

InspireMD, Inc.  
Form 10-K  
February 13, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON D.C. 20549**

**FORM 10-K**

**(Mark One)**

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

For the fiscal year ended December 31, 2017

**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**

Edgar Filing: InspireMD, Inc. - Form 10-K

(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:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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.

Edgar Filing: InspireMD, Inc. - Form 10-K

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2017, based on the price at which the common equity was last sold on the NYSE American on such date, was \$4,909,881. 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.

<b>Class</b>	<b>Outstanding at February 12, 2018</b>
Common Stock, \$0.0001 par value	1,675,592

**Documents incorporated by reference:**

None



## TABLE OF CONTENTS

	<b>Page</b>
<u>PART I</u>	3
Item 1. <u>Business.</u>	3
Item 1A. <u>Risk Factors.</u>	24
Item 1B. <u>Unresolved Staff Comments.</u>	47
Item 2. <u>Properties.</u>	47
Item 3. <u>Legal Proceedings.</u>	47
Item 4. <u>Mine Safety Disclosures.</u>	48
<u>PART II</u>	48
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u>	48
Item 6. <u>Selected Financial Data.</u>	48
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	49
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	57
Item 8. <u>Financial Statements and Supplementary Data.</u>	57
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.</u>	57
Item 9A. <u>Controls and Procedures.</u>	58
Item 9B. <u>Other Information.</u>	58
<u>PART III</u>	58
Item 10. <u>Directors, Executive Officers and Corporate Governance.</u>	58
Item 11. <u>Executive Compensation.</u>	62
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.</u>	72
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence.</u>	75
Item 14. <u>Principal Accounting Fees and Services.</u>	76
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules.</u>	77

## 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, and, in January 2018, received regulatory approval to commercialize CGuard EPS in India. 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. We cannot give any assurance that we will receive sufficient (or any) proceeds from any such financings or the timing of such financings, if ever. In addition, such additional financings may be costly or difficult to complete.

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 and, together with our first generation MGuard stent combining MicroNet with a bare-metal stainless steel stent, unless otherwise indicated, we refer to both kinds of bare-metal stents as our MGuard coronary products. We market and sell MGuard Prime EPS for the treatment of coronary disease in the European Union. 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.

We are also developing a neurovascular flow diverter (“NGuard”), which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have completed initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models. 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 resume further development of NGuard until we obtain sufficient funding for such purpose.

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 have been 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**

On March 14, 2017, we closed a “best efforts” public offering of 1,069,822 shares of Series C Convertible Preferred Stock (the “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 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 were exercisable immediately, had a term of six months and had an exercise price of \$56.00 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.

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 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 is \$1,000 and the conversion price is \$7.00. As a result of the issuance and sale of the Series D Preferred Stock, the conversion price of our outstanding shares of Series B Convertible Preferred Stock (the “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.



On August 17, 2017, we received a notice from NYSE American LLC (“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 24, 2017, NYSE American accepted our plan to regain compliance with Section 1003(a)(iii) of the Company Guide by February 7, 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. 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. Although we expect that the reverse stock split will result in an increase in the market price of our common stock, the reverse stock split may not result in a permanent increase in the market price of our common stock, which is dependent on many factors, including general economic, market and industry conditions and other factors. We have adjusted all outstanding restricted stock units, stock options, preferred stock and warrants entitling the holders to purchase shares of our common stock as a result of the reverse stock split, as required by the terms of these securities. In particular, we have reduced the conversion ratio for each security, and increased the exercise price in accordance with the terms of each security based on the reverse stock split ratio (i.e., the number of shares issuable under such securities has been divided by thirty-five, and the exercise price per share has been multiplied by thirty-five). Also, we reduced the number of shares reserved for issuance under the InspireMD, Inc. 2013 Long-Term Incentive Plan, proportionately based on the reverse stock split ratio. The reverse stock split does not otherwise affect any of the rights currently accruing to holders of our common stock, or options or warrants exercisable for our common stock. All share and related option and warrant information presented in this Annual Report on Form 10-K have been retroactively adjusted to reflect the reduced number of shares outstanding and the increase in share price which resulted from this action.

## **Business Segment and Geographic Areas**

For the twelve months ended December 31, 2017, 70% of our revenue was derived from sales of CGuard EPS, with the remaining 30% of our revenue from sales of MGuard Prime EPS. For financial information about our operating and reportable segment and geographic areas, refer to "Part II—Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II—Financial Statements and Supplementary Data—Note 12 - Entity Wide Disclosures."

## **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.

The potential global market value of carotid stents is approximately \$500 million, approximately \$300 million of which consists of the U.S. market and approximately \$200 million of which consists of the rest of the world (*source: JMP Securities 2014 and Cowen 2014*). 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 through 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 scarring 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 42<sup>nd</sup> 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, and, in January 2018, received regulatory approval to commercialize CGuard EPS in India.

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. We look forward to proceeding with the formal submission once sufficient funds are available.

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 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 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 delivery catheter will enable us to offer CGuard EPS for use in transradial catheterization, which, we believe, is gaining favor among interventionalists. However, we cannot give any assurance that we will receive sufficient (or any) proceeds from any 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 submit for CE mark approval within three calendar quarters of receiving such proceeds.

### ***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.

During the fourth quarter of 2014, due to a shift in industry preferences away from bare-metal stents in favor of drug-eluting (drug-coated) stents, we decided to curtail developing and promoting our bare-metal stent platform and instead focus on the development of a drug-eluting stent product, which, as further discussed below, has been tabled at this time. Although we have curtailed development and promotion of MGuard Prime EPS, our distributors and sales staff generally cover all of our current products in the market, including MGuard Prime EPS.

***Drug-Eluting Stent MicroNet Product Candidate.*** During 2015, we completed the second phase of development work for our MGuard DES, pursuant to which we incorporated our MicroNet with a drug-eluting stent manufactured by a prospective partner. We believe that a drug-eluting stent with MicroNet has the potential to improve certain performance metrics over the MGuard Prime EPS and attract a broader portion of the cardiologists in the worldwide stent market who are more accustomed to using drug-eluting stents. However, due to our limited resources we have tabled further development of MGuard DES at this time.

### ***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 42<sup>nd</sup> 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) was 0.0% at 30 days. At six months, there was one case of death, which was not stent or procedure-related, and MACCE was increased to 3.6%. At twelve months there were three cases of death, which were not stent or procedure-related, and MACCE was 11.1%.

	<b>30 days (n=30)</b>	<b>6 months (n=28)</b>	<b>12 months (n=27)</b>
MACCE (MI, stroke, death)	(0) 0.0 %	(1) 3.6 %	(3) 11.1 %
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) 11.1 %

In addition, 30 day and 6 month follow-up data from the CARENET study determined the following MACCE events as compared to MACCE events from studies using conventional carotid stents:

	<b>30 days</b>	<b>6 months</b>
	<b>(14 trials,</b>	<b>(3 trials,</b>
	<b>5255</b>	<b>1053</b>
	<b>patients)<sup>(1)</sup></b>	<b>patients)<sup>(2)</sup></b>
MACCE (MI, stroke, death)	5.72 %	8.09 %

(1) Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVeRIC 1+2, MAVeRIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS

(2) Values extrapolated from event curves (*source: The CARENET all-comer trial using the CGuard micronet-covered carotid embolic prevention stent, presented by Dr. Piotr Musialek at the LINC 2015 conference*)

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<sup>3</sup>. 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 ±, it indicates the rate of error.

	48 hours n=27		30 days n=26	
Subjects with new Acute Ischemic Lesions (“AIL”)	10		1	
Incidence of new lesions	37.0	%	4.0	%
Total number new AIL	83		1	
Avg. number new AIL per patient	3.19 ± 10.33		0.04 ± 0.20	
Average lesion volume (cm <sup>3</sup> )	0.039 ± 0.08		0.08 ± 0.00	
Maximum lesion volume (cm <sup>3</sup> )	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:

CARENET trial demonstrated safety of the CGuard EPS stent, with 30 day MACCE 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 change in peak systolic velocity between 6 months and 12 months, suggesting no restenosis concerns.

CGuard EPS offers enhanced benefits for patients undergoing CAS with unprecedented safety.

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

PARADIGM-101 (Prospective evaluation of All-comer percutaneous carotid revascularization in symptomatic and increased-risk asymptomatic carotid artery stenosis, using CGuard™ Mesh-covered embolic prevention stent system-101) was an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine anti-embolic stent system in 101 consecutive unselected all-comer patients referred for carotid revascularization, initiated in 2015. In May 2016, the 30-day positive results were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, and in the Journal of EuroIntervention. In November 2016, positive twelve month follow-up data was presented at the Transcatheter Cardiovascular Therapeutics (TCT) 2016 conference, documenting the benefits of the CGuard MicroNet technology at twelve months. In November 2017, preliminary 2 year follow-up results were presented at the 2017 VEITH Symposium in New York.

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 complications 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;

At 12 months, no new adverse events (0%) were noted by independent neurologist evaluation; and

At 24 months, preliminary results show no new adverse events (0%).

The results of the PARADIGM-101 study demonstrated that CGuard EPS can safely be used on a high risk, all-comer population of patients with carotid artery stenosis and indicate 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 double-layer stent for the internal carotid artery and the in vitro investigation of the stent'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 received carotid artery stenting with CGuard EPS between April 2015 and June 2016. In January 2017, 30-day results were presented at the Leipzig Interventional Course (LINC) 2017.

Key 30-day results presented are as follows:

100% success in implanting CGuard EPS;

No MI, major stroke or death at 30 days;

All vessels treated with CGuard EPS remained patent (open) at six months; and

DW-MRI performed pre procedure and 24/72 hours post-procedure in 61 patients, of which 12 patients had new micro emboli ( 19% ).

***Ongoing Investigator Initiated Independent Randomized Trial in Carotid Artery Revascularization Comparing the Stent (Acculink™) Versus CGuard EPS: Siberia Trial***

In October 2017, the first patients were enrolled and treated in an investigator initiated independent randomized trial in carotid artery revascularization. The objective of this ongoing trial is to assess the neuro protection and clinical superiority of the minimally invasive interventional procedure with the CGuard EPS as compared to Abbott's RX ACCULINK Carotid Stent in subjects at high risk for carotid endarterectomy.

This trial is a single-center randomized trial with two interventional arms comparing CGuard™ EPS to Acculink. The trial is planned to enroll 100 consecutive eligible patients with 50 patients in each arm. The primary endpoint of the trial will be new ischemic areas in the brain within 24 to 48 hours post procedure and new lesion permanence at 30-days as determined by Diffusion-Weighted Magnetic Resonance Imaging (DWMRI). Each patient will receive clinical and ultrasound follow-up at 1 year post procedure. The trial will be conducted at the Center of Vascular and Hybrid Surgery within the Scientific Research Institute of Circulation Pathology in Novosibirsk, Russia, which is associated with the Novosibirsk State University.

***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 stent 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 stent'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 stents 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 stent

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 stent. 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), all markers of optimal blood flow to the heart.

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 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.

**Grow our presence in existing and new markets for CGuard EPS.** We have launched CGuard EPS in most European and Latin American countries through a comprehensive distributor sales organizations network. We are also pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, the Middle East, Asia and Latin America.

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

**Establish relationships with collaborative and development partners to fully develop and market our existing and future products.** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and NGuard, as well as future efforts with MGuard Prime EPS, 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 (eight 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 carotid and neurovascular 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 the future, we believe that physicians will look to next-generation stent technology to compete with existing therapies. These new technologies will likely 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 in the future 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 both the European and the United States markets.

### *Neurovascular*

Stryker Corporation dominated the global interventional neurology market in 2014. The other key players in this market include Medtronic plc, Johnson & Johnson, Terumo Corporation, Penumbra, Abbott Laboratories, Merit Medical Systems, Inc., W. L. Gore & Associates, Inc., Microport Scientific Corporation, and Medikit Co., Ltd., among others. (*Source: Markets and Markets 2015*).

## **Research and Development Expenses**

During each of the twelve months ended December 31, 2017 and 2016, we spent \$1.3 million, on research and development.

## **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 our new 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 other key clinical specialties that implant carotid stents, the vascular surgeons, interventional cardiologists and interventional radiologists. All territories previously covered by our former European distributor have been transferred to local distributors by June 2017. We plan to focus our marketing efforts primarily on Europe, Asia Pacific region and Latin America, expanding our direct distribution model in those markets, especially in countries with current or near-term regulatory approval. In addition, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We plan to work with leading physicians to enhance our marketing efforts.

### ***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 2018 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 predilatation 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 payers. Third-party payers can include both government funded insurance programs and private insurance programs. While each payer develops and maintains its own coverage and reimbursement policies, the vast majority of payers have similarly established policies. The MGuard coronary product and CGuard product sold to date have been designed and labeled in such a way as to facilitate the utilization of existing reimbursement codes, 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 reimbursement for the MGuard coronary products and CGuard products or in order to obtain a higher reimbursement price. 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-seven pending patent applications, ten 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 65 patents and pending applications including eight issued U.S. patents. These patent rights are directed to cover the following eight (8) patent families:

<b>Base Title of Patent Family</b>	<b>Country Pending</b>	<b>Country/Patent No.</b>	<b>Issue Date</b>
Bifurcated Stent Assemblies	India	Israel 198,188	5/1/2014
		China ZL200780046676.2	9/26/2012
Deformable Tip for Stent Delivery and Methods of Use	US	—	—
	PCT/WIPO	—	—
		Canada 2,666,712	
		Canada 2,881,557	3/31/2015
In Vivo Filter Assembly		US 8,043,323	10/11/2016
		US 9,132,261	10/25/2011
	US	Israel 198,189	9/15/2015
	India	China ZL200780046659.9	2/1/2014
			6/13/2012
		China ZL201210119132.7	6/24/2015
	EP 07827228.3	8/30/2017	
Knitted Stent Jackets	Canada	(Germany, France, UK) Canada 2,666,728	6/23/2015
	India		10/10/2012

Edgar Filing: InspireMD, Inc. - Form 10-K

	US	China ZL200780046697.4	12/2/2015
			2/1/2014
		China ZL201210320950.3	3/29/2017
		Israel 198,190	
		EP 07827229.1	
		(Germany, France, UK)	
		China ZL201210454357.8	12/9/2015
		China ZL200780043259.2	1/2/2013
	Canada		
		Israel 198,665	5/28/2014
Optimized Stent Jacket	India		
		US 9,132,003	9/15/2015
	Israel		
		US 9,526,644	12/27/2016
	US		
		US 9,782,281	10/10/2017
		EP 07827415.6	10/11/2017
		(9 EP countries)	
		South Africa 2007/10751	10/27/2010
	US		
Stent Apparatuses for Treatment Via Body Lumens and Methods of Use		Canada 2609687	4/22/2015
	Israel		
		Canada 2,843,097	10/27/2015
	Europe (EPO)		
		US 8,961,586	2/24/2015
	Australia		
	Canada		
	Europe (EPO)	US 9,527,234	12/27/2016
Stent Thermoforming Apparatus and Methods	India	US 9,782,278	10/10/2017
	Japan		
	US		
Stent with Sheath and Metal Wire Retainer	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<sup>®</sup>, MGuard<sup>®</sup>, CGuard<sup>®</sup>, and MGuard Prime<sup>®</sup> 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<sup>®</sup>, NGuard<sup>®</sup>, PVGuard<sup>®</sup> and the MNP Micronet Protection Logo in the European Union and a supplemental registration for Micronet<sup>®</sup> in the United States. We have also applied to register the names PVGuard<sup>™</sup> as a trademark in the European Union, as well as Carenet<sup>™</sup>, CGuard<sup>™</sup> InspireMD<sup>™</sup>, SmartFit<sup>™</sup>, PVGuard<sup>™</sup>, NGuard<sup>™</sup>, AGuard<sup>™</sup>, and MGuard Prime<sup>™</sup> 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 regulatory approval and have 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, Austria, Belarus, Belgium, Brazil, Bulgaria, Chile, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hong Kong, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, and the United Kingdom. We have temporary regulatory approval to sell MGuard Prime EPS in Malaysia while we are in the registration process due to a regulatory change in November 2015. In addition, we are awaiting regulatory approval to sell our products in Ecuador, Peru, Australia, Mexico, Serbia, Turkey, Taiwan and Vietnam (for CGuard EPS). 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 those countries listed in the table below. We are currently seeking marketing approval for CGuard EPS in Ecuador, Peru, Australia, Mexico, Serbia, Turkey, Taiwan and Vietnam.

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**

<b>Countries</b>	<b>MGuard Prime EPS Approval</b>	<b>MGuard Prime EPS Sales</b>	<b>CGuard EPS Approval</b>	<b>CGuard EPS Sales</b>
Argentina	Y	Y	Y	Y
Australia	N	Y	(1) N	Y (2)
Austria	Y	Y	Y	Y
Belarus	Y	Y	Y	Y
Belgium	Y	Y	Y	Y
Brazil	Y	Y	N	N
Bulgaria	Y	N	Y	Y
Chile	N	Y	(3) 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
Estonia	Y	Y	Y	Y
Finland	Y	Y	Y	Y
France	Y	Y	Y	Y
Germany	Y	Y	Y	Y
Greece	Y	N	Y	N
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	N
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

Edgar Filing: InspireMD, Inc. - Form 10-K

Liechtenstein	Y	N	Y	N
Luxembourg	Y	Y	Y	N
Malaysia	Y	(4) Y	N	N
Malta	Y	Y	Y	N
Mexico	Y	Y	N	N
Norway	Y	Y	Y	N
Poland	Y	Y	Y	Y
Portugal	Y	N	Y	Y
Romania	Y	Y	Y	Y
Russia	Y	Y	Y	Y
Saudi Arabia	Y	Y	N	N
Serbia	Y	N	N	N
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y	(5) Y	N	N
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	Y
Switzerland	Y	Y	Y	Y
Taiwan	Y	N	N	N
United Kingdom	Y	Y	Y	Y

- (1) We have lost our approval due to administrative issues but are now in the process of renewing the approval.
- (2) The Australia Regulatory Authority (TGA) allows patients to receive treatment with unapproved device via a compassionate route.
- (3) 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.

- (4) Due to the changes made to the relevant regulations in Malaysia that became effective in November 2015, we are required to register our product. On November 29, 2015, we initiated the registration process required pursuant to the amended regulation. We have temporary authorization to sell and market MGuard Prime EPS in Malaysia pending a final determination of our application for registration which, we expect to receive around January 2019.

- (5) We believe that we have regulatory approval for MGuard Prime EPS in South Africa based upon information from our former distributor in such country, who was responsible for obtaining the regulatory approval for MGuard Prime EPS. However, the certificate evidencing regulatory approval was held by our former distributor 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.

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

Certain 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***

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 a premarket approval. Descriptions of the premarket approval and 510(k) clearance processes are provided below.

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.

Device classification depends on many factors including the device's intended use and its indications for use. In addition, classification is risk-based, that is, the risk the device poses to the patient and/or the user is a major factor in determining the class to which it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

*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.

*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 MDUFMA, 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.

### ***Premarket Approval Pathway***

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.

We anticipate that our CGuard EPS will be 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.



The U.S. Food and Drug Administration actively monitors compliance with laws and regulations through its review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The U.S. Food and Drug Administration can ban certain medical devices; detain or seize adulterated or misbranded medical devices (that is, medical devices that do not comply with the Federal Food, Drug, and Cosmetic Act, including as implemented through the U.S. Food and Drug Administration's regulations); order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The U.S. Food and Drug Administration may also enjoin and restrain a company for certain violations of the Federal Food, Drug, and Cosmetic Act and other amending laws pertaining to medical devices, or initiate action for criminal prosecution of such violations. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products, may limit our ability to obtain premarket approvals, and could result in a substantial modification to our business practices and operations.

### ***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 are subject once 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 intended to induce the purchase or recommendation of health care products and services. Other provisions of federal and state laws prohibit presenting, or causing to be presented, to third party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, other health care 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 health care programs. 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 potential purchasers of such products. The health care laws that may be applicable to our business or operations include:

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 health care 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 health care 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 prohibits 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 health care 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 health care 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 health care 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.

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 payers, 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.

For the twelve months ended December 31, 2017, 82% of our revenue was generated in Europe, and 15% of our revenue was generated in Latin America, with the remaining 3% of our revenue generated in the rest of the world. Our major customers in the twelve months ended December 31, 2017, were AB Medica, Deutschland GmbH & Co. KG., a distributor in Germany that accounted for 14% of our revenues, Nerin Assets OU, an Estonian distributor distributing our products in Russia that accounted for 12% of our revenues and Crossmed S.r.l., a distributor in Italy that accounted for 12% of our revenues.

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-expanding 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 12, 2018, we had 36 full-time employees. Except for one 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 \$8.4 million for the fiscal year ended December 31, 2017, and had a net loss of approximately \$8.5 million during the fiscal year ended December 31, 2016. As of December 31, 2017, we had an accumulated deficit of \$140 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, 2017, 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 only have sufficient capital to finance our operations through the next four months. 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 Organization and Our Common Stock, Preferred Stock and Warrants—The certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock and the Series D Purchase Agreement 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, the Series C Preferred Stock or the Series D 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. In connection with the Series D Private Placement closed in December 2017, we entered into the Series D Purchase Agreement, pursuant to which we agreed, among other things, (1) to refrain from issuing shares of common stock until March 1, 2018, except that we may commence an offering of our common stock or common stock equivalents for gross proceeds of at least \$8 million (a "Qualified Offering") at any time after February 26, 2018, and make certain other exempt issuances, and (2) to refrain from entering into certain variable rate transactions until June 1, 2018. In addition, pursuant to the Series D Purchase Agreement, upon consummation of a Qualified Offering, each share of outstanding Series B Preferred Stock and the shares of Series C Preferred Stock held by the investor that participated in the Series D Private Placement will be automatically exchanged into the securities we sell in a Qualified Offering (to the extent that stockholder approval for such exchange of Series C Preferred Stock is not required under the Company Guide). The holders of our Series D Preferred Stock also have the option to exchange their Series D Preferred Stock into the securities issued in a subsequent offering or into the securities we sell in a Qualified Offering upon consummation of a Qualified Offering. Furthermore, the certificate of designation for our Series B Preferred Stock and 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. 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.



***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 MGuard Prime EPS and CGuard 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 MGuard Prime EPS or CGuard 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 MGuard Prime EPS or CGuard 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 MGuard Prime EPS or CGuard 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 and published peer reviewed journal articles, 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 a substantial reduction in sales over the past three years. Such sales may never recover 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.

***Our products are based on a new technology, and 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 our products are new and long-term success measures have not been completely validated, 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 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.

Further, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. In addition, the healthcare regulatory environment may change in a way that restricts our operations.

***We are 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 health care 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

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, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends 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 will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant 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. 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 the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. This 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 competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. We face intense competition from Boston Scientific Corporation, Guidant Corporation, Medtronic, Inc., Abbott Vascular Devices, Johnson & Johnson, Terumo Corporation, Covidien Ltd., Cordis Corporation (currently part of Cardinal Health, Inc.) and others. 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 MGuard Prime EPS and CGuard 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.

***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.

***If we fail to obtain an adequate level of reimbursement for our products by third party payors, 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 will determine 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 health care 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 in the European Union, our business could be significantly and adversely affected by healthcare reform legislation and other administration and legislative proposals.***

The Affordable Care Act, enacted 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, that began on January 1, 2013, 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, 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. If we commence sales of our MGuard Prime EPS or CGuard EPS stent in the United States, this new 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 initiated and continue to evolve, including an Executive Order signed by the U.S. President directing 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. Recently, there have been renewed efforts to repeal or replace the Affordable Care Act following the 2017 changes in the U.S. presidential administrations and U.S. Congress. We cannot predict what healthcare programs and regulations will be implemented or changed at the federal or state level in the United States, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products 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 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 2014, Israel launched an additional operation against Hamas operatives in the Gaza strip in response to Palestinian groups launching rockets at Israel. Recent 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 2017 is 24% and 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 Organization and 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 or if our common stock continues to trade for a substantial period of time at law selling prices. 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 17, 2019, to regain compliance with the continued listing requirements.

We believe, based on our current estimate, we will be required to complete one or more offerings that will provide us with gross proceeds of at least \$20 million prior to February 17, 2019, in order 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 17, 2019 (which should also make us in compliance with Section(a)(ii) by having stockholders' equity of greater than \$4 million). Even if the net proceeds from our future capital raises provide us with 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.

In addition to our non-compliance with Sections 1003(a)(ii)-(iii) of the Company Guide, on January 16, 2018, 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 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. The NYSE American has also 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.

On February 7, 2018, we effected the reverse stock split of our common stock. One of the primary intents for the reverse stock split 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. There can be no assurance that the market price of our new common stock after the 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.

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.





***The reverse stock split may decrease the liquidity of the shares of our common stock.***

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that are outstanding following the reverse stock split. In addition, the reverse stock split increased the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

***There is no public market for our preferred stock.***

There is no established trading market for our preferred stock. A trading market for our preferred stock is not expected to develop, and even if a market develops for our preferred stock, it may not provide meaningful liquidity. The absence of a trading market or liquidity for our preferred stock may adversely affect their value.

***The certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock and the Series D Purchase Agreement 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, the Series C Preferred Stock or the Series D 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 2017 offering was below the then current Series B Preferred Stock conversion price, we reduced the Series B Preferred Stock conversion price upon closing of the March 2017 offering. The conversion price of our outstanding shares of Series B Preferred Stock was further reduced to \$7.00 upon closing of the sale of the Series D Preferred Stock. 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. Moreover, pursuant to the Series D Purchase Agreement and the certificate of designation for the Series D Preferred

Stock, the purchasers of Series D Preferred Stock have the option to exchange their Series D Preferred Stock into the securities issued in a subsequent offering or in a Qualified Offering, and the shares of Series C Preferred Stock held by the purchasers of Series D Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering (to the extent that stockholder approval for such exchange of Series C Preferred Stock is not required under the Company Guide). In connection with the Series D Private Placement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering. All of the foregoing features will increase the number of shares issuable upon conversion or exchange, assuming that the effective offering price of our common stock in a subsequent financing or a Qualified Offering is lower than the conversion price of these securities then in effect, and will result in a greater dilutive effect on our shareholders. 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 exchange of Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive. The potential for such additional issuances may depress the price of our common stock regardless of our business performance. We may find it more difficult to raise additional equity capital while any of our Series B Preferred Stock, Series C Preferred Stock or Series D Preferred Stock is outstanding.

***The mandatory exchange of shares of Series C Preferred Stock held by the purchasers of Series D Preferred Stock into the securities we sell in a Qualified Offering, as contemplated by the Series D Purchase Agreement, may require us to obtain stockholder approval under the Company Guide and delay or make it difficult for us to obtain additional financing.***

The Series D Purchase Agreement provides that the shares of Series C Preferred Stock held by the investor that participated in the Series D Private Placement will be automatically exchanged into the securities we sell in a Qualified Offering. The Company Guide Section 713(a)(ii) requires us to obtain stockholder approval in connection with a transaction other than a public offering involving the sale, issuance or potential issuance by the issuer of additional shares of common stock (or securities convertible into or exchangeable for common stock) equal to 20% or more of the number of shares of common stock outstanding before the issuance for a price that is less than the greater of book or market value of the stock on the date the issuer enters into a binding agreement for the issuance of such securities. Accordingly, if the effective offering price of our common stock is less than the greater of book or market value of our common stock at the time of such offering, and the issuance of shares of common stock or shares of common stock underlying securities convertible into common stock in a Qualified Offering upon the mandatory exchange of the then outstanding shares of Series C Preferred Stock held by the investor in the Series D Private Placement is equal to 20% or more of the number of shares of our common stock outstanding immediately prior to the offering, we will be required obtain stockholder approval under the Company Guide Section 713(a)(ii) to enable the exchange of the Series C Preferred Stock for securities sold in the Qualified Offering pursuant to the Series D Purchase Agreement. Such requirement may make any future financing to be both time consuming or difficult to obtain. In addition, if stockholder approval is required for the issuance of securities upon mandatory exchange of Series C Preferred Stock pursuant to the Series D Purchase Agreement, there is no assurance that our stockholders will approve such issuance. Furthermore, if we are not able to fully exchange the shares of Series C Preferred Stock in a future offering, we might be deemed to be in breach of the terms of our Series D Purchase Agreement, we could expose us to claims for damages.

***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.

***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.

***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 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. Moreover, pursuant to the Series D Purchase Agreement and the certificate of designation for the Series D Preferred Stock, the purchasers of Series D Preferred Stock have the option to exchange their Series D Preferred Stock into the securities issued in a subsequent offering having more favorable terms, such as a lower price, which would increase the number of shares of common stock issuable to the holders of Series D Preferred Stock following the exercise of such option. The Series D Purchase Agreement also provides for an automatic exchange of all outstanding shares of Series B Preferred Stock and Series C Preferred Stock held by the investor that participated in the Series D Private Placement into the securities we sell in a Qualified Offering (to the extent that stockholder approval for such exchange of Series C Preferred Stock is not required under the Company Guide), which, if the effective offering price of common stock is lower than the conversion price of Series C Preferred Stock then in effect, would also increase the number of shares issuable to the holder of Series C Preferred Stock. See “*Risk Factors — Risks Related to Our Organization and Our Common Stock, Preferred Stock and Warrants—The certificate of designation for the Series B Preferred Stock and the Series C Preferred Stock and the Series D Purchase Agreement 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, the Series C Preferred Stock or the*”

*Series D 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.

***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,” “should,” “could,” “would,” “predicts,” “potential,” “continue,” “expects,” “anticipates,” “future,” “intends,” “plans,” “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 payers for our products;

our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;

adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;

the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;

the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and

loss or retirement of key executives and research scientists.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. You should review carefully the risks and uncertainties described under the heading “Item 1A. Risk Factors” in this Annual Report on Form 10-K for a discussion of these and other risks that relate to our business and investing in shares of our common stock. The forward-looking statements contained in this Annual Report on Form 10-K are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

### **Item 1B. Unresolved Staff Comments.**

Not applicable.

### **Item 2. Properties.**

Our headquarters are located in Tel Aviv, Israel, where we lease a 1,000 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 April 26, 2016, Microbanc, LLC and Todd Spenla of Microbanc, LLC filed suit in the New York State Supreme Court (New York County) against us asserting claims for breach of agreement, quantum meruit, unjust enrichment and fraud and seeking approximately \$2.2 million and 9% of the amount of stock and warrants sold in 2011 and 2012 in alleged damages relating to certain alleged finders’ fees that they claim are owed. We removed the suit to federal court and filed a motion to dismiss all claims on June 30, 2016. 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. Microbanc, LLC and Todd Spenla had until March 16, 2017, to file a motion for application for leave to replead its claims for breach of contract. On March 16, 2017, Microbanc, LLC filed a motion for leave to file an amended complaint to replead all claims and to substitute Estate of Todd Spenla for the deceased plaintiff, Todd Spenla. We have opposed this motion,

which remains pending before the district court. On April 14, 2017, James D. Burchetta filed a motion to intervene as a plaintiff. On April 19, 2017, the court granted our request for an adjournment of this motion to intervene, pending resolution of Microbanc, LLC's motion for leave to file the amended complaint and to substitute the Estate of Todd Spenla for the deceased plaintiff, Todd Spenla. On January 22, 2018, the court denied such motion, and on January 23, 2018, the clerk entered judgment dismissing the complaint consistent with the District court's order. A notice of appeal must be filed by February 22, 2018. Should this matter continue on appeal, we intend to contest the matter vigorously. Due to the uncertainties of litigation, however, we can give no assurance that we will prevail on any claims made against us 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.

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. Discovery is ongoing at this time. 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 Microbanc, LLC and Todd Spenla and 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 following table sets forth the intra-day high and low sales price per share for our common stock, as reported on the NYSE American, for the period of January 1, 2016 to December 31, 2017. The sales prices for our common stock are adjusted for the one-for-thirty-five reverse stock split of our common stock that occurred on February 7, 2018.

Fiscal Year Ended December 31, 2017	High	Low
First Quarter	\$138.95	29.75
Second Quarter	\$36.05	17.50
Third Quarter	\$25.55	10.50
Fourth Quarter	\$20.30	4.20

Fiscal Year Ended December 31, 2016	High	Low
First Quarter	\$831.25	341.25
Second Quarter	\$542.50	271.25
Third Quarter	\$262.50	61.25
Fourth Quarter	\$153.65	49.35

The last reported sales price of our common stock on the NYSE American on February 12, 2018, was \$5.21 per share. As of February 12, 2018, there were approximately 236 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, and, in January 2018, received regulatory approval to commercialize CGuard EPS in India. 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. We cannot give any assurance that we will receive sufficient (or any) proceeds from any such financings or the timing of such financings, if ever. In addition, such additional financings may be costly or difficult to complete.

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. We market and sell MGuard Prime EPS for the treatment of coronary disease in the European Union. 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.

We are also developing a neurovascular flow diverter, NGuard, which is an endovascular device that directs blood flow away from cerebral aneurysms in order to ultimately seal the aneurysms. Our flow diverter would utilize an open cell, highly flexible metal scaffold to which MicroNet would be attached. We have completed initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models. 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 resume further development of NGuard until at least the third quarter of 2018.

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

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

## **Recent Events**

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.

## **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, share-based compensation 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 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, 2017 compared to the twelve months ended December 31, 2016***

*Revenues.* For the twelve months ended December 31, 2017, revenue increased by \$867,000, or 45.8%, to \$2,761,000, from \$1,894,000 during the twelve months ended December 31, 2016. This increase was predominantly driven by a 67.6% increase in sales of CGuard EPS from \$1,147,000 in 2016, to \$1,922,000 in 2017, as we transitioned from our prior exclusive distribution partner for most of Europe to local distributors, expanded into new geographies such as Russia, and continued focus on expanding existing markets such as Italy. The transition to local distributors reflects an effort to broaden our sales efforts from only interventional neuroradiologists to include vascular surgeons, interventional cardiologists and interventional radiologists, as well. In addition to the increase in sales of CGuard EPS, sales of MGuard Prime EPS increased by 12.3% or \$92,000, from \$747,000 in 2016, to \$839,000 in 2017.

With respect to regions, the increase in revenue was primarily attributable to an increase of \$640,000 in revenue from sales made in Europe (driven by \$735,000 growth of CGuard EPS for reasons mentioned above, offset by a decrease in revenues of MGuard Prime EPS largely driven by doctors increasingly using drug-eluting stents rather than bare metal stents such as MGuard Prime EPS in STEMI patients) as well as an increase of \$246,000 in sales made in Latin America (driven by \$222,000 growth of MGuard Prime EPS resulting from increased geographical coverage and an increase of \$24,000 in revenues from CGuard EPS).

*Gross Profit (Loss).* For the twelve months ended December 31, 2017, gross profit (revenue less cost of revenues) increased by 473.5%, or \$483,000, to \$585,000, compared to \$102,000 during the twelve months ended December 31, 2016. The increase in gross profit resulted primarily from an increase of \$324,000 due to the increase in revenues (as mentioned above), less the related material and labor costs; a decrease in write-offs of inventory of MGuard Prime EPS of \$108,000; and a decrease of \$99,000 of expenses related to the underutilization of our manufacturing resources. These increases in gross profit were partially offset by an increase of \$48,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 21.2% in the twelve months ended December 31, 2017 from 5.4% in the twelve months ended December 31, 2016

*Research and Development Expenses.* For the twelve months ended December 31, 2017, research and development expenses decreased by 1.2% or \$15,000 to \$1,276,000 from \$1,291,000 during the twelve months ended December 31, 2016. The decrease in research and development expenses resulted primarily from a decrease of \$15,000 in miscellaneous expenses.

*Selling and Marketing Expenses.* For the twelve months ended December 31, 2017, selling and marketing expenses increased by 61.5%, or \$898,000, to \$2,357,000, from \$1,459,000 during the twelve months ended December 31, 2016. This increase in selling and marketing expenses resulted primarily from an increase of \$234,000 in salary expenses; an increase of \$208,000 in travel expenses; an increase of \$162,000 in consulting fees; an increase of \$171,000 in share-based compensation expenses due to former employees' forfeiture of their share-based compensation in 2016, reducing our 2016 share-based compensation expenses, for which, no such reduction occurred during 2017; and an increase of \$136,000 in expenditures related to our participation in trade shows and promotional activities. These increases in expenses were partially offset by a decrease \$13,000 in miscellaneous expenses. The increase in selling and marketing expenses was primarily to support the new 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.

*General and Administrative Expenses.* For the twelve months ended December 31, 2017, general and administrative expenses increased by 3.7%, or \$184,000, to \$5,184,000, from \$5,000,000 during the twelve months ended December 31, 2016. The increase in general and administrative expenses resulted primarily from an increase of \$129,000 in rent and related expense, primarily due to a city tax refund we received in 2016, which reduced our 2016 rent and related expenses, while no such refund was received in 2017, as well as a one-time termination fee for our Boston office in the twelve months ended December 31, 2017, which increased our rent and related expenses in 2017, an increase of \$113,000 due to a salary related accrual, an increase of \$107,000 in employee share-based compensation due to two former employees' forfeiture of their share-based compensation in 2016, reducing our 2016 share-based compensation expenses, for which, no such reduction occurred during 2017, an increase of \$89,000 in legal expenses and an increase of \$82,000 in miscellaneous expenses. These increases in general and administrative expenses were partially offset by a decrease of \$336,000 in share-based compensation for the twelve months ended December 31, 2017, compared to the twelve months ended December 31, 2016, during which period we recognized all remaining unrecognized costs following the cancellation of certain options held by certain directors, resulting in higher share-based compensation expenses in the twelve months ended December 31, 2016.

*Financial Expenses.* For the twelve months ended December 31, 2017, financial expenses decreased by 78.0%, or \$633,000, to \$179,000, from \$812,000 during the twelve months ended December 31, 2016. The decrease in financial expenses primarily resulted from a decrease in interest expenses due to the repayment of the remaining balance of our outstanding indebtedness of \$1.2 million on March 21, 2017.

*Tax Expenses.* For the twelve months ended December 31, 2017, tax expenses increased by \$26,000 to \$27,000, from \$1,000 in the twelve months ended December 31, 2016.



*Net Loss.* Our net loss decreased by \$23,000, or 0.3%, to \$8,438,000 for the twelve months ended December 31, 2017, from \$8,461,000 during the twelve months ended December 31, 2016. The decrease in net loss resulted primarily from a decrease of \$633,000 in financial expenses and an increase of \$483,000 in gross profit, partially offset by an increase of \$1,067,000 in operating expenses and an increase of \$26,000 in tax expenses.

## Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2017 of \$140 million, as well as a net loss of \$8,438,000 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 for a period of up to four months from the date of filing of this Annual Report on Form 10-K. 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.

On March 21, 2016, we sold 2,201 shares of our common stock and warrants to purchase 1,114 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a

term of exercise of 5 years from the date of issuance and an exercise price of \$516.25. This offering resulted in gross proceeds to us of approximately \$1.1 million.

On March 21, 2016, we sold 1,183 shares of our common stock and warrants to purchase 592 shares of our common stock in a private placement. Each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the offering. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of \$516.25. This offering resulted in gross proceeds to us of approximately \$0.6 million.

These offerings on March 21, 2016, resulted in net proceeds to us of approximately \$1.4 million after deducting placement agent fees and other estimated offering expenses.

On July 7, 2016, we closed a public offering of 442,424 shares of Series B Preferred Stock and accompanying “Series A” warrants to purchase up to 50,620 shares of common stock. Each share of Series B Preferred Stock and the accompanying warrants were sold at a price of \$33.00. Each share of Series B Preferred Stock was initially 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, upon closing of the March 2017 offering, we reduced the Series B Preferred Stock conversion price upon closing of the March 2017 offering to \$56.00 per share of common stock, and each share of Series B Preferred Stock became convertible into 0.589 shares of common stock. As a result of the issuance and sale of the Series D Preferred Stock, the conversion price for the Series B Preferred Stock was further adjusted to \$7.00 per share, and each share of Series B Preferred Stock became convertible into 4.714 shares of common stock. In connection with the Series D Private Placement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering. 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 warrants sold in this offering commenced trading on the NYSE American under the ticker symbol “NSPR.WS” on August 1, 2016. We received gross proceeds of approximately \$14.6 million from the offering, before deducting placement agent fees and offering expenses payable by us.

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 were exercisable immediately, had a term of exercise of six months from the date of issuance and had an exercise price of \$56.00 per share of common stock. 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 Preferred Stock in the Series D Private Placement, for aggregate gross proceeds of \$750,000. The initial stated value of each share of Series D Preferred Stock is \$1,000 and the initial conversion price is \$7.00.

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. In addition, pursuant to the Series D Purchase Agreement and the certificate of designation for the Series D Preferred Stock, the purchasers of Series D Preferred Stock have the option to exchange their Series D Preferred Stock into the securities issued in a subsequent offering or in a Qualified Offering, and the shares of Series C Preferred Stock held by the purchasers of Series D Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering (to the extent that stockholder approval for such exchange of Series C

Preferred Stock is not required under the Company Guide). In connection with the Series D Private Placement, the certificate of designation for the Series B Preferred Stock was amended to provide that each share of outstanding Series B Preferred Stock will be automatically exchanged into the securities we sell in a Qualified Offering. 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 or upon automatic exchange into the securities we sell in a Qualified Offering, or upon exchange of the Series D Preferred Stock into securities we sell in a subsequent offering or in a Qualified Offering 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, Series C Preferred Stock or Series D Preferred Stock is outstanding. As of February 12, 2018, 17,303 shares of Series B Preferred Stock, 741,651 shares of Series C Preferred Stock and 750 shares of Series D Preferred Stock were outstanding.

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 111,443 shares of common stock. We received an aggregate of \$557,205 from the placement agent for the exercise of the unit purchase option and the subsequent conversion of the Series B Preferred Stock included in the units.

*Twelve months ended December 31, 2017 compared to the twelve months ended December 31, 2016*

*General.* At December 31, 2017, we had cash and cash equivalents of \$3,710,000, as compared to \$7,516,000 as of December 31, 2016. 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, 2017, net cash used in our operating activities increased by \$636,000 to \$8,131,000, from \$7,495,000 in the same period in 2016. The primary reason for the increase in cash used in our operating activities was an increase of payments for third party related expenses and for professional services of \$1,187,000, including the end of term charge of \$520,000 to Hercules, from \$5,257,000 to \$6,444,000, as well as an increase of \$18,000 in salary payments from \$4,164,000 in the twelve months ended December 31, 2016 to \$4,182,000 during the same period in 2017. These increases in cash used in operating activities was partially offset by an increase of \$569,000 in payments received from customers from \$1,926,000 in the twelve months ended December 31, 2016 to \$2,495,000 in the same period in 2017.

Cash used by our investing activities was \$318,000 during the twelve months ended December 31, 2017, resulting primarily from the purchase of production equipment, compared to \$70,000 of cash provided during the same period in 2016 resulting primarily from the receipt of cash previously funded to employee retirement funds.

Cash provided by financing activities for the twelve months ended December 31, 2017 was \$4,633,000, compared to \$11,703,000 during the same period in 2016. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2017, was the funds received from our March 2017 offering of 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. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2016 was the funds received from the issuance of preferred stock and warrants in a public offering closed on July 7, 2016, as well issuance of shares and warrants in a concurrent public offering and private placement closed on March 21, 2016, for approximately \$14,365,000 of net proceeds, offset by loan repayments of \$2,648,000.

As of December 31, 2017, our current assets exceeded our current liabilities by a multiple of 2.1. Current assets decreased by \$3,477,000 during the period and current liabilities decreased by \$2,296,000 during the period. As a result, our working capital decreased by \$1,181,000 to \$2,673,000 at December 31, 2017.

## **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 are currently evaluating the impact this ASU will have on our consolidated financial statements.

The FASB has issued the following standards that we have determined will not have a material impact on its consolidated financial statements upon their adoption:

In May 2017, the FASB issued ASU 2017-9 on changes to terms and conditions of share-based payment awards. The amendment provides guidance about which changes to terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance is effective for the fiscal year beginning on January 1, 2018, including interim periods within that year (early adoption is permitted). We do not anticipate that such guidance will have a material impact on our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Codification (“ASC”) 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after December 15, 2017. We will adopt the standard using the modified retrospective method.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The new standard is effective for annual periods and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income.

In February 2016, the FASB issued ASU 2016-02, Leases, which requires to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The accounting standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

## **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, 2017 and 2016  
Consolidated Statements of Operations for the Years Ended December 31, 2017 and 2016  
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2017 and 2016  
Consolidated Statements of Cash Flows for the Years Ended December 31, 2017 and 2016  
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, 2017, 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, 2017.

**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, 2017. 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, 2017.

## **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, 2017 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.

<b>Name</b>	<b>Age</b>	<b>Position</b>
James Barry, Ph.D.	58	President, Chief Executive Officer and Director
Craig Shore	56	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
Agustin V. Gago	58	Executive Vice President, Chief Commercial Officer
Michael Berman <sup>(1)(2)</sup>	60	Director
Campbell Rogers, M.D.	56	Director
Paul Stuka <sup>(1)(2)(3)</sup>	62	Chairman of the Board of Directors
Thomas J. Kester <sup>(1)(3)</sup>	71	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 also serves as a director of pSivida Corp (NASDAQ: PSDV). 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. From February 2008 through June 2009, Mr. Shore served as chief financial officer of World Group Capital Ltd. and Nepco Star Ltd., both publicly traded companies on the Tel Aviv Stock Exchange, based in Tel Aviv, Israel. From March 2006 until February 2008, Mr. Shore served as the chief financial officer of Cellnets Solutions Ltd., a provider of advanced cellular public telephony solutions for low to middle income populations of developing countries based in Azur, Israel. Mr. Shore has over 25 years of experience in financial management in the United States, Europe and Israel. 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.

**Agustin V. Gago** has served as our executive vice president and chief commercial officer since October 24, 2016. Mr. Gago has over 25 years of experience in building profitable international commercial, sales and marketing organizations. Prior to joining us, Mr. Gago served as a principal at Dash International, LLC, a consulting firm he founded in 2013, advising senior management of major medical device companies on business strategy. From 2009 to 2013, Mr. Gago served as chief commercial officer at Delcath Systems, Inc. (NASDAQ: DCTH), an interventional oncology company, creating its direct and contract sales forces as well as a distributor infrastructure serving Europe, Asia and South America. From 2011 to 2013, Mr. Gago also served as a director of Delcath Systems, Inc.'s subsidiary in Galway, Ireland. From 2008 to 2009, Mr. Gago was vice president of international oncology surgery sales at AngioDynamics, Inc. (NASDAQ: ANGO), a provider of minimally invasive medical devices for cardiology vascular disease and oncology. Mr. Gago also worked from 1998 to 2008 in various leadership roles at E-Z-EM, Inc. (acquired by Bracco Diagnostics Inc.), a global manufacturer of medical devices and contrast agents for gastrointestinal imaging, and served as a director of E-Z-EM, Inc.'s subsidiaries in the United Kingdom and the Netherlands, eventually being appointed as vice president of global gastrointestinal business and vice president of international operations of E-Z EM, Inc. Mr. Gago received a B.S. degree in business management from Hofstra 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. 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 2011 as a co-founder and director of Rebiotix Inc., a company developing an innovative treatment for C Diff colitis, (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 2016 as a director at EndoSpan Ltd., (xi) since 2014 as a venture partner at RiverVest Ventures and (xii) 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 interventional cardiology, 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, 2017, 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, except for one late report on Form 4 for Dr. Barry, with respect to a payment of tax liability by withholding securities in connection with vesting of restricted stock.

### **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.

*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.

*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.

## **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](http://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, 2017 and 2016.

Year	Restricted Option	All Other
------	-------------------	-----------

Edgar Filing: InspireMD, Inc. - Form 10-K

Name and Principal Position		Salary (\$)	Bonus (\$)		Stock Awards (\$) <sup>(1)</sup>	Awards (\$) <sup>(1)</sup>	Compensation (\$)	Total (\$)
James Barry, Ph.D. President and Chief Executive Officer	2017	365,000	-	(2)	-	-	50,319	(3) 415,319
	2016	288,958	106,458	(4)	334,871	235,783	25,820	(3) 991,890
Craig Shore Chief Financial Officer, Secretary and Treasurer	2017	267,106 <sup>(5)</sup>	-	(5)	-	-	98,181	(5)(6) 365,286 <sup>(5)</sup>
	2016	290,341 <sup>(5)(7)</sup>	50,000	(5)(8)	83,718	60,711	95,343	(5)(6) 580,113 <sup>(5)</sup>
Agustin Gago Executive Vice President And Chief Commercial Officer	2017	275,000	50,000	(9)	-	-	28,334	(3) 353,334
	2016	51,225	25,000	(10)	-	61,241	-	137,466

(1) The amounts reflect the dollar amounts recognized for financial statement reporting purposes with respect to the twelve month periods ended December 31, 2017 and 2016 in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies — Share-based compensation”.

(2) The compensation committee has not yet approved cash bonus earned by the named executive officer in the year ended in 2017, and the compensation committee plans to determine such bonus and make payment of such bonus, if any, upon closing of one or more equity financings in fiscal year 2018. Therefore, whether the named executive earned any cash bonus in the year ended in 2017 and the amount of such cash bonus, if any, is not calculable or determinable as of the date of this report.

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

(4) Pursuant to the fourth amendment of Dr. Barry’s employment agreement dated June 6, 2016.

(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 3.846 NIS per dollar which was the exchange rate as of June 30, 2016. The average exchange rate for the twelve month period ended December 31, 2017 and 2016 were 3.5997 NIS per dollar and 3.8409 NIS per dollar, respectively.

(6) Mr. Shore’s other compensation consisted solely of benefits in the twelve months ended December 31, 2017 and 2016. 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. Shore’s salary for 2016 includes cash paid in lieu of accrued vacation of \$51,678.

(8) Bonuses for the 2016 calendar year were approved by the compensation committee in July 2016.

(9) \$50,000 of cash bonus earned by Mr. Gago in the 2017 calendar year was approved by the compensation committee in May 2017. The compensation committee has not yet approved whether additional cash bonus was earned by Mr. Gago in the year ended in 2017, and the compensation committee plans to determine such bonus and make payment of such bonus, if any, upon the closing of one or more equity financings in fiscal year 2018. Therefore, whether Mr. Gago earned any additional cash bonus in the year ended in 2017 and the amount of such cash bonus, if any, is not calculable or determinable as of the date of this report.

(10) Pursuant to Mr. Gago’s employment agreement, dated October 24, 2016.

## 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. Dr. Barry was previously a director and continues his role as a director. The term of Dr. Barry's employment will continue until July 31, 2018, with Dr. Barry resigning as a member of the board of directors at the end of such term if requested by us. In the event that the term is not extended beyond July 31, 2018 by mutual agreement of the parties and we do not offer Dr. Barry a position as chief executive officer on the same or more favorable terms with an annual base salary that is at least \$400,000, Dr. Barry's termination will be deemed a termination without cause.

Under the employment agreement, as amended, Dr. Barry is entitled to an annual base salary of at least \$365,000. 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 Dr. Barry, 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 we raise an aggregate of \$7 million from such investors, Dr. Barry's annual base salary shall increase to \$400,000, commencing on the pay period immediately following the applicable closing for the remainder of the term of his employment under the employment agreement. The base salary will be reviewed annually by the board for increase as part of its annual compensation review.

In November 2015, due to our efforts to preserve cash, Dr. Barry agreed to temporarily forego, in exchange for a corresponding reduced time commitment to us, 50% of his base salary. We formalized such voluntarily agreement by entering into an amendment to Dr. Barry's employment agreement, dated March 28, 2016. The foregoing amendment to Dr. Barry's employment agreement provides that, until the earlier of (1) the end of the term of his employment, and (2) we raise an aggregate of \$5 million from investors, Dr. Barry shall receive 50% of his base salary and shall be eligible for 50% of any annual bonus or other incentive compensation, during which period Dr. Barry shall devote 50% less business time than he ordinarily has devoted or would devote to us for the performance of his services under his employment agreement.

On June 6, 2016, in connection with Dr. Barry's appointment as our president and chief executive officer, we further amended Dr. Barry's employment agreement to provide that, for the period beginning on June 1, 2016 and ending on the earlier of (i) the closing of a transaction with investors where we raise an aggregate of \$5 million and (ii) March

15, 2017, Dr. Barry would receive 50% of his base salary in cash payments, payable in accordance with our regular payroll practices, with the remaining 50% of his base salary paid in a lump-sum payment on the first to occur of (a) the first payroll period that is on or after the 20th business day following such transaction or (b) March 15, 2017.

Pursuant to the June 6, 2016, amendment, Dr. Barry became eligible to receive annual bonus compensation in an amount equal to 100% of his base salary upon the achievement of reasonable target objectives and performance goals as may be determined by the board of directors in consultation with Dr. Barry. In addition, on the first to occur of (a) the first payroll period that is on or after the 20th business day following closing of a transaction with investors where we raise an aggregate of \$5 million or (b) March 15, 2017, Dr. Barry would receive a lump-sum retention bonus in an amount equal to \$106,458, subject to Dr. Barry's continued employment through such date, which amount was paid on July 14, 2016. Dr. Barry is also eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion.

Pursuant to the June 6, 2016, amendment, within 20 business days of the closing of the transaction with investors where we raise an aggregate of \$5 million, Dr. Barry was to be granted, subject to the board's approval and Dr. Barry's continued employment through the applicable grant date, (i) a nonqualified stock option relating to the number of shares of our common stock equal to 2% of outstanding common stock on the date of the closing of such transaction and (ii) an award of a number of restricted shares of our common stock equal to 2% of outstanding common stock on the date of the closing of such transaction, in each case, subject to the terms and conditions of the InspireMD, Inc. 2013 Long-Term Incentive Plan and a nonqualified stock option agreement and a restricted stock award agreement to be entered into by us and Dr. Barry. Such transaction occurred on July 7, 2016, and following the closing of the transaction, Dr. Barry was granted an option to purchase 2,015 shares of common stock and 2,015 shares of restricted shares. The fifth amendment to Dr. Barry's employment agreement, dated September 5, 2017, amended this provision to provide that Dr. Barry will be eligible to receive, subject to Dr. Barry's continued employment through the applicable grant date, (i) a nonqualified stock option relating to the number of shares of the our 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 our 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. To the extent shares are not available for grant under the InspireMD, Inc. 2013 Long-Term Incentive Plan for the full amount of the Financing Equity Grant on the date of grant, the Financing Option will be for 50% of the maximum number of shares that remain available on the date of grant for grant under the InspireMD, Inc. 2013 Long-Term Incentive Plan, and the Financing Restricted Stock Award will be for 50% of the maximum number of shares that remain available on the date of grant for grant under the InspireMD, Inc. 2013 Long-Term Incentive Plan. The Financing Equity Grant is subject to the terms and conditions of separate award agreements between us and Dr. Barry and the terms and conditions of the InspireMD, Inc. 2013 Long-Term Incentive Plan.

Pursuant to Dr. Barry's employment agreement, if Dr. Barry's employment is terminated upon his death or disability, by Dr. Barry for good reason (as such term is defined in Dr. Barry's employment agreement), or by us without cause (as such term is defined in Dr. Barry's employment agreement), 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 200% of his base salary, calculated with a base salary amount at the annual rate of \$425,000, 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 100% of all unvested stock options, restricted stock, 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 until the earlier of (a) eighteen months from the date of termination, or (b) the latest date that each stock option or stock appreciation right 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 18 months after termination or until Dr. Barry obtains 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 payments described 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 his 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 (iv) above. If, during the term of his employment agreement, we terminate Dr. Barry's employment for cause or by Dr. Barry voluntarily, Dr. Barry will only be entitled to unpaid amounts owed to him 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 employment agreement or right to any severance payments or other benefits solely as a result of a change in control. However, if within 24 months following a change in control, (a) Dr. Barry terminates his employment for good reason, or (b) we terminate his employment without cause, Dr. Barry will receive the same payments he would receive if his employment is terminated upon his death or disability, by Dr. Barry for good reason (as such term is defined in Dr. Barry's employment agreement), or by us without cause (as such term is defined in Dr. Barry's employment agreement).



Dr. Barry's employment agreement also contains certain noncompetition, no solicitation, confidentiality, and assignment of inventions requirements for Dr. Barry.

Pursuant to an option cancellation and release agreement, dated January 26, 2016, between us and Dr. Barry, Dr. Barry agreed to cancel options to purchase 78 shares of our common stock at exercise prices ranging from \$6,300 to \$68,250 previously granted to him. In exchange for the cancellation of Dr. Barry's options, we granted to Dr. Barry, pursuant to the InspireMD, Inc. 2013 Long-Term Incentive Plan and the 2013 Employee Stock Incentive Plan, which is a sub-plan to the InspireMD, Inc. 2013 Long-Term Incentive Plan, one share of our common stock as of January 26, 2016.

### *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 21<sup>st</sup> 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 21<sup>st</sup> 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.

Mr. Shore was initially entitled to a monthly gross salary of \$8,750, which amount had increased to \$10,620 by 2012. In addition, Mr. Shore's annual base salary was increased to \$175,000 on April 22, 2013, retroactive to January 1, 2013, and to \$220,200 in May 2014, retroactive to January 1, 2014. 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. On January 5, 2015, we amended Mr. Shore's amended and restated employment agreement to remove from the amended and restated employment agreement the provision disallowing payment of annual bonus compensation if Mr. Shore achieved less than 70% of the target objectives and performance goals determined by our board of directors in consultation with him. Pursuant to such amendment, 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.

The second amendment to the amended and restated employment agreement provides a grant of equity awards to Mr. Shore on or within 10 business days of July 25, 2016 (the “Date of Grant”), with respect to an aggregate number of shares of our common stock equal to 1% of our outstanding common stock and common stock issuable upon the conversion of our outstanding Series B Preferred Stock on the Date of Grant, 50% of which shall be granted as restricted stock and 50% of which shall be granted as nonqualified stock options, which will be subject to the terms and conditions of the InspireMD, Inc. 2013 Long-Term Incentive Plan and a nonqualified stock option agreement and a restricted stock award agreement to be entered into by us and Mr. Shore and a one-time lump-sum cash bonus in an amount equal to \$50,000, payable on or before September 1, 2016.

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, 2017 was \$122,220, 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, 2017, Mr. Shore would have been entitled to receive \$164,151 in severance under Israeli law, thereby requiring us to pay Mr. Shore \$41,931, in addition to releasing the \$122,220 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.

Pursuant to an option cancellation and release agreement, dated January 26, 2016, between us and Mr. Shore, Mr. Shore agreed to cancel options to purchase 51 shares of our common stock at exercise prices ranging from \$6,300 to \$43,124.20 previously granted to him. In exchange for the cancellation of Mr. Shore's options, we granted to Mr. Shore, pursuant to the InspireMD, Inc. 2013 Long-Term Incentive Plan and the 2013 Employee Stock Incentive Plan, which is a sub-plan to the InspireMD, Inc. 2013 Long-Term Incentive Plan, one share of our common stock as of January 26, 2016.

### *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 ends on October 23, 2018, unless earlier terminated or extended for additional one-year periods on October 23, 2018, and on each and every October 23

thereafter, provided that either party may elect not to extend the term of the employment by prior written notice at least two months prior to the expiration date or the next renewal date.

Pursuant to Mr. Gago's employment agreement, Mr. Gago is entitled to an annual base salary of \$275,000, which shall automatically increase to \$300,000, effective as of January 1, 2018. Mr. Gago is 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 shall be 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 may 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 will receive a one-time bonus of \$25,000 in the event that our net sales for the fourth quarter of 2016 exceed our forecast by at least 20%. Mr. Gago is also entitled to a one-time bonus of \$25,000, payable on or before November 15, 2016, 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 may also be 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.

Either party may terminate the agreement at any time, provided that Mr. Gago provides 90 day's prior written notice to us of his voluntary resignation and we provide 90 days' prior written notice of termination by us without cause (as defined in Mr. Gago's employment agreement) to Mr. Gago. In addition, we may terminate Mr. Gago's employment for cause, after a 30 day cure period, if the circumstances are curable. If we terminate Mr. Gago's employment without cause or Mr. Gago's death, Mr. Gago is 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. Mr. Gago has no specific right to terminate Mr. Gago's employment agreement as a result of a change in control (as defined in the InspireMD, Inc. 2013 Long-Term Incentive Plan); however, if following a change in control, during the term of Mr. Gago's employment, if we terminate Mr. Gago without cause, or the purchaser or surviving entity following the change in control does not offer Mr. Gago a comparable offer of employment, all stock options or similar stock-based rights granted to Mr. Gago shall vest in full and become immediately exercisable.

Mr. Gago's employment agreement also contains certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Mr. Gago.

### Outstanding Equity Awards at December 31, 2017

The following table shows information concerning unexercised options and unvested restricted shares outstanding as of December 31, 2017 for each of our named executive officers.

Name	Option Awards		Option exercise price (\$)	Option expiration date	Stock Awards	
	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable			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	1	(1) \$4
Craig Shore					2	(1) \$8

	168	336	(3)	166.25	07/25/2026	336 <sup>(2)</sup> \$1,509
Agustin V. Gago	458	457	(4)	65.10	10/24/2026	
	385	-		65.10	10/24/2026	

(1) These restricted shares vested on January 26, 2018.

(2) These restricted shares vest annually, with one-half vesting on each of July 25, 2018 and July 25, 2019.

(3) These options vest annually, with one-half vesting on each of July 25, 2018 and July 25, 2019.

(4) These options will vest on October 24, 2018.



## **Option Exercises and Stock Vested**

There were no stock options exercised by our named executive officers during the twelve months ended December 31, 2017.

## **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.

## **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.

## Director Compensation

The following table shows information concerning our directors, other than James Barry, Ph.D., during the twelve months ended December 31, 2017.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Sol J. Barer, Ph.D. <sup>(1)</sup>	13,917	-	-	-	13,917
Isaac Blech <sup>(2)</sup>	12,500	-	-	-	12,500
Paul Stuka	39,000	-	-	-	39,000
Michael Berman	37,000	-	-	-	37,000
Campbell Rogers, M.D.	26,000	-	-	-	26,000
Thomas Kester	39,333	-	-	-	39,333

(1) Dr. Barer resigned from our board as of June 2, 2017.

(2) Mr. Blech resigned from our board as of June 29, 2017.

In connection with Dr. Barer's resignation from the Board, on June 2, 2017, we amended (i) the nonqualified stock option agreement we entered into with Dr. Barer on December 7, 2016, to accelerate the vesting of the option to purchase 572 shares of common stock so that the option are fully vested as of June 2, 2017, and to permit Dr. Barer to exercise such option at any time prior to the tenth anniversary of the grant date, and (ii) the nonqualified stock option agreements we entered into with Dr. Barer on November 16, 2011, March 31, 2015, June 30, 2015, September 30, 2015, and June 30, 2016, to permit Dr. Barer to exercise the fully vested options to purchase an aggregate of 243 shares of common stock at any time prior to the tenth anniversary of the grant date.

For the 2017 calendar year, our board approved the following compensation for our independent directors: (i) a \$25,000 stipend, payable quarterly; (ii) 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; (iii) 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; (iv) an option to purchase 358 shares of our common stock for each board member; and (v) an option to purchase an additional 215 shares of our common stock for the chairman of the board. The research and development committee was dissolved following the second quarter of 2017.

### **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 12, 2018 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 12, 2018, we had 1,675,592 shares outstanding.

Name of Beneficial Owner	Number of Shares Beneficially Owned <sup>(1)</sup>		Percentage Beneficially Owned <sup>(1)</sup>	
<b>5% Owners</b>				
Sol J. Barer, Ph.D.	171,141	(2)	9.99	%
Sabby Healthcare Master Fund, Ltd.	172,124	(3)	9.99	%
<b>Officers and Directors</b>				
Craig Shore	1,752	(4)	*	
James Barry, Ph.D.	3,399	(5)	*	
Michael Berman	272	(6)	*	
Campbell Rogers, M.D.	260	(7)	*	
Paul Stuka	38,775	(8)	2.32	%
Thomas Kester	127	(9)	*	
Agustin V. Gago	843	(10)	*	
All directors and executive officers as a group (7 persons)	45,636		2.73	%

\* Represents ownership of less than one percent.

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 12, 2018. Shares (1) 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.

Includes (i) options to purchase 818 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, (ii) warrants to purchase 4,592 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, (iii) 133,631 shares of common stock and (iv) includes 32,100 shares of common stock issuable upon conversion of Series B Preferred Stock that are currently convertible within (2) 60 days of February 12, 2018. Does not include 110,650 shares of common stock issuable upon conversion of Series B Preferred Stock, which shares were excluded because the certificate of designation for the Series B Preferred Stock contain provisions that block conversion if such conversion will result in the holder having beneficial ownership of more than 9.99% of our common stock.

Based on Schedule 13G filed with the Securities and Exchange Commission on December 14, 2017, and includes 46,858 shares of common stock issuable upon conversion of Series C Preferred Stock that are currently convertible (3) within 60 days of February 12, 2018. Does not include 10,285 shares of common stock issuable upon conversion of Series C Preferred Stock, which shares were excluded because the certificate of designation for the Series B Preferred Stock contain provisions that block conversion if such conversion will result in the holder having beneficial ownership of more than 9.99% of our common stock.

(4) Consists of (i) 524 shares of common stock, (ii) options to purchase 168 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, and (iii) 1,060 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.

(5) Consists of (i) 1,382 shares of common stock, (ii) options to purchase 2,015 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, and (iii) warrants to purchase 2 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018.

(6) Includes options to purchase 267 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018.

(7) Includes options to purchase 244 shares of common stock and warrants to purchase 5 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018.

(8) 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 12, 2018 in addition to (B) personally holding (i) options to purchase 299 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, (ii) warrants to purchase 347 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018, and (iii) 24,999 shares of common stock.

(9) Consists of (i) 8 shares of common stock and (ii) options to purchase 119 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018.

(10) Includes options to purchase 843 shares of common stock that are currently exercisable or exercisable within 60 days of February 12, 2018.

### Equity Compensation Plan Information

The following table provides certain information as of December 31, 2017, 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
---------------	---	---	--



	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
Equity compensation plans approved by security holders	8,114	316.84	8,888
Equity compensation plans not approved by security holders	102	(1) 59,895	—
Total	8,216	1,047.17	—

- (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 current director: in November 2011, we issued options to purchase an aggregate of 84 shares of common stock to Dr. Barer, the chairman of our board of directors. The exercise price of these options is \$68,250 per share. An option to purchase 21 shares of common stock vested on April 11, 2013, when our common stock was first listed on a national securities exchange. An option to purchase 21 shares of common stock vested on May 10, 2013, after we received research coverage from a second investment bank that ranked in the top twenty investment banks in terms of life science underwritings. The option to purchase 42 shares of common stock vested in substantially equal monthly installments (with any fractional shares vesting on the last vesting date) on the last business day of each calendar month over a two year period from the date of grant, with the first installment having vested on November 30, 2011, provided that Dr. Barer was still providing services to us in some capacity as of each such vesting date.

Options issued to our former vice president of global marketing and strategy: in September 2013, we issued options to purchase 18 shares of common stock to David Blossom. The exercise price of these options was \$19,512.50 per share. The options vest annually with one-third vesting on September 16, 2014, September 16, 2015 and September 16, 2016. The options expire on December 16, 2018.

### **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 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, our director, 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 Convertible Preferred Stock, the conversion price for the Series B Convertible Preferred Stock was adjusted, and each share of Series B Convertible Preferred Stock is currently convertible into 4.714 shares of common stock at \$7.00 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, our director, 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.

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, and our former directors, Dr. Sol Barer, who resigned from our board as of June 2, 2017, and Mr. Isaac Blech who resigned from our board as of June 29, 2017, 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, 2017 and 2016 are described below.

#### **Audit Fees**

Kesselman billed us audit fees in the aggregate amount of \$119,000 for the years ended December 31, 2017 and 2016. 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 \$52,000 and \$109,000 for the year ended December 31, 2017 and 2016, respectively. 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.

The fees for the year ended December 31, 2016 mostly related to our prospectus supplement filed with the Securities and Exchange Commission on March 16, 2016 and July 1, 2016.

### **Tax Fees**

Kesselman billed us tax fees in the aggregate amount of \$38,675 for the year ended December 31, 2017 and 2016, 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, 2017 and 2016.

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, 2017 and 2016  
Consolidated Statements of Operations for the Years Ended December 31, 2017 and 2016  
Consolidated Statements of Changes in Equity for the Years Ended December 31, 2017 and 2016  
Consolidated Statements of Cash Flows for the Years Ended December 31, 2017 and 2016  
Notes to Consolidated Financial Statements

#### 2. Financial Statement Schedules

None

#### 3. Exhibits

See Index to Exhibits

### **Item 16 . Form 10-K Summary**

Not applicable.

77

**Index to Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
3.1	<u>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)</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)</u>
3.3	<u>Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)</u>
3.4	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)</u>
3.5	<u>Certificate of 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)</u>
3.6	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)</u>
3.7	<u>Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)</u>
3.8	<u>Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)</u>
3.9	<u>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)</u>
3.10	<u>Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)</u>
3.11	<u>Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 22, 2017)</u>
3.12	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)</u>
4.1	



Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 5, 2013)

- 4.2 Rights Agreement dated as of October 22, 2013 between InspireMD, Inc. and Action Stock transfer Corporation, as Rights Agent, including exhibits thereto (incorporated by reference to an exhibit to the Registration Statement on Form 8-A filed with Securities and Exchange Commission on October 25, 2013)
- 4.3 Form of Series B Warrant Agent Agreement and Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Amendment No.3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2017)
- 4.4 Form of Series C Warrant Agent Agreement and Form of Series C Warrant (incorporated by reference to Exhibit 4.4 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 October 24, 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)
- 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

The following materials from the Company's Annual Report on Form 10-K for the twelve months ended December 31, 2017, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance  
101\* 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 13, 2018 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/ James Barry</i> James Barry, Ph.D.	President, Chief Executive Officer and Director (principal executive officer)	February 13, 2018
<i>/s/ Craig Shore</i> Craig Shore	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer (principal financial and accounting officer)	February 13, 2018
<i>/s/ Paul Stuka</i> Paul Stuka	Chairman of the Board of Directors	February 13, 2018
<i>/s/ Michael Berman</i> Michael Berman	Director	February 13, 2018
<i>/s/ Thomas J. Kester</i> Thomas J. Kester	Director	February 13, 2018
<i>/s/ Campbell Rogers, M.D.</i> Campbell Rogers, M.D.	Director	February 13, 2018



**INSPIREMD, INC.**

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2017

F-1

**INSPIREMD, INC.**

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2017

TABLE OF CONTENTS

	<b>Page</b>
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	F-3
<b>CONSOLIDATED FINANCIAL STATEMENTS:</b>	
<u>Consolidated Balance Sheets</u>	F-4 - F-5
<u>Consolidated Statements of Operations</u>	F-6
<u>Statements of Equity (Capital Deficiency) Consolidated</u>	F-7 - F-8
<u>Consolidated Statements of Cash Flows</u>	F-9
<u>Notes to the Consolidated Financial Statements</u>	F- 10 - F-39

F-2

## **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 as of December 31, 2017 and 2016, and the related consolidated statements of operations, changes in equity (capital deficiency) and cash flows for each of the two years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017 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 13, 2018 Certified Public Accountants (Isr.)  
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,	
	2017	2016
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$3,710	\$7,516
Accounts receivable:		
Trade, net	643	356
Other	207	195
Prepaid expenses	62	65
Inventory	533	500
<b>TOTAL CURRENT ASSETS</b>	<b>5,155</b>	<b>8,632</b>
<b>NON-CURRENT ASSETS:</b>		
Property, plant and equipment, net	476	379
Fund in respect of employee rights upon retirement	476	399
<b>TOTAL NON-CURRENT ASSETS</b>	<b>952</b>	<b>778</b>
<b>TOTAL ASSETS</b>	<b>\$6,107</b>	<b>\$9,410</b>

F-4

**INSPIREMD, INC.****CONSOLIDATED BALANCE SHEETS**

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

	December 31,	
	2017	2016
<b>LIABILITIES AND EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturity of long-term loan	\$-	\$2,680
Accounts payable and accruals:		
Trade	328	618
Other	2,134	1,447
Advanced payment from customers	20	33
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,482</b>	<b>4,778</b>
<b>LONG-TERM LIABILITIES-</b>		
Liability for employees rights upon retirement	624	587
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>624</b>	<b>587</b>
<b>COMMITMENTS AND CONTINGENT LIABILITIES (Note 9)</b>		
<b>TOTAL LIABILITIES</b>	<b>3,106</b>	<b>5,365</b>
<b>REDEEMABLE PREFERRED SHARES</b>	<b>274</b>	<b>-</b>
<b>EQUITY:</b>		
Common stock, par value \$0.0001 per share; 150,000,000 shares authorized at December 31, 2017 and 2016; 1,483,808 and 42,653 shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Preferred B shares, par value \$0.0001 per share; 500,000 shares authorized at December 31, 2017 and 2016; 27,075 and 311,521 shares issued and outstanding at December 31, 2017 and 2016, respectively	-	-
Preferred C shares, par value \$0.0001 per share; 1,172,000 shares authorized at December 31, 2017; 741,651 shares issued and outstanding at December 31, 2017	-	-
Preferred D shares, par value \$0.0001 per share; 750 shares authorized at December 31, 2017; 750 issued and outstanding at December 31, 2017	-	-
Additional paid-in capital	143,079	135,959
Accumulated deficit	(140,352)	(131,914)
Total equity	2,727	4,045
Total liabilities, redeemable preferred shares and equity	<b>\$6,107</b>	<b>\$9,410</b>



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

F-5

**INSPIREMD, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS**

(U.S. dollars in thousands, except per share data)

	Year Ended December 31,	
	2017	2016
REVENUES	\$2,761	\$1,894
COST OF REVENUES	2,176	1,792
GROSS PROFIT	585	102
OPERATING EXPENSES:		
Research and development	1,276	1,291
Selling and marketing	2,357	1,459
General and administrative	5,184	5,000
Total operating expenses	8,817	7,750
LOSS FROM OPERATIONS	(8,232 )	(7,648 )
FINANCIAL EXPENSES, net:		
Interest expenses	119	721
Other financial expenses	60	91
Total financial expenses	179	812
LOSS BEFORE TAX EXPENSES	(8,411 )	(8,460 )
TAX EXPENSES	27	1
NET LOSS	\$(8,438 )	\$(8,461 )
BASIC AND DILUTED LOSS PER SHARE:		
Beneficial conversion feature of series C preferred shares	\$(633 )	\$-
Extinguishment of series B preferred shares	(3,957 )	-
NET LOSS APPLICABLE TO ORDINARY SHARES	\$(13,028 )	\$(8,461 )
NET LOSS PER SHARE - basic and diluted	(34.98 )	(207.72)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	372,460	40,732

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

**INSPIREMD, INC.****CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CAPITAL DEFICIENCY)**

(U.S. dollars in thousands, except share data)

	Common stock		Preferred B stock		Preferred C stock		Preferred D stock		Additional paid-in capital	Accumulated deficit	Total equity (capital deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT JANUARY 1, 2016	9,433	*		-					\$ 120,050	\$(122,996 )	\$(2,946 )
Net loss										(8,461 )	(8,461 )
Cumulative effect adjustment related to adoption of share-based compensation standard (ASU 2016-09)								457		(457 )	-
Issuance of common stock, preferred shares and warrants, net of \$1,966 issuance costs	3,384		442,424	*					14,365		14,365
Conversion of preferred shares to common shares	26,181	*	(130,903)	*							
Warrants granted to lender in a debt modification									123		123
Share-based compensation related to restricted stock award, net of forfeitures of 36 shares	3,674								84		84
Share-based compensation related to stock options award									894		894
Exercise of options by employee and non-employee	9	*									-
Issuance of shares for options cancelled	8	*									-
Taxes withheld in respect of share issuance	(36 )	*							(14 )		(14 )
BALANCE AT DECEMBER 31, 2016	42,653	*	311,521	*					\$ 135,959	\$(131,914 )	\$ 4,045

F-7

## INSPIREMD, INC.

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CAPITAL DEFICIENCY)

(U.S. dollars in thousands, except share data)

	Common stock		Preferred B stock		Preferred C stock		Preferred D stock		Additional paid-in capital	Accumulated deficit	Total equity (capital deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE AT DECEMBER 31, 2016	42,653	*	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
									339		339

Share-based compensation related to stock options award											
Taxes withheld in respect of share issuance	(657 )	*					(10 )		(10 )		
BALANCE AT DECEMBER 31, 2017	1,483,808	*	27,075	*	741,651	*	750	*	\$ 143,079	\$(140,352 )	\$ 2,727

\* 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,	
	2017	2016
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(8,438)	\$(8,461)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	178	191
Loss from sale of property, plant and equipment	8	-
Change in liability for employees rights upon retirement	37	(119)
Financial expenses and interest paid	(511)	222
Share-based compensation expenses	672	978
Gains on amounts funded in respect of employee rights upon retirement, net	(17)	(16)
Changes in operating asset and liability items:		
Decrease in prepaid expenses	3	10
Decrease (increase) in trade receivables	(287)	49
Increase in other receivables	(37)	(15)
Decrease (increase) in inventory	(33)	253
(Decrease) increase in trade payables	(290)	106
(Decrease) increase in other payable and advanced payment from customers	584	(693)
Net cash used in operating activities	(8,131)	(7,495)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment	(258)	(49)
Amounts funded in respect of employee rights upon retirement, net	(60)	119
Net cash provided by (used in) investing activities	(318)	70
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of shares and warrants, net of \$776 and \$1,966 issuance costs, respectively	6,822	14,365
Repayment of long-term loan	(2,179)	(2,648)
Taxes withheld in respect of share issuance	(10)	(14)
Net cash provided by financing activities	4,633	11,703
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	10	(19)
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(3,806)	4,259
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR</b>	7,516	3,257
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	\$3,710	\$7,516
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Income taxes	\$-	\$6
Interest paid	\$583	\$399
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:</b>		
Warrants granted to lender in a debt modification, see Note 6b	-	\$123

Edgar Filing: InspireMD, Inc. - Form 10-K

Issuance Costs	\$90	
Classification of Redemption Obligation of Preferred Shares to Mezzanine, see Note 10a	\$274	-

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

F-9



**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, 2017, 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 only has sufficient resources to fund operations for a period of up to four months from the date of issuing these consolidated financial statements. 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.

F-10

**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, fair value of financial instruments, share based compensation 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 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).

F-12

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

**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 \$193,000 and \$57,000 for the years ended December 31, 2017 and 2016, 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) by the weighted average number of shares of common stock outstanding during the period, including 23,481 and 17,218 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the years ended December 31, 2017 and 2016, 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 the 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)

**s. Issued 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. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements.
- 1)
- 2) The FASB has issued the following standards that the Company has determined will not have a material impact on its consolidated financial statements upon their adoption:

In May 2017, the FASB issued ASU 2017-9 on changes to terms and conditions of share-based payment awards. The amendment provides guidance about which changes to terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance is effective for the fiscal year beginning on January 1, 2018, including interim periods within that year (early adoption is permitted). The Company does not anticipate that such guidance will have a material impact on its consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Codification ("ASC") 606, Revenue from contracts with customers. The objective of the new revenue standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The revenue standard contains principles that an entity will apply to determine the measurement of revenue and timing of when it is recognized. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those

goods or services, based on a five step model that includes the identification of the contract with the customer and the performance obligations in the contract, determination of the transaction price, allocation of the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies a performance obligation. The revenue standard is effective for annual periods beginning on or after December 15, 2017. The Company will adopt the standard using the modified retrospective method.

F-15

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES** (continued):

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The new standard is effective for annual periods and interim periods beginning after December 15, 2017, and upon adoption, an entity should apply the amendments by means of a cumulative-effect adjustment to the balance sheet at the beginning of the first reporting period in which the guidance is effective. Early adoption is not permitted except for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income.

In February 2016, the FASB issued ASU 2016-02, Leases, which requires to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The accounting standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years.

**NOTE 3 - FAIR VALUE MEASUREMENT**

**Fair value of financial instruments**

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

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

**NOTE 4 - PROPERTY, PLANT AND EQUIPMENT**

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

	December 31,	
	2017	2016
	(\$ in thousands)	
Cost:		
Computer equipment	\$214	\$227
Office furniture and equipment	75	107
Machinery and equipment	1,209	1,001
Leasehold improvements	143	143
	1,641	1,478
Less - accumulated depreciation and amortization	(1,165)	(1,099)
Net carrying amount	\$476	\$379

b. Depreciation and amortization expenses totaled approximately \$153,000 and \$142,000 for the years ended December 31, 2017 and 2016, respectively.

F-16

**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 \$154,000 and \$130,000 for the years ended December 31, 2017 and 2016, respectively.

Defined contribution plan expenses were approximately \$223,000 and \$157,000 for the years ended December 31, 2017 and 2016, respectively.

The Company expects contribution plan expenses in 2018 to be approximately \$266,000.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 6 - loan**

2013 Security and Loan Agreement

**a. Loan and Security Agreement**

On October 23, 2013, the Company and InspireMD Ltd. entered into a Loan and Security Agreement (the “Loan and Security Agreement”), pursuant to which a lender made a term loan to the Company and InspireMD Ltd. in the aggregate amount of \$10 million (the “Loan”). The annual interest rate on the Loan was prime plus 4%, but was not to be reduced below 10.5%. Payments under the Loan and Security Agreement were for the interest portion only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017.

The Company was permitted to prepay all or a portion of the Loan under the terms stipulated in the agreement. The Company and InspireMD Ltd. was also required to pay the lender an aggregate end of term charge (the “End of Term Charge”) of \$500,000 when the Loan is paid in full or matures.

**b. Loan Amendment**

On June 13, 2016, the Company amended (the “Amendment”) the Loan and Security Agreement, dated October 23, 2013, as amended, to provide that, among other things, the principal payment would be suspended for a four month period beginning May 1, 2016, provided that the Company receives unrestricted and unencumbered net cash proceeds in an amount of at least \$10 million from the sale of the Company’s equity securities with investors acceptable to the lender on or prior to June 30, 2016. The Amendment also modified the term loan maturity date under the Loan and security Agreement to (i) April 1, 2017, if the Company does not complete such sale of its equity securities and the lender does not waive such condition to complete such sale prior to June 30, 2016, or (ii) June 1, 2017, if the Company completes such sale of its equity securities, or if the lender waives such condition to complete such sale of its equity securities, prior to June 30, 2016. In addition, the Company 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. In connection with the Amendment, the Company and its subsidiary granted a security interest in their intellectual property to the lender. In connection with the Amendment, the Company issued the lender warrants to purchase up to the number of shares of common stock equal to \$182,399 divided by (i) the lowest effective price per share, determined on a common stock-equivalent basis, for which the Company’s equity securities are sold and issued by the Company in an equity financing in which the Company receives unrestricted aggregate gross cash proceeds of at least \$7.5 million, subject to adjustment from time to time in accordance with the terms of the warrant agreement, or (ii) if such equity financing shall not have been consummated on or before July 30, 2016, or if, prior to the consummation of such equity financing, there shall be a transaction involving a

change of control or a dissolution, liquidation or winding-up of the Company, then the closing price of a share of common stock on June 13, 2016, subject to adjustment thereafter from time to time in accordance with the terms of the warrant agreement. The warrants are immediately exercisable and have a five-year term. The principal payments of May 1, 2016 and June 1, 2016 were suspended and, although the July 2016 Offering (see Note 10a) 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. The Loan under the Loan and Security Agreement, as amended by the Amendment, would have matured on June 1, 2017.



**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 6 – loan** (continued):

The Company has concluded that the above changes to the terms of the Loan and security Agreement do not constitute a troubled debt restructuring as no concession has been granted. As such, the Company applied the guidance in ASC 470-50, Modifications and Extinguishments. The accounting treatment is determined by whether (1) the Investors remain the same and (2) the change in the debt terms is considered substantial.

Since the lenders remained the same before and after the Amendment, the Company has made a quantitative test, to determine whether the Loan and Security Agreement, as amended by the Amendment, is substantially different from the Loan and security Agreement prior to the Amendment became effective. According to ASC 470-50-40-10, from the debtor's perspective, an exchange of debt instruments between or a modification of a debt instrument by a debtor and a creditor is deemed to have been accomplished with debt instruments that are substantially different if the present value of the cash flows under the terms of the new debt instrument is at least 10 percent different from the present value of the remaining cash flows under the terms of the original instrument. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is less than 10 percent, the debt instruments are not considered to be substantially different.

Based on the accounting analysis performed, the Company concluded that the Loan and Security Agreement, as amended by the Amendment, was not substantially different from the Loan and Security Agreement prior to the Amendment becoming effective, and, as such, accounted for the Amendment as a modification. Accordingly, no gain or loss was recorded and a new effective interest rate was established based on the carrying value of the Loan and Security Agreement prior to the Amendment became effective and the revised cash flows pursuant to the Loan and Security Agreement, as amended by the Amendment, including the fair value of the warrants issued to the lender.

Following the closing of the July 2016 Offering (see Note 10a), pursuant to the warrant agreement discussed above, the Company issued to the lender warrants to purchase 1,106 shares of common stock. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of \$164.85. Given the settlement mechanism described above, the warrants as of the Amendment date were classified as a liability and, subsequently, upon closing of the July 2016 Offering, were reclassified as equity.

**c. Loan repayment**

During the three months ended March 31, 2017, the Company paid the remaining interest and principal balances under the Loan and Security Agreement, in consideration of \$2,684,000. 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, with the CEO resigning as a member of the Board of Directors at the end of such term if requested by the Company 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 shall be paid a base salary of no less than \$30,416.67 per month (\$365,000 on an annualized basis) while he is 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 the Company raises an aggregate of \$7 million from such investors (the “Financing”), the CEO’s annual base salary shall increase to \$400,000, commencing on the pay period immediately following the applicable closing for the remainder of the term of his employment under the employment agreement. The base salary will be reviewed annually by the board for increase as part of its annual compensation review.

Pursuant to the Fifth Amendment, the CEO will be 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”). To the extent shares are not available for grant under the 2013 Plan for the full amount of the Financing Equity Grant on the date of grant, the Financing Option will be for 50% of the maximum number of shares that remain available on the date of grant for grant under the 2013 Plan, and the Financing Restricted Stock Award will be for 50% of the maximum number of shares that remain available on the date of grant for grant under the 2013 Plan. The Financing Equity Grant is subject to the terms and conditions of separate award agreements between the Company and the CEO and the terms and conditions of the 2013 Plan.



**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 7 - RELATED PARTIES TRANSACTIONS** (continued):

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, 2017 and 2016, 657 and 7 shares were withheld by the Company to satisfy tax withholding obligations, respectively. The payment, amounting to \$10,000 and \$2,000, respectively, was deducted from equity.

On January 16, 2016, the Board of Directors appointed a new director and Vice Chairman of the Board, effective as of January 22, 2016, with a term expiring at the Company's 2017 annual meeting of stockholders. The new director and Vice Chairman of the Board was not nominated for re-election at the Company's 2017 annual meeting of stockholders. On April 30, 2016, in connection with his appointment, the director was granted an option to purchase 892 shares of the Company's common stock at an exercise price equal to the closing fair market value of the common stock on the date of grant on April 30, 2016, subject to the terms and conditions of the 2013 Plan. Options to purchase 223 shares of common stock vested and became exercisable immediately upon the time of grant, and, until all 892 options shall have vested, options to purchase 223 shares of common stock will vest and

**b.** become exercisable each time upon (i) the Company raising at least \$15 million through an equity offering; (ii) the Company's market cap becoming equal to or greater than \$25 million; (iii) the Company receiving research coverage by three new analysts at a leading investment bank; or (iv) the tripling of the Company's market cap from the date of appointment. Any of the foregoing conditions, if achieved following the director's appointment but prior to April 30, 2016, would have been deemed satisfied on the date of grant. However, in the event (i) of the director's death or permanent disability, (ii) a change in control (as defined in the 2013 Plan) or (iii) if the director is asked to resign for any reason other than cause (as defined in the Company's form of Nonqualified Stock Option Agreement under its 2013 Plan), the options shall vest immediately in full. The options have a term of 10 years from the date of grant and the exercise price may be paid in either cash or on a cashless basis.

The fair value of options with market cap related conditions reflect the probability of achieving the respective condition and are recognized through the date in which it is expected to be met. The fair value of such options was determined using the Monte-Carlo option-pricing model with the following primary assumptions: the probability to achieve various gross proceeds in future offerings, dividend yield of 0%; expected term of 10 years; expected volatility of 85.73%; and risk-free interest rate of 1.81%. The fair value of the above options with market conditions, using the Monte-Carlo option-pricing model, was approximately \$96,000.

The remaining tranches would vest upon achievement of performance conditions. Accordingly, the fair value of such options would be recognized based upon the number of options expected to vest and when the occurrence of the condition is considered probable.

In calculating the fair value of the above options with performance conditions the Company used the following assumptions: dividend yield of 0%; expected term of 5.5 years; expected volatility of 85.81%; and risk-free interest

rate of 1.25%. The fair value of the above options with performance conditions, using the Black-Scholes option-pricing model, was approximately \$66,000.

F-21

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 7 - RELATED PARTIES TRANSACTIONS** (continued):

c. On January 26, 2016 the Company entered into an option cancellation and release agreement with certain directors, the former CEO, the CEO who at the time was acting as the Company’s Chief Operating Officer and the Chief Financial Officer (“CFO”) (collectively “the Optionholders”), pursuant to which the parties agreed to cancel options to purchase an aggregate of 484 shares of common stock of the Company previously granted to each of the Optionholders. For accounting purposes, the cancellation was treated as a settlement for no consideration and accordingly all remaining unrecognized compensation cost amounting to approximately \$800,000 was recognized.

d. On June 2, 2017 the Company’s 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.

e. 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.

f. During the year ended December 31, 2017, the Company did not grant any stock options to directors and executive officers. During the year ended December 31, 2016, the Company granted stock options to directors to purchase a total of 3,836 shares of the Company’s common stock. The options have exercise prices of \$106.40 - \$437.50 per share, which were the fair market value of the Company’s common stock on the date of each respective grant. Of the 3,836 options granted in 2016, 2,358 options are subject to a three-year vesting period with one-third of such awards vesting each year, 587 options were in lieu of cash compensation that was owed to them for their services as directors for the fourth quarter of 2015 and the first and second quarters of 2016 and are fully vested as of their grant date and the remaining options are subject to certain market and performance conditions.

The fair value of the above options, using the Black-Scholes option-pricing model, was approximately \$526,000.

**g. Balances with related parties:**

December  
31,  
2017 2016  
(\$ in  
thousands)

Current liabilities:

Other accounts payable \$ 47 \$ 77

**h. Transactions with related parties:**

Year ended  
December 31,  
2017 2016  
(\$ in thousands)

Compensation expenses (including share-based compensation) \$1,208 \$1,499

F-22



**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, 2017      2016 (\$ in thousands except share and share data)	
Net Loss	\$(8,438 )	\$(8,461 )
Beneficial conversion feature of series C preferred shares	(633 )	
Extinguishment of series B preferred shares, see also Note 10a	(3,957 )	-
Adjusted Loss	\$(13,028 )	\$(8,461 )
Weighted average of Ordinary Shares outstanding during the period	372,460	40,732
Basic and diluted loss per share (dollars)	\$(34.98 )	\$(207.72)

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 510,823 and 76,232 for the years ended December 31, 2017 and 2016, respectively.

**NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES****a. Lease commitments:**

The Company had a lease agreement for its facilities in the U.S., which originally would have expired in October 1)2017. In March 2017, the Company terminated the lease agreement prior to expiration of the lease and paid an early termination fee of \$53,000.

The Subsidiary has a lease agreement for a facility in Israel, which expires on December 31, 2018 with an option to extend the agreement for two additional years until December 31, 2020 under the terms stipulated in the agreement.

Rent expense included in the consolidated statements of operations totaled approximately \$379,000 and \$319,000 for the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017, the aggregate future minimum lease obligations for office rent under non-cancelable operating lease agreements are as follows:

	(\$ in thousands)
Year Ended December 31:	
2018	\$ 307
	\$ 307

2) The Company leases its motor vehicles under operating lease agreements. As of December 31, 2017, the aggregate non-cancelable future minimum lease obligations for motor vehicles were approximately \$3,000.

**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. 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.

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 May 25, 2016 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 increase the Company's number of authorized shares of common stock from 50,000,000 to 150,000,000. Accordingly, as of December 31, 2017, the Company has authorized 155,000,000 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.

On September 28, 2016, 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-twenty-five reverse stock split of its common stock, par value \$0.0001 per share, effective as of October 7, 2016, which decreased the number of issued and outstanding shares of common stock and restricted shares of common stock from 1.02 million shares to 0.042 million shares.

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.

On January 26, 2016 the Company entered into option cancellation and release agreements with the Optionholders. See Note 7c.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 10 – EQUITY** (continued):

On March 21, 2016, the Company sold 3,384 shares of its common stock and warrants to purchase 1,706 shares of common stock in concurrent underwritten public offering and private placement (the “March 2016 Offering”). The common stock was sold at a price of \$516.25 per share and each purchaser received a warrant to purchase one half of one share of common stock for each share of common stock that it purchased in the March 2016 Offering. The warrants, which are classified as equity, are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of \$516.25. The March 2016 Offering resulted in gross proceeds to the Company of approximately \$1.7 million (\$1.4 million after deducting underwriting discount, placement agent fees and other offering expenses).

In connection with the March 2016 Offering, on March 21, 2016, the Company issued to the underwriter and placement agent five-year warrants to purchase up to 168 shares of common stock at an exercise price of \$645.31 per share. The warrants, which are classified as equity, are exercisable at any time during the period commencing six months following the date of issuance and ending five years from the date of issuance.

*Series B Convertible Preferred Stock*

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. As further described below, in accordance with the anti-dilution price protection contained in the certificate of designation for the Series B Convertible Preferred Stock, the conversion price for the Series B Convertible Preferred Stock was adjusted in connection with the March 2017 Offering and the Series D Private Placement, and as of December 31, 2017, each share of Series B Convertible Preferred Stock is convertible into 4.714 shares of common stock at \$7.00 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 (the “Dividend Entitlement), payable in cash or common stock, at the Company’s discretion.

The Series B Convertible Preferred Stock will automatically convert into shares after five years from issuance. Additionally, holders of the shares 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 the 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 has certain anti-dilution provisions. In addition, 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. 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 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.

*Lender Warrants*

Following the closing of the July 2016 Offering, pursuant to a warrant agreement (see Note 6b), the Company issued to a lender warrants to purchase 1,106 shares of common stock.

*Series C Convertible Preferred Stock*

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 is

convertible into 0.114 shares of common stock reflecting a conversion price equal to \$56.00 per share.

The Company received gross proceeds of approximately \$6.8 million from the 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.

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 were exercisable immediately and had a term of exercise of six months from the date of issuance and had an exercise price of \$56.00 per share of common stock. As of December 31, 2017, all Series C warrants were expired, 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 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 amendment to existing preferred stock*

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 in a private placement (the “Series D Private Placement”) pursuant to a securities purchase agreement (the “SPA”), dated November 28, 2017, for aggregate gross proceeds of \$750,000. The initial stated value of each share of Series D Preferred Stock is \$1,000, and each share of Series D Preferred Stock is convertible into 142.86 shares of common stock at \$7.00 per share. The Series D Preferred Stock does 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 contains a "most favored nation" provision, which provides 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 investor who participated in the Series D Private Placement 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 "MFN Adjustment"). The surrender of Series D Preferred Stock shall be in lieu of any cash subscription amount required for the participation in such Subsequent Financing. The purchaser of Series D Preferred Stock also has the option to exchange their Series D Preferred Stock into the securities issued in a Qualified Offering upon consummation of a Qualified Offering.

F-27

**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 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 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 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 purchaser of the Series D Preferred Stock executing the SPA 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 Preferred Stock ("Redemption Obligation").

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 Preferred Stock upon the consummation of a Qualified Offering subject to the beneficial ownership limitation.

In addition, upon the consummation of a Qualified Offering, the shares of Series C Preferred Stock owned by the purchaser of the Series D Preferred Stock will 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 shall be 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.

If in the future, while any of the Series B Convertible Preferred Stock or Series C Convertible Preferred Stock is outstanding, the Company issues additional shares of common stock or common stock equivalents at an effective

common stock purchase price of less than the applicable conversion price of our Series B Convertible Preferred Stock or Series C Convertible Preferred Stock, as then in effect, the Company will be required, subject to certain limitations and adjustments as provided in the respective certificate of designation for the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock, to reduce the relevant conversion price or exchange the securities into offering securities as described above, which will result in a greater number of shares of common stock being required to be issued to the holders of Series B and C Convertible Preferred Stock. Such issuance of additional shares of common stock or common stock equivalents at an effective common stock purchase price of less than the applicable conversion price of our Series D Preferred Stock will also result in a greater number of shares of common stock being required to be issued to the holder of the Series D Preferred Stock pursuant to the MFN Adjustment or the option to exchange the Series D Preferred Stock into securities sold in a Subsequent Financing or a Qualified 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.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 10 – EQUITY** (continued):

In addition, the Company analyzed the classification of the Redemption Obligation 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 since the Redemption Obligation is outside of its control, the Series B Convertible Preferred Stock is 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 subsequent financing and the related payment of Redemption Obligation is 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.

In addition, the Company analyzed whether the conversion feature embedded in the shares of the Series B Convertible Preferred Stock subject to the Redemption Obligation should be bifurcated. As certain shares of the Series B Convertible Preferred Stock is contingently redeemable, 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.

The Company values Level 3 embedded derivative 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.

In addition, the company analyzed whether the change in the conversion price of the convertible preferred B constitutes an extinguishment 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 3.9 million, was added to the basic loss per share contributable to the company ordinary share holders.

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 purchaser of Series D Convertible Preferred Stock. Therefore, as of December 31, 2017, the purchaser of Series D Convertible Preferred Stock held 8,295 shares Series B Convertible Preferred Stock with a stated value of \$274,000. Accordingly, the maximum Redemption Obligation amount as of December 31, 2017, was \$274,000. In addition, following these conversions of Series B Convertible Preferred Stock, the value of the embedded derivative as of December 31, 2017, was \$0.

During the year ended December 31, 2017, 284,446 shares of Series B Convertible Preferred Stock were converted into 1,404,424 shares of common stock.

During the year ended December 31, 2017, 328,171 shares of Series C Convertible Preferred Stock were converted into 37,506 shares of common stock.

During the year ended December 31, 2017, there was no conversions of Series D Preferred Stock.

As of December 31, 2017, the outstanding shares of Series B Convertible Preferred Stock are convertible into 223,344 shares of common stock, including the Dividend Entitlement but excluding effect of future conversion price adjustment, if any.

As of December 31, 2017, the outstanding shares of Series C Convertible Preferred Stock are convertible into 84,753 shares of common stock.

As of December 31, 2017, the outstanding shares of Series D Convertible Preferred Stock are convertible into 107,143 shares of common stock.

As of December 31, 2017, the outstanding Series A Warrants are convertible into 50,620 shares of common stock.

As of December 31, 2017, the outstanding Series B Warrants are convertible into 122,269 shares of common stock.

In the event of our liquidation, dissolution, or winding up, holders of Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock will be 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.

As of December 31, 2017, the Company issued warrants to purchase an aggregate of 180,367 shares of common stock.

**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 10 – EQUITY** (continued):

**b. Share-Based Compensation**

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, 2017, the Company had 276 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 and September 28, 2016, 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 and 7,200 shares of common stock, respectively, to a total of 19,737 shares of common stock. As of December 31, 2017, the Company reserved 8,612 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, 2017 and 2016, the Company granted stock options to the CEO, employees and directors to purchase a total of 118 and 9,392 shares of the Company's common stock, respectively. The options have exercise prices ranging from \$24.85-\$34.65 and \$65.1-\$437.5 per share, respectively, 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 and the Monte-Carlo option pricing models, was approximately \$3,000 and \$1,023,000, respectively. The 118 stock options granted in 2017 are subject to a three-year vesting period, with one-third of such awards vesting each year. Of the 9,392 stock options granted in 2016, 4,601 options are subject to a three-year vesting period with one-third of such awards vesting each year, 915 options are subject to a two-year vesting period with one-half of such awards vesting each year, 2,399 options are subject to a one-year vesting period, 810 options are fully vested as of their grant date and the remaining options are subject to certain market and performance conditions.

3) During the year ended December 31, 2017 and 2016, the Company granted to the CEO, employees and directors 84 and 3,710 restricted shares of the Company's common stock, respectively. The fair value of these restricted shares was approximately \$3,000 and \$545,000. 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. Of the 3,710 restricted shares granted during the year ended December 31, 2016, 2,015 restricted shares are subject to a one-year vesting period and the remaining restricted shares 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		Year ended December 31	
	2017	2016	2017	2016
	Number of warrants and options	Weighted average exercise price	Number of warrants and options	Weighted average exercise price
Outstanding - beginning of period	9,655	\$891.8	864	\$26,337.5
Granted	118	32.2	9,392	159.95
Forfeited	(1,606)	414.05	(596 )	24,131.45
Exercised	-	-	(5 )	-

Edgar Filing: InspireMD, Inc. - Form 10-K

Outstanding -end of period	8,167	\$970.55	9,655	\$891.8
Exercisable at the end of the period	5,295	\$1,431.85	1,465	\$5,087.25

F-31

**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			
	2017		2016	
	Number of warrants and options	Weighted average exercise price	Number of warrants and options	Weighted average exercise price
Outstanding - beginning of period	61	\$31,164.7	155	\$39,690
Granted	-	-	-	-
Forfeited	(12)	58,165.8	(107)	44,749.25
Exercised	-	-	(5 )	-
Outstanding - end of period	49	\$21,238.7	43	\$31,164.7
Exercisable at the end of the period	31	\$20,874.35	43	\$31,019.8

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

	Year ended December 31	
	2017	2016
	Number of restricted shares	
Outstanding - beginning of period	3,755	197
Granted	84	3,710
Forfeited	(202 )	(37 )
Vested	(2,544)	(115 )
Outstanding - end of period	1,093	3,755

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

Exercise price	Outstanding as of December 31, 2017		
	Options outstanding	Weighted average remaining contractual life (years)	Options exercisable
\$0-\$65.1	1,483	8.8	850
\$106.4-\$113.75	3,452	8.69	1,532
\$166.25-\$288.75	3,049	8.56	2,714
\$1,487.5-\$7,262.5	98	6.43	96
\$19,512.5-\$73,500	134	3.26	134
	8,216	8.54	5,326

The weighted average of the remaining contractual life of total vested and exercisable options as of December 31, 2017 was 8.47 years.

The aggregate intrinsic value of the total exercisable warrants and options as of December 31, 2017 was approximately \$49.

**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 10 – EQUITY** (continued):

The weighted average fair value of options granted was approximately \$24.85 and \$108.85 for the years ended December 31, 2017 and 2016, respectively. 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 years ended December 31, 2017 and 2016:

	Year ended December 31	
	2017	2016
Expected life	5-6.5 years	5-6.5 years
Risk-free interest rates	1.78%-2.18%	1.01%-2.06%
Volatility	94.42%-97.62%	85.8%-91.03%
Dividend yield	0	% 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, 2017, the total unrecognized compensation cost on employee and non-employee stock options and restricted shares, related to unvested stock-based compensation, amounted to approximately \$0.2 million. This cost is expected to be recognized over a weighted-average period of approximately 0.83 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	
	2017	2016
	(\$ in thousands)	
Cost of revenues	\$7	\$1
Research and development	32	182
Sales and marketing	86	(85 )
General and administrative	547	880
	\$672	\$978

F-33

**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 corporate tax rate in 2017 is 34%. On December 22, 2017, the Tax Cuts and Jobs Act (the “2017 Act”) was enacted and the applicable tax rate was reduced to 21% from 2018 and thereafter.

**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%. As a result, the corporate tax rate was 24% in 2017 and will be 23% in 2018 and 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 24% 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 carryforward tax 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 24% on the amount distributed, subject to certain conditions. In addition, dividends originating from income attributable to the “Beneficiary Enterprises” will be subject to a 15% 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, 2017, InspireMD Ltd. had a net carry forward tax loss of approximately \$72 million. Under Israeli tax laws, the carry forward tax losses can be utilized indefinitely. The Company had a net carry forward tax loss of approximately \$36 million.

Under the U.S. tax laws, for net operating losses (NOLs) arising after December 31, 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.

**d. Loss before income taxes**

The components of loss before income taxes are as follows:

	Year ended	
	December 31	
	2017	2016
	(\$ in thousands)	
Loss before taxes on income:		
InspireMD, Inc.	\$(3,673)	\$(3,640)
Subsidiaries	(4,738)	(4,820)
	\$(8,411)	\$(8,460)

**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, 2017 and 2016 were as follows:

	Year ended December 31	
	2017	2016
	(\$ in thousands)	
Balance at the beginning of the year	\$29,682	\$28,970
Changes during the year:		
Changes following enactment of the Act	(5,879)	
Other changes	3,437	712
Balance at the end of the year	\$27,240	\$29,682

**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, 2017:

	Year ended December 31, 2017
	(\$ in thousands)
Balance at beginning of period	\$-

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

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

<b>Jurisdiction</b>	<b>Years</b>
U.S.	2014-2017
Israel	2013-2017
Germany	2012-2017
United Kingdom	2014-2015

F-36

**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 11 - TAXES ON INCOME** (continued):**g. Deferred income tax:**

	December 31,	
	2017	2016
	(\$ in thousands)	
Short-term*:		
Allowance for doubtful accounts	\$-	\$64
Allowance for bonus		
Provision for vacation and recreation pay		34
	-	98
Long-term*:		
Allowance for doubtful accounts	3	
Allowance for bonus	54	
Provision for vacation and recreation pay	37	
R&D expenses	289	459
Share-based compensation	2,577	4,027
Carry forward tax losses	24,245	25,053
Accrued severance pay, net	35	45
	27,240	29,584
Less-valuation allowance	(27,240)	(29,682)
	\$-	\$-

\* 2017 balances are presented under long term deferred taxes, due to implementation of ASU 2015-17.

**NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:****Balance sheets:**

**a. Accounts receivable:**

The changes in “Allowance for doubtful accounts” during the years ended December 31, 2017 and 2016 are as follows:

	Year ended December 31, 2017 2016 (\$ in thousands)	
Balance at beginning of period	\$336	\$346
Additions during the period	-	-
Bad debt written-off during the period	(270)	-
Exchange rate differences	6	(10)
Balance at end of period	\$72	\$336

**b. Inventories:**

	December 31, 2017 2016 (\$ in thousands)	
Finished goods	\$174	\$83
Work in process	63	233
Raw materials and supplies	296	184
	\$533	\$500

For the years ended December 31, 2017 and 2016, the Company recorded expenses for slow moving inventory in the amounts of \$0 and \$50,000, respectively.

**INSPIREMD, INC.**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION** (continued):**c. Accounts payable and accruals-other:**

	December 31,	
	2017	2016
	(\$ in thousands)	
Employees and employee institutions	\$853	\$357
Accrued vacation and recreation pay	165	137
Accrued clinical trials expenses	462	467
Provision for sales commissions	109	56
Accrued expenses	514	425
Other	31	5
	\$2,134	\$1,447

**NOTE 13 - 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,	
	2017	2016
	(\$ in thousands)	
Italy	\$557	\$382
Germany	551	691
Russia	343	-
Other	1,310	821
	\$2,761	\$1,894

By product:

	Year ended December 31,	
	2017	2016
	(\$ in thousands)	
CGuard™ EPS	\$1,922	\$1,147
MGuard Prime™ EPS	839	747
	\$2,761	\$1,894

By principal customers:

	Year ended December 31,	
	2017	2016
Customer A	14 %	0 %
Customer B	12 %	0 %
Customer C	12 %	13 %
Customer D	2 %	28 %

All tangible long lived assets are located in Israel.



**INSPIREMD, INC.**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

**NOTE 14 - SUBSEQUENT EVENTS:**

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 and the subsequent conversion of the Series B Convertible Preferred Stock included in the units.

On January 8, 2018, the purchaser of Series D Convertible Preferred Stock converted its remaining 8,295 shares Series B Convertible Preferred Stock. Accordingly, the Company will not be required to redeem any shares of Series B Convertible Preferred Stock upon closing of a subsequent financing.

Regarding the Company's one-for-thirty-five reverse stock split of its common stock that occurred on February 7, 2018, which has been retroactively applied to the financial statements, see Note 10a.

On February 7, 2018, at a special meeting of the Company's stockholders, the stockholders approved the issuance of more than 19.99% of the Company's outstanding common stock (measured as of November 28, 2017) at a price per share less than book or market value to investors who participated in the Series D Private Placement. See Note 10a.

