2018, the Series D Investor converted its remaining 8,295 shares Series B Convertible Preferred Stock. Accordingly, following such conversions, the Company was no longer required to redeem any shares of Series B Convertible Preferred Stock held by the Series D Investor upon closing of a Subsequent Financing and the maximum Redemption Obligation of Series B was reduced to $0.

Placement Agent Unit Purchase Option Exercise and Series B Convertible Preferred Stock Conversion

During January and February 2018, the placement agent from the July 2016 Offering exercised its unit purchase option to purchase 13,508 units and received 13,508 shares of Series B Convertible Preferred Stock and 1,545 Series A warrants to purchase common stock. The placement agent subsequently converted its Series B Convertible Preferred Stock and received an aggregate of 111,443 shares of common stock. The Company received an aggregate of $557,205 from the placement agent for the exercise of the unit purchase option.

Series D Amendments and 2018 Equity Offerings

On February 21, 2018, the SPA was amended ("February 2018 SPA amendment") to require the Company (i) to use 15% of the proceeds from any subsequent offering of the Company's securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Convertible Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Convertible Preferred Stock, and (ii) upon closing of any subsequent offering that is a Qualified Offering, to exchange all remaining outstanding shares of Series C Convertible Preferred Stock held by the Series D Investor for any securities issued in such Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis (subject to the beneficial ownership limitation set forth in the certificate of designation for the Series C Convertible Preferred Stock). The February 2018 SPA amendment provided that in the event that the Company fails, or is unable, to issue securities issued in the Qualified Offering to the Series D Investor in exchange for such investor's remaining Series C Convertible Preferred Stock due to limitations mandated by the NYSE American, the Securities and Exchange Commission, or for any other reason, the Company would be required to offer to purchase from such investor those shares of Series C Convertible Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Convertible Preferred Stock. This requirement to purchase from the Series D Investor those shares of Series C Convertible Preferred Stock not exchanged for the securities sold in the Qualified Offering at a per share purchase price equal to the stated value of Series C Convertible Preferred Stock in case of a Qualified Offering, and the requirement to use 15% of the proceeds from any subsequent offering of the Company's securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Convertible Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Convertible Preferred Stock are referred to as "Redemption Obligation of Series C."

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

For accounting purposes, as of the effective date of the February 2018 SPA amendment, the Company analyzed the classification of the Series C Convertible Preferred Stock in light of the Redemption Obligation of Series C regarding such preferred stock held by the Series D Investor, as agreed upon in the February 2018 SPA amendment. Based on ASC 480-10-S99 the Company determined that since the Redemption Obligation of Series C may occur upon contingent events, such as subsequent financing transactions not meeting the threshold for a Qualified Offering, that are not solely within the Company's control, as of the effective date of the February 2018 SPA amendment the Series C Convertible Preferred Stock was considered as contingently redeemable and should be classified outside of permanent equity, within mezzanine equity.

In addition, as of the effective date of the February 2018 SPA amendment, the Company analyzed whether the conversion feature embedded in the shares of the Series C Convertible Preferred Stock subject to the Redemption Obligation of Series C should be bifurcated. As certain shares of the Series C Convertible Preferred Stock were contingently redeemable, as of the effective date of the February 2018 SPA amendment, the host contract was determined to be akin to debt, and the conversion feature not clearly and closely to the debt host given the anti-dilution protection included in the terms of these Series C Convertible Preferred Stock. Consequently, an embedded derivative was separated from the host contract and accounted for as a derivative instrument pursuant to Subtopic 815-10.

As of the effective date of the February 2018 SPA amendment, the Company classified an amount of $3,200,000 from permanent equity to "Redeemable Preferred Shares" and "Derivative Liability" in an amount of $2,580,000 and $620,000, respectively.

The Company values Level 3 derivative liability using an internally developed valuation model, whose inputs include potential equity transactions probability of completing successful fund raising during the relevant period and stock prices.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

On February 26, 2018, the Company and the Series D Investor entered into a waiver agreement (the "Waiver Agreement") which provided that (i) the Series D Exchange Right, which was provided by the original SPA, would not be applicable to an offering of up to $7,000,000 which occurred no later than March 9, 2018, (ii) the Company shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock in such offering, and (iii) instead of using 15% of the proceeds from such offering to redeem shares of Series C Convertible Preferred Stock held by the Series D Investor, which was provided by the February 2018 SPA amendment, the Company was required to use 15% of the proceeds from such offering to redeem a portion of the outstanding shares of Series D Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On March 1, 2018, the Company closed an underwritten public offering of 1,000,000 shares (the "March 2018 Offering") of the Company's common stock. The offering price to the public of the shares sold at the March 2018 Offering was $3.00 per share. The Company received gross proceeds of $3.0 million from the offering, before deducting underwriter commissions and discounts and other fees and expenses payable by the Company .In connection with the March 2018 Offering, the Company issued to the underwriter warrants to purchase up to 60,000 shares of common stock, or 6% of the number of shares of common stock sold in the offering (the "March Underwriter Warrants"). The March Underwriter Warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending February 27, 2023, at a price per share equal to $3.75 (125% of the offering price to the public per share).

Pursuant to the SPA, as amended by February 2018 SPA amendment and the Waiver Agreement, following the closing of the offering on March 1, 2018, the Company used $450,000 (representing 15% of the gross proceeds from the March 2018 Offering) to purchase from the Series D Investor 450 shares of the Series D Preferred Stock at a per share purchase price equal to the stated value of the Series D Preferred Stock.

As a result of the March 2018 Offering, the respective conversion price for each of the Series B Convertible Preferred Stock, the Series C Convertible Preferred Stock and the Series D Preferred Stock was reduced to $3.00 per share, and the number of shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock, the Series C Convertible Preferred Stock and the Series D Preferred Stock had increased as follows:

- an aggregate of 190,333 additional shares of common stock upon conversion of the Series B Convertible Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Convertible Preferred Stock outstanding as of March 1, 2018.
- an aggregate of 1,497,427 additional shares of common stock upon conversion of the Series C Convertible Preferred Stock, based on 741,651 shares of Series C Convertible Preferred Stock outstanding as of March 1, 2018.
- an aggregate of 142,857 additional shares of common stock upon conversion of the Series D Preferred Stock, based on 750 shares of Series D Preferred Stock outstanding as of March 1, 2018.

For accounting purposes, as of the closing of the March 2018 Offering, the Company analyzed whether the change in the conversion price of the Series D Preferred Stock constitutes an extinguishment for accounting purposes, by comparing the fair value of the Series D Preferred Stock immediately before and after such change in terms. Since the fair value increased substantially, i.e by more than 10%, the change in terms was accounted for as an extinguishment. As a result, the difference between the fair value of the Series D Preferred Stock immediately after the change in term (the reduction of the conversion price from $7.00 per share to $3.00 per share, pursuant to the SPA, as amended by February 2018 SPA amendment and the Waiver Agreement) and the carrying amount immediately before such change, in the amount of $49,000, was added to the basic loss per share attributable to the Company’s common stockholders.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

On March 28, 2018, the Company and the Series D Investor entered into the second waiver agreement (the "Second Waiver Agreement") which provided that (i) the Series D Exchange Right, which was provided by the original SPA, would not be applicable to a subsequent financing consisting solely of shares of common stock, which shall be publicly registered on Form S-3 for gross proceeds to us of up to $5,000,000, to be consummated by not later than April 3, 2018 (the "Planned April 2018 Offering"), (ii) the Company's obligation to use 15% of the proceeds from any subsequent offering of our securities that is not a Qualified Offering to redeem the outstanding shares of the Series C Convertible Preferred Stock held by the Series D Investor, which was provided by the February 2018 SPA amendment, would not be applicable to the Planned April 2018 Offering, (iii) the Company shall reduce the conversion price of the Series D Preferred Stock to the public offering price of our common stock sold in the Planned April 2018 Offering, and (iv) the Company shall use $300,000 of the proceeds from the Planned April 2018 Offering to redeem outstanding shares of Series C Convertible Preferred Stock held by the Series D Investor at a per share purchase price equal to the stated value of the Series C Convertible Preferred Stock.

On April 2, 2018, the Company closed an underwritten public offering of 2,857,143 shares (the "April 2018 Offering") of the Company's common stock at the offering price to the public of $1.75 per share. 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.

In connection with the April 2018 Offering, the Company agreed to issue to the underwriter warrants to purchase up to 171,429 shares of common stock, or 6% of the April 2, 2018 Shares sold in the offering (the "April Underwriter Warrants"). The April Underwriter Warrants will be exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending March 28, 2023, at a price per share equal to $2.1875 (125% of the offering price to the public in the April 2018 Offering).

Pursuant to the SPA, as amended by the February 2018 SPA amendment, the Waiver Agreement and the Second Waiver Agreement, following the closing of the April 2018 Offering, the Company used $300,000 of the net proceeds of the offering to purchase from the Series D Investor 46,875 shares of the Series C Convertible Preferred Stock at a per share purchase price equal to the stated value of the Series C Convertible Preferred Stock.

As a result of the April 2018 Offering, the conversion price of the outstanding shares of Series D Preferred Stock was reduced to $1.75 pursuant to the Second Waiver Agreement, and the number of shares of common stock issuable upon conversion of the Series D Preferred Stock increased by an aggregate of 71,429 additional shares of common stock, based on 300 shares of Series D Preferred Stock outstanding as of April 2, 2018.

For accounting purposes, as of the closing of the April 2018 Offering, the Company analyzed whether the change in the conversion price of the Series D Preferred Stock constituted an extinguishment for accounting purposes, by comparing the fair value of the Series D Preferred Stock immediately before and after such change in terms. Since the fair value increased substantially, i.e by more than 10%, the change in terms was accounted for as an extinguishment. As a result, the difference between the fair value of the Series D Preferred Stock immediately after the change in term (the further reduction of the conversion price from $3.00 per share to $1.75 per share, pursuant to the SPA, as amended by February 2018 SPA amendment, the Waiver Agreement and the Second Waiver Agreement) and the carrying amount immediately before such change, in the amount of $32,000, was subtracted from the basic loss per share attributable to the Company’s common stockholders.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

Upon execution of the underwriting agreement for the April 2018 Offering, as of March 28, 2018, the respective conversion price of the outstanding shares of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock was reduced to $1.75 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 237,916 additional shares of common stock upon conversion of the Series B Convertible Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Convertible Preferred Stock outstanding as of March 28, 2018.
- an aggregate of 688,297 additional shares of common stock upon conversion of the Series C Convertible Preferred Stock, based on 451,695 shares of Series C Convertible Preferred Stock outstanding as of March 28, 2018.

On June 28, 2018, the Company and the Series D Investor entered into a letter agreement (the “Letter Agreement”) which further amended the SPA to provide that, notwithstanding anything to the contrary in the prior agreements, in the event the Company consummates a Qualified Offering in which the Series D Investor and its affiliates invest at least $3 million, (i) instead of an automatic exchange of all outstanding shares of Series C Convertible Preferred Stock held by the Series D Investor into securities issued in a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis, all outstanding shares of Series C Convertible Preferred Stock held by the Series D Investor will be redeemed at a per share purchase price equal to the stated value of the Series C Convertible Preferred Stock, and (ii) all outstanding shares of Series D Preferred Stock will be redeemed at a per share purchase price equal to the stated value of the Series D Preferred Stock.

On June 29, 2018, the Company entered into an underwriting agreement relating to an underwritten public offering (the “July 2018 Offering”) of (i) 10,851,417 common units (“Common Units”), with each Common Unit being comprised of one share of the Company’s common stock, par value $0.0001 per share, and one Series D warrant (collectively, the “Series D Warrants”) to purchase one share of common stock and (ii) 22,481,916 pre-funded units (“Pre-Funded Units”), with each Pre-Funded Unit being comprised of one pre-funded warrant (collectively, the “Pre-Funded Warrants”) to purchase one share of common stock and one Series D Warrant, which closed on July 3, 2018. The offering price to the public was $0.30 per Common Unit and $0.29 per Pre-Funded Unit. The Company also granted the Underwriter a 30-day option to purchase up to an additional 4,999,999 shares of common stock at a purchase price of $0.29 per share and/or up to 4,999,999 additional Series D Warrants to purchase 4,999,999 shares of common stock at a purchase price of $0.01 per Series D Warrant, less the underwriting discounts and commissions of $0.0203 per share and

$0.0007 per Series D Warrant. The Underwriter exercised its option to purchase an additional 4,999,999 Series D Warrants to purchase 4,999,999 shares of common stock.

Pursuant to the Letter Agreement, the Company had revised its estimate as of June 30, 2018, of the expected timing of redemption of Series C Convertible Preferred stock to the estimated closing date of the July 2018 Offering (July 3, 2018). As a result, the total of $438,000 (accretion of the redeemable preferred shares) was recorded against Additional paid-in capital and added to basic loss per share attributable to the Company’s common stockholders.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

The Series D Warrants included in the Common Units and the Pre-Funded Units are immediately exercisable at a price of $0.30 per share of common stock, subject to adjustment in certain circumstances, and expire five years from the date of issuance.

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

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 Convertible Preferred Stock, the conversion price of the outstanding shares of the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock was reduced to $0.30 per share, effective as of the date of the underwriting agreement entered for the July 2018 Offering, 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 2,759,829 additional shares of common stock upon conversion of the Series B Convertible Preferred Stock and as payment of the dividends thereunder in common stock, based on 17,303 shares of Series B Convertible Preferred Stock outstanding as of June 29, 2018.
- an aggregate of 6,696,448 additional shares of common stock upon conversion of the Series C Convertible Preferred Stock, based on 378,840 shares of Series C Convertible Preferred Stock outstanding as of June 29, 2018.

On July 2, 2018, the Company filed with the office of the Secretary of State of the State of Delaware a Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock which removes the provision providing for an automatic exchange of all outstanding shares of Series B Convertible Preferred Stock into securities issued in a Qualified Offering on a $1.00 per stated value for $1.00 new subscription amount basis upon a Qualified Offering.

On July 3, 2018, the Company closed the July 2018 Offering. The Company received gross proceeds of $9.8 million from the offering, before deducting underwriter discounts and commissions and other fees and expenses payable by

the Company.

For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the Pre-funded Warrants have been included since the shares are issuable for a negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them.

Pursuant to the underwriting agreement relating to the July 2018 Offering, the Company, upon closing of the July 2018 Offering, issued to the underwriter warrants to purchase up to 2,000,000 shares of common stock, or 6% of the aggregate number of shares of common stock sold in the July 2018 Offering (including the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants sold in the July 2018 Offering). The underwriter warrants are exercisable at any time and from time to time, in whole or in part, following the date of issuance and ending July 3, 2023, at a price per share equal to $0.375 (125% of the offering price to the public per Common Unit).

Pursuant to the Letter Agreement, on July 3, 2018, upon closing of the July 2018 Offering, which was a Qualified Offering, the Company used $2,264,269 of the net proceeds of the July 2018 Offering to redeem 306,917 shares of Series C Convertible Preferred Stock and 300 shares of Series D Preferred Stock held by the Series D Investor.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

During the year ended December 31, 2018, the Company issued a total of 20,880,250 shares of its common stock in connection with the exercise of 20,880,250 Pre-Funded Warrants. The Company received aggregate cash proceeds equal to approximately $ 208,803 in connection with such exercises. As of December 31, 2018, the outstanding Pre-Funded Warrants are exercisable into 1,601,666 shares of common stock.

As of December 31, 2018, 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	3,330,828 *
Series C Convertible Preferred Stock	61,423	1,310,357
Total		4,641,185

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

As of December 31, 2018, the Company has outstanding warrants to purchase an aggregate of 40,746,189 shares of common stock as follows:

	Number of underlying Common stock	Weighted average exercise price
Series A Warrants	52,165	$ 175.00
Series B Warrants	122,269	$ 70.00
Series D Warrants	40,333,332	$ 0.30

Other warrants	238,423	$ 88.47
Total Warrants	40,746,189	$ 1.25

As of December 31, 2018, 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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

b. Share-Based Compensation

1) On March 28, 2011, the board of directors and stockholders of the Company adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan (the "Umbrella Plan") which expires on March 27, 2021. Under the Umbrella Plan, as subsequently amended, the Company reserved 572 shares of common stock as awards to employees, consultants, and service providers. As of December 31, 2018, the Company had 310 shares of common stock available for future issuance under the plans as described above.

On December 16, 2013, the board of directors and stockholders of the Company adopted and approved the 2013 Plan. Under the 2013 Plan, the Company initially reserved 572 shares of common stock for awards to employees, officers, directors, consultants, and service providers. On September 9, 2015, May 24, 2016, September 28, 2016 and October 24, 2018, the stockholders approved an amendment to the 2013 Plan to increase the number of shares of common stock available for issuance pursuant to awards under the 2013 Plan by 537, 11,428, 7,200 and 8,900,000 shares of common stock, respectively, to a total of 8,919,737 shares of common stock. As of December 31, 2018, the Company reserved 8,910,610 shares of common stock available for future issuance under the plans as described above.

The 2013 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 2013 Plan is administered by the Company's compensation committee.

In 2004, Section 409A was added to the U.S. Internal Revenue Code of 1986, as amended (the "Code") to regulate all types of deferred compensation. Certain performance awards, stock options, stock appreciation rights, restricted stock units, and certain types of restricted stock are subject to Section 409A of the Code.

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.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

2) During the years ended December 31, 2018 and 2017, the Company granted stock options to the CEO, employees and directors to purchase a total of 0 and 118 shares of the Company's common stock, respectively. The options granted in the year ended 2017 have exercise prices ranging from $24.85-$34.65 per share, which were the fair market value of the company's common stock on the date of each respective grant. The fair value of the above options, using the Black-Scholes option pricing models, was approximately $3,000. The 118 stock options granted in 2017 are subject to a three-year vesting period, with one-third of such awards vesting each year.

3) During the year ended December 31, 2018 and 2017, the Company granted to the CEO, employees and directors 0 and 84 restricted shares of the Company's common stock, respectively. The fair value of these restricted shares granted in the year ended December 31, 2017 was approximately $3,000. The 84 restricted shares granted during the year ended December 31, 2017 are subject to a three-year vesting period, with one-third of such awards vesting each year.

4) The following table summarizes information about warrants and share options to employees:

	Year ended December 31			
	2018		2017	
	Number of warrants and options	**Weighted average exercise price**	Number of warrants and options	**Weighted average exercise price**
Outstanding - beginning of period	8,167	$970.55	9,655	$891.8
Granted	-		118	32.2
Forfeited	(1,808)	628.62	(1,606)	414.05
Exercised	-	-		
Outstanding -end of period	6,359	$1,158.55	8,167	$970.55
Exercisable at the end of the period	5,111	$1,414.42	5,295	$1,431.85

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

5) The following table summarizes information about warrants and share options to non-employees:

	Year ended December 31			
	2018		2017	
	Number of warrants and options	Weighted average exercise price	Number of warrants and options	Weighted average exercise price
Outstanding - beginning of period	49	$21,238.7	61	$$31,164.7
Granted	-	-	-	-
Forfeited	(19)	12,417.53	(12)	58,165.8
Exercised	-	-	-	-
Outstanding - end of period	30	32,348.23	49	$21,238.7
Exercisable at the end of the period	28	31,578.81	31	$20,874.35

6) The following table summarizes information about restricted shares to employees:

	Year ended December 31	
	2018	2017
	Number of restricted shares	
Outstanding - beginning of period	1,093	3,755
Granted	-	84
Forfeited	(201)	(202)
Vested	(486)	(2,544)
Outstanding - end of period	406	1,093

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

	Outstanding as of December 31, 2018		
Exercise price	Options outstanding	Weighted average remaining contractual life (years)	Options exercisable
$0-$65.1	127	7.68	48
$106.4-$113.75	3,003	7.92	2,002
$166.25-$437.5	3,051	7.56	2,883
$1,180-$19,512.5	86	6.54	86
$25,550-$73,500	122	2.6	119
	6,389	7.62	5,138

The weighted average of the remaining contractual life of total vested and exercisable options as of December 31, 2018 was 7.57 years.

The aggregate intrinsic value of the total exercisable warrants and options as of December 31, 2018 was approximately $1.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 10 – EQUITY (continued):

The weighted average fair value of options granted was $24.85 for the year ended December 31, 2017. The weighted average fair value of warrants and options granted was estimated using the Black-Scholes option-pricing model.

8) 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, 2017:

	Year ended December 31 2017	
Expected life	5-6.5 years	
Risk-free interest rates	1.78%-2.18	%
Volatility	94.42%-97.62	%
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.

9) As of December 31, 2018, the total unrecognized compensation cost on employee and non-employee stock options and restricted shares, related to unvested stock-based compensation, amounted to approximately $38 thousand. This cost is expected to be recognized over a weighted-average period of approximately 0.55 years. This expected cost does not include the impact of any future stock-based compensation awards.

10)

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

	Year ended December 31	
	2018	2017
	($ in thousands)	
Cost of revenues	$ 4	$ 7
Research and development	-	32
Sales and marketing	6	86
General and administrative	60	547
	$ 70	$ 672

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - 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 2018 is 21%. State tax may also apply.

Taxation in Israel

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate in 2016 and thereafter, from 26.5% to 25%.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. The corporate tax rate was 23% in 2018 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 2007, as a year of election and 2011 as an additional year of election.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - 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, 2018, the Company had a net carry forward tax loss of approximately $40 million, of which approximately $36 million (arising before January 1, 2018), expires until 2037, and approximately $4 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.

As of December 31, 2018, InspireMD Ltd. had a net carry forward tax loss of approximately $71 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	
	2018	2017
	($ in thousands)	
Loss before taxes on income:		
InspireMD, Inc.	$(2,884)	$(3,673)
Subsidiaries	(4,356)	(4,738)
	$(7,240)	$(8,411)

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - 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, 2018 and 2017 were as follows:

	Year ended December 31	
	2018	2017
	($ in thousands)	
Balance at the beginning of the year	$27,240	$29,682
Changes during the year:		
Changes following enactment of the Act		(5,879)
Losses during the year (including foreign exchange rate effect)	400	3,437
Balance at the end of the year	$27,640	$27,240

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, 2018:

	Year ended December 31,	
	2018	2017
	($ in thousands)	

Balance at beginning of period	$ 28	$ -
Increase in uncertain tax positions because of tax positions taken during the year	-	28
Balance at end of period	$ 28	$ 28

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

Jurisdiction	Years
U.S.	2015-2018
Israel	2014-2018
Germany	2013-2018
United Kingdom	2014-2015

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 11 - TAXES ON INCOME (continued):

g. Deferred income tax:

	December 31,	
	2018	2017
	($ in thousands)	
Long-term:		
Allowance for doubtful accounts	3	3
Allowance for bonus	-	54
Provision for vacation and recreation pay	38	37
R&D expenses	339	289
Share-based compensation	2,581	2,577
Carry forward tax losses	24,643	24,245
Accrued severance pay, net	36	35
	27,640	27,240
Less-valuation allowance	(27,640)	(27,240)
	$-	$-

NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

a. Accounts receivable:

The changes in “Allowance for doubtful accounts” during the years ended December 31, 2018 and 2017 are as follows:

	Year ended December 31,

	2018	2017
	($ in thousands)	
Balance at beginning of period	$72	$336
Additions during the period	-	-
Bad debt written-off during the period	-	(270)
Exchange rate differences	-	6
Balance at end of period	$72	$72

b. Inventories:

	December 31, 2018	**2017**
	($ in thousands)	
Finished goods	$284	$174
Work in process	111	63
Raw materials and supplies	739	296
	$1,134	$533

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):

c. Accounts payable and accruals-other:

	December 31,	
	2018	2017
	($ in thousands)	
Employees and employee institutions	$828	$853
Accrued vacation and recreation pay	171	165
Accrued expenses	903	976
Provision for sales commissions	37	109
Other	27	31
	$1,966	$2,134

NOTE 13 – 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,	
	2018	**2017**
	($ in thousands)	
Germany	$855	$551
Italy	632	557
Russia	351	343
Other	1,763	1,310
	$3,601	$2,761

By product:

	Year ended December 31,	
	2018	2017
	($ in thousands)	
CGuard™ EPS	$2,970	$1,922
MGuard Prime™ EPS	631	839
	$3,601	$2,761

By principal customers:

	Year ended December 31,	
	2018	2017
Customer A	22 %	14 %
Customer B	10 %	12 %
Customer C	10 %	12 %

All tangible long lived assets are located in Israel.

INSPIREMD, INC.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

NOTE 14 - SUBSEQUENT EVENTS:

On February 4, 2019, the Company and the Company's CEO, entered into an amended and restated employment agreement (the "A&R Employment Agreement"). The A&R Employment Agreement amended, restated and superseded the CEO's prior employment agreement with the Company, including any amendments thereto. The A&R Employment Agreement, among other things, (i) modify the term of the CEO's employment to end on December 31, 2020 ("the A&R Term"), unless earlier terminated; (ii) grant the CEO 2,000,000 shares of restricted stock; (iii) upon achievement of certain criteria, the CEO will be eligible to receive an equity bonus relating to the number of shares of the Company's common stock equal to 5% of the Company's shares outstanding on the date of the grant (inclusive of, rather than in addition to, the 2,000,000 shares granted in (ii)), subject to Board approval, which shall be comprised of as close as is practicable to 50% stock options and 50% shares of restricted stock; (iv) entitle the CEO to a one-time lump sum severance payment of $850,000 if, during the A&R Term, the employment is terminated under certain conditions; provided, however, that if we have offered to extend the A&R Employment Agreement beyond December 31, 2020 on terms no less favorable than the terms of the A&R Employment Agreement and the CEO does not agree to such extension, the CEO will receive a one-time lump sum severance payment would be $600,000 instead of $850,000. In addition, as provided by the A&R Employment Agreement, in February 2019, we paid $33,000 to the CEO for his accrued but unused vacation time through the calendar year 2018.

In February 2019, the Company granted 3,437,275 restricted shares to certain employees and directors, inclusive of the 2,000,000 restricted shares issued to the CEO as mentioned above.