InspireMD, Inc.
Form 10-K
March 28, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

OR

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

COMMISSION FILE NUMBER: 001-35731

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

321 Columbus Avenue
Boston, Massachusetts 02116
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(857) 453-6553**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 par value	NYSE MKT

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2015, based on the price at which the common equity was last sold on the NYSE MKT on such date, was $19,428,337. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

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

Class	**Outstanding at March 28, 2016**
Common Stock, $0.0001 par value	10,726,841

Documents incorporated by reference:

None

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PART I

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

Item 1. Business.

Overview

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

Our CGuard™ carotid embolic prevention system (“CGuard EPS”) combines our MicroNet mesh 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 the CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September 2015, we also received regulatory approval to commercialize the CGuard EPS in Argentina and Columbia.

Our MGuard™ coronary product, 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). We market and sell MGuard Prime EPS, a bare-metal cobalt-chromium based stent, 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. Due to limited resources, though, our efforts to date have been limited to incorporating our MicroNet in-house onto a drug-eluting stent manufactured by a potential partner.

We are also developing a neurovascular flow diverter, 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 commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

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 open diseased vessels in the brain.

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

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard™ EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

Effective as of October 1, 2015, we amended our certificate of incorporation in order to (i) effectuate a one-for-ten reverse stock split of our outstanding shares of common stock and (ii) reduce the number of authorized shares of our common stock from 125,000,000 to 50,000,000. All share and related option and warrant information presented in this prospectus supplement have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

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

We make available, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports on our website at www.inspiremd.com as soon as reasonably practicable after those reports and other information is electronically filed with, or furnished to, the Securities and Exchange Commission.

Business Segment and Geographic Areas

Prior to October 2014, all revenue was derived from sales of MGuard Prime EPS, our bare-metal coronary stent. For the twelve months ended December 31, 2015, 70% of our revenue was derived from sales of this product. For financial information about our one 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 though an incision in the neck, and then surgically removes the plaque. Endovascular techniques using stents and EPS 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 among 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 global market for the endovascular treatment of cerebral aneurysms, which currently stands at $980 million, is expected to reach $1.4 billion by 2020, at a compound average annual growth rate of 5% per year (*source: Medtech Ventures, Endovascular Cerebral Aneurysm Repair Market, October 2013*).

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.

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.

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

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.

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 the CGuard EPS by our distribution partner, Penumbra, Inc., in 18 CE marked countries in Europe. In October 2015, we received regulatory approval to commercialize the CGuard EPS in Argentina and Columbia. We are currently preparing materials required to conduct a clinical trial in the United States. Once complete, we plan to request a pre-submission guidance meeting with the U.S. Food and Drug Administration.

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.

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.

NVGuard – Neurovascular

We are developing a neurovascular flow diverter, which is an endovascular device that directs blood flow away from cerebral aneurysms to ultimately seal 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 reaccess 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 both human coronary arteries using the MGuard Prime EPS and aneurysms in the carotid arteries using the 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 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.

In addition to our plan to develop our own flow diverter, we are also evaluating the opportunity to partner with a device company that either has an existing flow diverter or is looking for an entry into the market.

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

MACCE (myocardial infarction ("MI"), stroke or death) 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%.

	30 days (n=30)	**6 months (n=28)**	**12 months (n=27)**
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 %

CAS carries the risk of cerebral embolization during and following the procedure, leading to life-threatening complications, mainly cerebral ischemic events. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a sensitive tool used to identify cerebral emboli during CAS by measuring "lesions" within the brain which are areas that are ischemic and do not receive oxygenated blood due to cerebral emboli. In the CARENET trial, 37.0% of patients treated with CGuard EPS had new ischemic lesions at 48 hours after the procedure, with an average volume of 0.039 cm^3. Of these lesions, there was only one that remained at 30 days following the procedure and all others had resolved. Complete details appear in the following table. Where there is a second number shown below after a ±,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^3)	0.039 ± 0.08	0.08 ± 0.00
Maximum lesion volume (cm^3)	0.445	0.116
Permanent AIL at 30 days	-	1

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

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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 ultrasound analysis is indicative of healthy healing without restenosis concern.
- CGuard EPS offers unique clinical benefits for patients undergoing CAS with unprecedented safety.

Ongoing Physician-Sponsored Clinical Trials for CGuard — PARADIGM Study

PARADIGM (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization **I**n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C**G**uard™ **M**esh-covered embolic prevention stent system) is an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine anti-embolic stent system in unselected, consecutive carotid patients (all-comers) referred for carotid revascularization, initiated in 2015.

The PARADIGM included evaluation of 71 CGuard EPS procedures in 68 unselected all-comer patients and continues to show favorable angiographic and clinical outcomes in using CGuard EPS in patients with carotid artery disease as follows:

- CGuard EPS success and procedure success rate were 100%.
- Periprocedural complications were 0% and remained at 0% at 30 days following the procedure.
- No major adverse cardiac or neurological events occurred periprocedurally or at 30 days following the procedure, pursuant to operator-independent neurologist and non-invasive cardiologist evaluation.

Completed Clinical Trials for MGuard Bare-Metal Coronary Stent Plus MicroNet

We have completed eight clinical trials with respect to our MGuard and MGuard Prime EPS coronary stents. 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 STMEI 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 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 an MGuard stent 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 stent compared to patients receiving a commercially-approved bare metal or drug-eluting stent (57.8% vs. 44.7%).

- Patients receiving the MGuard Coronary stent 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 the MGuard Coronary stent 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 Coronary and commercially-approved bare metal or drug-eluting stents.

The six month results from the MASTER I trial, which 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:

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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 e. el, *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 stent 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 stent 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 Coronary	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 the CGuard EPS in specific indications. These trials would be designed to facilitate market acceptance and expand the use of the product. We should 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 technology 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 in order to achieve this objective.

- **Grow our presence in existing and new markets for CGuard EPS.** We have fully launched CGuard EPS in most European and Latin American countries, through a combination of distributor sales organizations as well as a partnership with Penumbra, Inc., a global interventional therapies company focused on the neuro and peripheral vascular specialties, to distribute CGuard EPS in Europe in 18 CE marked countries. We are also pursuing additional registrations and contracts in other countries in Europe, Asia and Latin America.

- **Continue to leverage 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 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.

- **We work closely with leading physicians to evaluate and ensure the efficacy and safety of our products.** Some of these prominent physicians serve on our Scientific Advisory Board, which is our advisory committee that advises our board of directors and advises and participates in the operation of our clinical trials. These physicians have and will continue to generate and publish scientific data on the use of our products, and to present their findings at various key clinical conferences.

- **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 our NVGuard flow diverter, 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. Twelve separate patent applications have been filed 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 technology 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 the next generation of drug-eluting stent incorporating MicroNet.** 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 a drug-eluting stent that incorporates MicroNet.

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. Gore Medical and Terumo Medical Corporation produce mesh-covered carotid stents. 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 channels 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, Inc., 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 the twelve months ended December 31, 2015 and 2014, we spent $3.6 million and $8.7 million, respectively, on research and development.

Sales and Marketing

Sales and Marketing

In October 2007, the MGuard coronary stent system with a bio-stable MicroNet received CE mark approval in the European Union. Currently, we are actively selling our MGuard coronary stent system 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 commercially launched CGuard EPS in CE marked countries in early 2015. We initially sold CGuard products through a distributor network as we did with MGuard coronary products. On August 5, 2015, InspireMD, Ltd., our wholly owned subsidiary, entered into a distribution agreement with Penumbra, Inc., and, in September 2015, we announced full market launch of the CGuard EPS by Penumbra, Inc. in 17 CE marked countries in Europe.

We plan to focus our marketing efforts primarily on Europe, Asia and Latin America. In addition to utilizing local and regional distributor networks, 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 stent system has 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 2016 as more and more positive clinical data is presented. 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. All of the MGuard and CGuard products 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 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 filed sixteen patent applications, twelve of which are pending in the United States covering aspects of our MGuard and CGuard technology. We have filed corresponding patent applications to some of these in Canada, China, Europe, Israel, India and South Africa, for an aggregate total of 46 patents and pending applications including four issued U.S. patents. These patent rights are directed to cover percutaneous therapy, knitted stent jackets, stent and filter assemblies, *in vivo* filter assembly, optimized stent jackets, stent apparatuses for treatment via body lumens and methods of use, stent apparatuses for treatment via body lumens and methods of manufacture and use, among others. 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. On October 27, 2010, our South African patent application pertaining to "Stent Apparatus for Treatment via Body Lumens and Method of Use" was issued as South African Patent No. 2007/10751. On October 25, 2011, our patent application pertaining to "In Vivo Filter Assembly," U.S. Patent Application 11/582,354, was issued as U.S. Patent 8,043,323. On June 13, 2012, our patent application pertaining to "Filter Assemblies," Chinese Patent Application No. 200780046659.9, was issued as Chinese Patent No. ZL200780046659.9. On September 26, 2012, our patent application pertaining to "Bifurcated Stent Assemblies," Chinese Patent Application No. 200780046676.2, was issued as Chinese Patent No. ZL200780046676.2. On October 10, 2012, our patent application pertaining to "Knitted Stent Jackets," Chinese Patent Application No. 200780046697.4, was issued as Chinese Patent No. ZL200780046697.4. On January 2, 2013, our patent application pertaining to "Optimized Stent Jacket," Chinese Patent Application No. 200780043259.2, was issued as Chinese Patent No. ZL200780043259.2. We have also had Israeli Patent No. 198189 entitled "Filter Assemblies" issued March 27, 2014, and Patent No. 198190, entitled "Knitted Stent Jackets" issued Feb. 1, 2014, and Canadian Patent No. 2609687 entitled

"Stent Apparatuses For Treatment Via Body Lumens" issued April 22, 2014. Israeli Patent No. 198,188 entitled "Bifurcated Stent Assemblies" issued May 1, 2014 and Israeli Patent No. 198,665 entitled "Optimized Stent Jacket" issued May 28, 2014. U.S. Patent Application No. 11/797,168, filed May 1, 2007, was issued as U.S. Patent No. 8,961,586 on February 24, 2015. Canadian Patent No. 2,666,712 entitled "Filter Assemblies" issued March 31, 2015. Canadian Patent No. 2,666,728 entitled "Knitted Stent Jackets" issued June 23, 2015. U.S. Patent No. 9,132,261 entitled "*In Vivo* Filter Assembly" and U.S. Patent No. 9,132,003, entitled "Optimized Drug-Eluting Stent Assembly" each issued September 15, 2015. Canadian Patent No. 2,843,097 entitled "Stent Apparatuses for Treatment Via Body Lumens and Methods of Use" issued October 27, 2015. Chinese Patent No. 201210320950.3 entitled "Knitted Stent Jackets" issued December 2, 2015. Chinese Patent No. ZL201210454357.8, entitled "Optimized Stent Jacket" issued December 9, 2015. 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.

Trademarks

We use the InspireMD®, MGuard® and MGuard Prime® trademarks in connection with our products. We have registered these trademarks in the European Union. The trademarks are renewable indefinitely, so long as we make the appropriate filings when required. We also have registrations for Carenet®, CGuard® and the MNP Micronet Protection Logo in the European Union and a supplemental registration for Micronet® in the United States. We have also applied to register the names Carenet™, CGuard™ InspireMD™, SmartFit™, PV Guard™ , AGuard™,and MGuard Prime™ as trademarks in the United States We also use and may have common law rights to various trademarks, trade names, and service marks.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the European Union CE mark, the U.S. Food and Drug Administration 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 clearance, clinical tests 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 efficiency and timeliness of international market introduction of our products. For countries in the European Union, medical devices must display a CE mark before they may be imported or sold. 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 and passing initial and annual quality management system audit inspections to the 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 annual facilities audit inspections conducted by European Notified Body inspectors.

As noted below, we have regulatory approval and are selling MGuard Prime EPS, CGuard EPS or both products either through distributors pursuant to distribution agreements or directly , in the following countries: Argentina, Australia, Austria, Belarus, Belgium, Brazil, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Malta, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, and the United Kingdom. In addition, we have distribution agreements for our products in Uzbekistan, Canada, Venezuela, Kazakhstan, and Armenia, although we have not yet obtained regulatory approval to sell our products in those countries, and we are awaiting regulatory approval to sell our products in Russia and Malaysia. 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. We are currently seeking marketing approval for the MGuard Prime EPS in India, Malaysia, Russia and Singapore. We are focused on seeking marketing approval in these countries because we believe that these countries represent the strongest opportunities for us to grow with respect to our sales.

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 the CGuard EPS in Brazil and Russia.

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

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

Countries	MGuard Prime EPS Approval	MGuard Prime EPS Sales	CGuard EPS Approval	CGuard EPS Sales
Argentina	Y	Y	Y	N
Armenia	N	N	N	N
Australia	Y	Y	N	N
Austria	Y	Y	Y	N
Belarus	Y	Y	Y	Y
Belgium	Y	Y	Y	N
Brazil	Y	Y	N	N
Chile	N	Y (1)	N	Y (1)
Colombia	Y	Y	Y	Y
Croatia	Y	Y	Y	N
Cyprus	Y	Y	Y	Y
Czech Republic	Y	Y	Y	N
Denmark	Y	N	Y	N
Estonia	Y	Y	Y	N
Finland	Y	Y	Y	N
France	Y	Y	Y	N
Germany	Y	Y	Y	Y
Greece	Y	N	Y	N
Holland (Netherlands)	Y	Y	Y	Y
Hungary	Y	Y	Y	N
Iceland	Y	N	Y	N
India	Y	N	N	N
Ireland	Y	Y	Y	N
Israel	Y	Y	Y	Y
Italy	Y	Y	Y	Y
Kazakhstan	N	N	N	N
Latvia	Y	Y	Y	Y
Lithuania	Y	Y	Y	Y
Liechtenstein	Y	N	Y	N
Luxemburg	Y	N	Y	N
Malaysia	N	Y (2)	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	N
Romania	Y	Y	Y	Y
Russia	N [3]	Y	N	N
Saudi Arabia	Y	Y	N	N
Serbia	Y	N	N	N
Slovakia	Y	Y	Y	Y
Slovenia	Y	Y	Y	Y
South Africa	Y [4]	Y	N	N
Spain	Y	Y	Y	Y
Sweden	Y	Y	Y	N
Switzerland	Y	Y	Y	N
Taiwain	Y	N	N	N
United Kingdom	Y	Y	Y	N
Uzbekistan	N	N	N	N
Venezuela	N	N	N	N

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(1) 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.

(2) Due to the changes made to the relevant regulations in Malaysia that became effective in November 2015, we are required to register our product. Sales of MGuard Prime EPS were made to our distributor in Malaysia prior to the date such change became effective. On November 29, 2015 we initiated registration process required pursuant to the amended regulation.

(3) Following the voluntary field action, the Russian ministry of health is holding the registration of MGuard Prime EPS pending its approval of subsequent bench testing results initially submitted on November 18, 2015, and supplementary information submitted on February 26, 2016.

(4) We believe that we have regulatory approval for MGuard Prime EPS in South Africa based upon information from our distributor in such country, who was responsible for obtaining the regulatory approval for MGuard Prime EPS. However, the certificate evidencing regulatory approval is held by our distributor and we cannot guarantee that it is in full force and effect.

In the United States, the medical devices that will be manufactured and sold by us will be subject to laws and regulations administered by the U.S. Food and Drug Administration, including regulations concerning the prerequisites to commercial marketing, the conduct of clinical investigations, compliance with the Quality System Regulation and labeling. We anticipate that our CGuard EPS will be classified as a Class III medical device by the U.S. Food and Drug Administration.

A manufacturer may seek market authorization for a new medical device through the rigorous premarket approval application process, which first requires that the U.S. Food and Drug Administration determine that the device is safe and effective for the purposes intended.

We will also be required to register with the U.S. Food and Drug Administration as a medical device manufacturer. As such, our manufacturing facilities will be subject to U.S. Food and Drug Administration inspections for compliance with 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. If the U.S. Food and Drug Administration believes that a manufacturer is not in compliance with the law, it can institute enforcement proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the manufacturer, its officers and employees.

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, Australia, South Africa and Latin America. We are currently in discussions with additional distribution companies in Europe, Asia, and Latin America.

Unless otherwise indicated below, all of the distribution agreements described under “Customers” are subject to automatic annual extensions unless affirmatively terminated.

For the twelve months ended December 31, 2015, 79% of our revenue was generated in Europe, and 17% of our revenue was generated in Latin America, with the remaining 4% of our revenue generated in the rest of the world. Our major customers in the twelve months ended December 31, 2015 were Avidal Group GmbH, a distributor in Germany that accounted for 11% of our revenues, and Cardio Medical Sales L.P, a distributor in Belarus that accounted for 10% of our revenues.

Our agreement with Avidal Group GmbH grants Avidal Group GmbH the right to be a distributor of MGuard Prime EPS and CGuard EPS in Germany until March 2017, subject to the achievement of certain order minimums. Under our agreement with Avidal Group GmbH, as amended, Avidal Group GmbH was required to purchase 850 MGuard Prime EPS and 225 CGuard EPS from us in 2015. Although Avidal Group GmbH did not adhere to their order minimum for 2015, we did not terminate their right to be our distributor of MGuard Prime EPS and CGuard EPS in Germany.

Our agreement with Cardio Medical Sales L.P grants Cardio Medical Sales L.P the right to be the exclusive distributor of MGuard Prime EPS and CGuard EPS in Belarus until December 2016, subject to the achievement of certain order minimums. Under our agreement with Cardio Medical Sales L.P, Cardio Medical Sales L.P is required to purchase 450 MGuard Prime EPS from us in 2015, 70 MGuard Prime EPS in 2016 and 30 CGuard EPS in 2016. Although Cardio Medical Sales L.P did not adhere to their order minimum for 2015, we did not terminate their right to be our exclusive distributor of MGuard Prime EPS and CGuard EPS in Belarus.

Penumbra Distribution Agreement

On August 5, 2015, InspireMD, Ltd., our wholly owned subsidiary, entered into a distribution agreement with Penumbra, Inc., pursuant to which Penumbra, Inc. will act as the exclusive distributor of CGuard EPS in Austria, France, Sweden, Denmark, Norway, Finland, Estonia, Lithuania, Portugal, Switzerland and the United Kingdom and Ireland. The territory covered by the distribution agreement also includes non-exclusive rights to distribute CGuard EPS in Latvia, Belgium, the Netherlands, Luxembourg, Germany and Poland.

Under the terms of the distribution agreement, we will use all commercially reasonable efforts to obtain all required permits, licenses and other approvals necessary to import, market or sell the CGuard EPS in the territory covered by the distribution agreement. Within 60 days after receipt of all such required approvals in a given territory, Penumbra, Inc. shall place its initial stocking order for CGuard EPS, for which Penumbra, Inc. will pay one-half of the purchase

price upon placing such order and the remainder of the purchase price 30 days after receipt of the CGuard products and our invoice for such CGuard EPS products. If, in our reasonable discretion, Penumbra, Inc. fails to order a sufficient quantity of CGuard EPS to successfully commercialize the CGuard EPS in the applicable territory, then we may reduce the territory covered by the distribution agreement upon providing 60 days' notice to Penumbra, Inc.

The distribution agreement requires Penumbra, Inc. to use commercially reasonable efforts to purchase CGuard EPS in certain minimum target amounts agreed to by the parties for the 2015 and 2016 calendar years. For all subsequent calendar years during the term of the distribution agreement, the parties will agree to the minimum annual purchase targets at least 30 days prior to the commencement of such calendar year, which shall be determined in good faith by mutual agreement, taking into account various relevant factors, such as the sales attained during the preceding calendar year and prevailing market conditions, among others. The parties fixed the initial prices to be paid by Penumbra, Inc. for CGuard EPS through December 31, 2015, which were subject to certain reductions for inventory shelf life and other adjustments negotiated by the parties.

The initial term of the distribution agreement ends on December 31, 2018, unless sooner terminated pursuant to the termination rights set forth therein. Either party may terminate the distribution agreement (i) without cause upon providing 60 days' notice to the other party, (ii) upon the other party's material breach of the distribution agreement, which is not cured 30 days after written notice thereof from the non-breaching party and (iii) immediately without notice upon the bankruptcy, insolvency, dissolution, assignment for the benefit of creditors or similar event with respect to the other party. We may also terminate the distribution agreement if it reasonably believes that Penumbra, Inc., or any party acting on its behalf, has violated the United States Foreign Corrupt Practices Act of 1977. In addition, if at any time during the term of the distribution agreement, Penumbra, Inc. distributes or offers for sale products that, in our reasonable judgment, compete with CGuard EPS, then we may terminate the distribution agreement or change the exclusive rights granted to non-exclusive rights upon providing 30 days' notice to Penumbra, Inc.

Pursuant to the distribution agreement, we are subject to customary covenants and other continuing regulatory, record-keeping and reporting obligations.

The distribution agreement also contains a limited three year warranty for CGuard EPS and other mutual confidentiality and indemnification obligations for us and Penumbra, Inc.

Current and future agreements with distributors stipulate that, while we are responsible for training, providing marketing guidance, marketing materials, and technical guidance, distributors 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 approximately 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., which may be terminated by us upon eight months' notice, calls for a minimum order of 2,000 catheters and commitment to purchase the remaining stock of components for production of the catheters in the event we fail to meet the minimum order for up to approximately $87,000 in 2016.

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 have mutual indemnification

obligations with Svelte Medical Systems Inc. for any damages suffered as a result of third party actions based upon breaches of representations and warranties or the failure to perform certain covenants in the license agreement, and Svelte Medical Systems Inc. will also indemnify us for any damages suffered as a result of third party actions based upon intellectual property or design claims against the cobalt-chromium stent for the MGuard Prime EPS.

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 balloon 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.

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. This material is readily available in the market as well, because it is used for many medical applications. In the event that our supplier can no longer supply this material in fiber form, we would need to qualify another supplier, which could take several months. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to insure that their products meet our predetermined specifications

A CGuard EPS consists of a CGuard stent and the delivery system. Each CGuard stent is manufactured from two main components, a self-expending stent and the mesh polymer. The stent is made out of nitinol. This material is readily available and we acquire it in the open market. The mesh is made from polyethylene terephthalate. 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 March 28, 2016, we had 40 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 $15.6 million for the fiscal year ended December 31, 2015 and had a net loss of approximately $25 million during the fiscal year ended December 31, 2014. As of December 31, 2015, we had an accumulated deficit of $123 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 at December 31, 2015, 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 out stockholders' ownership interests.

The net proceeds from the offering of our shares of common stock that closed on March 21, 2016, will only be sufficient to enable us to continue operations for a short period of time. In order to fully realize all of our business objectives, absent any non-dilutive funding from a strategic partner or some other strategic transactions, we will need to raise additional capital no later than May 2016, 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.
- pursuing growth opportunities, including more rapid expansion;
- making capital improvements to improve our infrastructure;
- hiring and retaining qualified management and key employees;
- responding to competitive pressures;
- complying with regulatory requirements such as licensing and registration; and
- maintaining compliance with applicable laws.

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

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

Furthermore, any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. If we are unable to obtain such 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.

The voluntary field action of our MGuard Prime EPS we initiated in 2014 could continue to have a significant adverse impact on us.

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.

On April 30, 2014 we initiated a voluntary field corrective action of our MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime EPS stent dislodgements in patients. Although there have been no reports of death or serious injury as a result of such dislodgements, we decided to suspend shipments of the MGuard Prime EPS and implement a field corrective action to enhance the reliability and performance of the affected product units in the field. We received European regulatory approval to resume manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, and we began shipping products to new customers in our direct markets in Western Europe in late September 2014. We completed the full re-launch of MGuard Prime EPS in 2015, with the exception of Russia.

As a result of our voluntary field action, we are subject to numerous risks and uncertainties, including the following:

- although we resumed manufacturing and distribution of our MGuard Prime EPS stent with a modified stent securement process, our suspension of shipments has and may continue to adversely impact revenue;

- we are more susceptible to claims such as product liability claims, distributor claims and class action lawsuits as a result of the reported product malfunction and voluntary field action, which could significantly increase our costs and may have a material adverse effect on our business, financial condition and results of operations;

- our decision to implement the voluntary field action and discontinue shipments, and any additional action related to such decision, may harm our reputation or the market's perception of our products, which could have a negative impact on our future sales and our ability to generate profits.

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, such as the MGuard Prime EPS stent dislodgements, 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.

In addition to the foregoing, since we initiated our voluntary field action we have received a demand from one distributor that we refund approximately $160,000 in lieu of receiving refitted product and a demand from a second distributor to provide unspecified compensation for pre-paid goods subject to the voluntary field action, related costs and any third claims. We do not believe that these distributors are entitled to any compensation or refunds due to the voluntary field action and we intend to defend ourselves against any such claims, however, regarding the demand from the second distributor, we believe that a loss from any related future proceedings that could range from a minimal amount up to 1,075,000 Euros is reasonably possible. While we are disputing these claims, should an action be filed we could be forced to pay damages which could result in a material adverse effect on our business.

We expect to derive our revenue from sales of our MGuard Prime EPS and CGuard EPS stent products and other products we may develop, such as NVGuard. 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 MGuard Prime EPS and CGuard 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 NVGuard. 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. For example, we decided to discontinue our MASTER II trial notwithstanding the resources we had spent on the trial due to the change in market demand for bare metal stents.

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 we have noticed a reduction in the sales level of MGuard Prime EPS compared to the sales level we had in the past. 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 five employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

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

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

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

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

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;

- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- product seizure or detention, or refusal to permit the import or export of our product candidates; and

- injunctions, the imposition of civil penalties or criminal prosecution.

The 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.

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 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.

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 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 in the United States and 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. When we commercialize our products, we expect to face intense competition from Boston Scientific Corporation, Guidant Corporation, Medtronic, Inc., Abbott Vascular Devices, Johnson & Johnson, Terumo Corporation, Covidien Ltd., Cordis Corporation 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. For example, we are aware of one public company that is pursuing patent protection directed to layered materials disposed over a particular stent configuration. 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, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

These companies 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 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 product 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 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 clinical trials. We may also be exposed to product liability claims based on the sale of any such products 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 products incorporating our licensed technology if marketing approval is obtained for such products, 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 may face risks associated with future 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, personal injury and product liability matters. In November 2015, we received written communication from a service provider to remit payment amounting to $1,965,000. Given the preliminary stage, our management and legal counsel cannot estimate the outcome of any legal proceedings or settlements related to this communication, however we believe that neither a court loss nor settlement are probable. 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.

The successful management of operations depends on our ability to attract and retain talented personnel.

We depend on the expertise of our senior management and research personnel, which would be difficult to replace. The loss of the services of any of our senior management could compromise our ability to achieve our objectives. Furthermore, recruiting and retaining qualified personnel will be crucial to future success. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the 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, our operations may be jeopardized 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 manufacture 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.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

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 product candidates 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 product candidates. The efficacy, safety, performance and cost-effectiveness of our product candidates 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 currently under development and limit our ability to sell our product candidates 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 Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were enacted into law in the United States in March 2010. Certain provisions of these acts are not yet fully implemented, it may be a number of years before certain provisions are fully implemented, there remain to be programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts 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 Medicare provisions aimed at improving quality and decreasing costs. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include 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. 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, some 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.

Some 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. Further, the C&R Committee has not yet set specific guidelines regarding the method for calculating this remuneration or the criteria or circumstances under which an employee's waiver of his right to remuneration will be disregarded. 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 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 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 2015 is 26.5% and in 2016 is 25% 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 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

Our stock price has been and may continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock has been and is 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 price of our common stock.

Our common stock could be delisted from the NYSE MKT if we fail to regain compliance with the NYSE MKT's continued listing standards on the schedule required by the NYSE MKT.

On January 20, 2015, we received a notice indicating that we do not meet certain of the NYSE MKT's continued listing standards as set forth in Part 10 of the NYSE MKT Company Guide ("Company Guide"). Specifically, we are not in compliance with Section 1003(a)(iii) of the Company Guide because we reported stockholders' equity of less than $6 million as of September 30, 2014 and had net losses in our five most recent fiscal years. In addition, the NYSE MKT indicated that we are not in compliance with Section 1003(a)(iv) of the Company Guide because we have sustained losses that are substantial in relation to our overall operations or our existing financial resources, or our financial condition has become impaired such that it appears questionable, in the opinion of the NYSE MKT, as to whether we will be able to continue operations and/or meet our obligations as they mature. As a result, we have become subject to the procedures and requirements of Section 1009 of the Company Guide.

In order to maintain our listing on the NYSE MKT, we submitted a plan of compliance to the NYSE MKT on February 19, 2015 addressing how we intend to regain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016 and Section 1003(a)(iv) of the Company Guide by June 1, 2015. On March 9, 2015, we closed a public offering of our common stock and warrants that resulted in net proceeds of approximately $12.5 million after deducting placement agent fees and other estimated offering expenses. In light of this, the NYSE MKT determined that we have resolved the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide. In addition, the NYSE MKT has accepted our plan to gain compliance with the Section 1003(a)(iii) of the Company Guide by July 20, 2016.

If we do not regain compliance with Section 1003(a)(iii) of the Company Guide by July 20, 2016, or if we do not maintain our progress consistent with the plan during the applicable plan period, the NYSE MKT will initiate delisting proceedings. The market price and liquidity of our common stock could be adversely affected by the commencement of such proceedings. If those proceedings resulted in delisting of our common stock and resulting cessation of trading of the stock on the NYSE MKT, we believe that the market price and liquidity of our common stock would be adversely affected.

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. We are also subject to certain restrictions pursuant to our loan and security agreement with Hercules Technology Growth Capital, Inc., which prohibits us from paying dividends or distributions on our common stock. 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.

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 of 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, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or 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.

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

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Our stockholders and the holders of our options and warrants may sell substantial amounts of our common stock in the public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing 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 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.

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

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

Risks Related to our Indebtedness

Our obligations under our $10 million principal term loan are secured by substantially all of our assets, so if we default on those obligations, the lender could foreclose on our assets. As a result of these security interests, such

assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. In addition, the existence of these security interests may adversely affect our financial flexibility.

The lender under our $10 million principal term loan has a security interest in substantially all of our assets and those of InspireMD Ltd., our wholly-owned subsidiary. As a result, if we default under our obligations to the lender, the lender could foreclose on its security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the lender would have a prior right to substantially all of our assets to the exclusion of our general creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations secured by the lender, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of any unsecured creditors would any amount be available for our equity holders.

The pledge of these assets and other restrictions may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged under the $10 million principal term loan, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

Our loan and security agreement contains customary events of default. In addition, an event of default will include the occurrence of a circumstance that would reasonably be expected to have a material adverse effect upon (i) our business, operations, properties, assets, prospects or condition (financial or otherwise), (ii) our ability to perform our obligations under the agreement and any related loan documents or (iii) the collateral, the lender's liens on the collateral or the priority of such liens.

We have a substantial amount of indebtedness, which may adversely affect our cash flow and our ability to operate our business.

Pursuant to the terms of our loan and security agreement, the lender made a term loan to us and InspireMD Ltd. in aggregate amount of $10 million. We are required to make monthly payments of interest and principal in the amount of approximately $380,000 per month. The final payment of the loan will be February 1, 2017. The current principal amount of the loan as of March 1, 2016 was $4.0 million.

The terms of our term loan could have negative consequences to us, such as:

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;
- the amount of our interest expense may increase because our term loan has a variable rate of interest at any time that the prime rate, as reported in the Wall Street Journal, is above 5.5%;
- we will need to use a substantial portion of our cash flows to pay principal and interest on our term loan, which will reduce the amount of money we have for operations, working capital, capital expenditures, expansion, acquisitions or general corporate or other business activities;
- we may have a higher level of debt than some of our competitors, which may put us at a competitive disadvantage;

- we may be unable to refinance our indebtedness on terms acceptable to us, or at all; and
- we may be more vulnerable to economic downturns and adverse developments in our industry or the economy in general.

Our ability to meet our expenses and debt obligations will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors, such as economic conditions. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable to refinance all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all, and the lender could foreclose on its security interests and liquidate some or all of our assets.

Our loan and security agreement contains covenants that could limit our financing options and liquidity position, which would limit our ability to grow our business.

Covenants in our loan and security agreement impose operating and financial restrictions on us. These restrictions prohibit or limit our ability, and the ability of InspireMD Ltd., to, among other things:

- pay cash dividends to our stockholders;

- redeem or repurchase our common stock or other equity;
- incur additional indebtedness;
- permit liens on assets;
- make certain investments (including through the acquisition of stock, shares, partnership or limited liability company interests, any loan, advance or capital contribution)
- sell, lease, license, lend or otherwise convey an interest in a material portion of our assets; and
- cease making public filings under the Securities Exchange Act of 1934, as amended.

These restrictions may limit our ability to obtain additional financing, withstand downturns in our business or take advantage of business opportunities. Moreover, additional debt financing we may seek, if permitted, may contain terms that include more restrictive covenants, may require repayment on an accelerated schedule or may impose other obligations that limit our ability to grow our business, acquire needed assets, or take other actions we might otherwise consider appropriate or desirable.

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;
- market acceptance of our existing and new 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;

- our dependence on single suppliers for certain product components and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;

- 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;

- our limited manufacturing capabilities and reliance on subcontractors for assistance;

- loss of a key customer or supplier;

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

- product malfunctions;

- 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;
- legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions;
- the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain;
- 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.

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 Boston, Massachusetts, where we lease approximately 1,580 square feet of executive office space. In addition, in Tel Aviv, Israel, we currently have 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. As of the date of this filing, we are not aware of any 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.

There are no 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 an adverse party or has a material interest adverse to our interest.

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 MKT 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 MKT, for the period of January 1, 2014 to December 31, 2015. The sales prices for our common stock prior to October 1, 2015 are adjusted for the one-for-ten reverse stock split of our common stock that occurred on such date.

Fiscal Year Ended December 31, 2015	High	Low
First Quarter	$10.10	2.30
Second Quarter	$4.20	1.90
Third Quarter	$3.20	1.50
Fourth Quarter	$2.12	0.63

Fiscal Year Ended December 31, 2014	High	Low
First Quarter	$38.00	$24.80
Second Quarter	$32.50	$17.90
Third Quarter	$30.20	$18.10
Fourth Quarter	$22.30	$7.00

The last reported sales price of our common stock on the NYSE MKT on March 25, 2016, was $0.50 per share. As of March 25, 2016, there were approximately 214 holders of record of our common stock.

Dividend Policy

In the past, we have not declared or paid cash dividends on our common stock. Our loan and security agreement with Hercules Technology Growth Capital, Inc., dated October 23, 2013, prohibits us from paying dividends or distributions on our common stock. Even if we are permitted to pay cash dividends in the future, we do not intend to

do so. Rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

Recent Sales of Unregistered Securities.

On June 25, 2013, we issued 6,780 shares of our common stock pursuant to the InspireMD, Inc. 2011 UMBRELLA Option Plan in connection with the settlement of a dispute with a former consultant. These shares of common stock were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

On March 21, 2016, we sold to certain of our officers and directors 1,033,051 shares of our common stock and warrants to purchase 516,526 shares of our common stock in a private placement. The common stock was sold at a price of $0.59 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 private placement. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. We received gross proceeds from the private placement of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses payable by us. These shares of common stock were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

In connection with the private placement, on March 21, 2016, we issued to Dawson James Securities, LLC, the exclusive placement agent in the private placement, warrants to purchase 51,653 shares of our common stock. The placement agent's warrants will be exercisable at any time and from time to time, in whole or in part, during the period commencing on September 17, 2016 and ending on March 16, 2021, at $0.7375 per share. These warrants were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold in reliance on the exemption from registration under the Securities Act of 1933, as amended, provided by Section 4(a)(2) of the Securities Act of 1933, as amended.

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 condensed 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 coronary and vascular 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 MGuard Prime EPS, which incorporate our MicroNet platform technology, is marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions (bypass surgery).

Our second product, CGuard EPS combines our MicroNet mesh 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 the CGuard EPS in Europe through a distribution agreement with Penumbra, Inc. In September

2015, we also received regulatory approval to commercialize the CGuard EPS in Argentina and Columbia.

We are also developing a neurovascular flow diverter, 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 commenced initial pre-clinical testing of this product in both simulated bench models and standard in vivo pre-clinical models.

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 open diseased vessels in the brain.

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

Recent Events

Effective as of October 1, 2015, we amended our certificate of incorporation in order to (i) effectuate a one-for-ten reverse stock split of our outstanding shares of common stock and (ii) reduce the number of authorized shares of our common stock from 125,000,000 to 50,000,000. All share and related option and warrant information presented in this prospectus supplement have been retroactively adjusted to reflect the reduced number of shares outstanding which resulted from this action.

During the first quarter of 2015, we implemented a cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses to those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.). In addition, we decided to alter our commercial strategy by using third party distributors to drive future sales, as opposed to direct sales to hospitals and clinics, which had previously been our focus.

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 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 $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million, before deducting the underwriting discount and estimated offering expenses.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 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 private placement. The warrants are exercisable immediately and have a term of exercise of 5 years from the date of issuance and an exercise price of $0.59. This private placement resulted in gross proceeds to us of approximately $0.6 million, before deducting placement agent fees and estimated offering expenses.

These sales of securities on March 21, 2016 resulted in aggregate net proceeds to us of approximately $1.4 million, after deducting underwriting discount, placement agent fees and other offering expenses.

Critical Accounting Policies

We prepared our consolidated financial statements for inclusion in this report 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, royalty buyout 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 market 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 and risks and rewards for the products are transferred to the customer, collection is reasonably assured and product returns can be reliably estimated.

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 estimate forfeitures based on historical experience and anticipated future conditions.

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 share-based awards are performance based and dependent upon achieving certain goals. With respect to these 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.

Uncertain tax and value added tax positions

We follow 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. Our policy is to include interest related to unrecognized tax benefits within “Financial expenses (income) – net.”

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.

Allocation of issuance proceeds

When debt or equity is issued with other components that are subsequently measured at fair value, the proceeds are allocated first to such components (such as warrants and embedded derivatives in the debt that require bifurcation at their fair values), then the residual amount of the proceeds is allocated to the debt or equity. When other components are classified in equity, the proceeds are allocated based on relative fair values.

Results of Operations

Twelve months ended December 31, 2015 compared to the twelve months ended December 31, 2014

Revenues. For the twelve months ended December 31, 2015, revenue decreased by $0.5 million, or 18.1%, to $2.3 million, from $2.8 million during the same period in 2014. This decrease was predominantly driven by a decrease in sales of our MGuard coronary products of $1.2 million, or 42.6%, from $2.8 million in the twelve months ended December 31, 2014 to $1.6 million in the same period in 2015. This decrease in sales of MGuard Prime EPS was predominantly driven by a decrease in sales volume of $0.8 million, or 28.9% due to the trend of doctors increasingly using drug-eluting stents rather than bare metal stents in STEMI patients, which impacted current sales. Price decreases to our distributors drove the remaining decrease of $0.4 million, or 13.7%, of MGuard Prime EPS, due to lower average sales prices necessary to remain competitive amongst sharp price decreases in the coronary stent market, as well as the effects of the weakening of the Euro against the U.S dollar. These decreases, however, were partially offset by an increase of $0.7 million of sales of our new product CGuard EPS, which was launched in October 2014.

With respect to regions, the decrease in revenue was primarily attributable to a decrease of $0.7 million in revenue from our distributors in the Middle East and a decrease of $0.1 million in revenue from our distributors in Asia, partially offset by an increase of $0.3 million in revenue from our distributors in Europe.

Gross Profit (Loss). For the twelve months ended December 31, 2015, we had a gross loss (revenue less cost of revenues) of $0.3 million, as compared to a gross profit of $0.8 million during the same period in 2014, representing a decrease of 137.8%, or $1.1 million. This decrease in gross profit was attributable to a decrease in revenues of $0.5 million (see above for explanation), an increase of write-offs of inventory of $0.4 million, which were primarily related to write-offs of MGuard Prime EPS units due to expected lower sales in the future resulting from industry preferences for drug eluting stents, and our transition to a third party distributor commercial strategy, an increase in labor and material costs of $0.3 million attributable to higher material and labor costs for CGuard EPS, as well as an increase of $0.3 million related to underutilization of our manufacturing resources. These increases, however, were partially offset by a decrease of $0.4 million in costs associated with the voluntary field action. Gross margin (gross profits as a percentage of revenue) decreased from 27.8% in the twelve months ended December 31, 2014 to (12.8)% in the same period in 2015. The decrease in gross margin of 40.6% was driven mainly by write-offs of inventory, the change in product mix, including a higher percentage of CGuard EPS, which has higher material and labor costs than our MGuard coronary products, and a lower average sales price of MGuard Prime EPS.

Research and Development Expenses. For the twelve months ended December 31, 2015, research and development expenses decreased by 58.3%, or $5.1 million, to $3.6 million, from $8.7 million during the same period in 2014. This decrease in research and development expenses resulted primarily from a decrease of $3.4 million in clinical trial expenses associated with our MASTER II trial, a decrease of $0.5 million in clinical trial and development costs associated with CGuard EPS, which were predominantly related to our CARENET trial, a decrease of $0.3 million in compensation expenses, a decrease of $0.3 million of expenses related to our stent retention program, which we concluded in 2014, a decrease of $0.2 million in travel expenses and a decrease of $0.4 million in miscellaneous clinical and development expenditures related to MGuard Prime EPS. The decreases in compensation, travel and miscellaneous clinical and development expenditures related to MGuard Prime EPS are the results of the implementation of our cost reduction/focused spending plan in the first quarter of 2015. Research and development expenses as a percentage of revenue decreased to 157.7% for the twelve months ended December 31, 2015, from 310.3% in the same period in 2014.

Selling and Marketing Expenses. For the twelve months ended December 31, 2015, selling and marketing expenses decreased by 51.9%, or $3.4 million, to $3.2 million, from $6.6 million during the same period in 2014. This decrease in selling and marketing expenses resulted primarily from a decrease of $2.2 million in compensation expenses due to our transition away from direct sales in favor of using third party distributors, a decrease of $0.5 million in travel expenses associated with the decreased size of our sales force, a decrease of $0.5 million in trade show participation related expenditures and a decrease of $0.2 million in miscellaneous expenses. The decrease in spending of the above was a result of our cost reduction/focused spending plan. Selling and marketing expenses as a percentage of revenue decreased to 137.6% in the twelve months ended December 31, 2015 from 234.7% in the same period in 2014.

General and Administrative Expenses. For the twelve months ended December 31, 2015, general and administrative expenses decreased by 30.0%, or $2.7 million, to $6.4 million, from $9.1 million during the same period in 2014. The decrease in general and administrative expenses resulted primarily from a decrease of $2.1 million in compensation due to a decrease in share-based compensation driven by lower valued ESOP grants made to our management and directors, as well as a decrease in salary expenses due to a reduced headcount as part of our cost reduction/focused

spending plan. In line with our cost reduction/focused spending plan, we also had a decrease of $0.2 million in legal expenses, a decrease of $0.1 million in travel expenditures and a decrease of $0.4 million in miscellaneous expenses. General and administrative expenses as a percentage of revenue decreased to 276.5% in the twelve months ended December 31, 2015 from 323.8% in the same period in 2014.

Restructuring and Impairment Expenses. For the twelve months ended December 31, 2015, we incurred $1.0 million of restructuring and impairment expenses made up of $0.6 million of expenses related to the impairment of an MGuard Prime EPS royalty buyout option due to anticipated lower sales in the future due to the shift in industry preferences away from bare metal stents in favor of drug eluting stents, $0.2 million of cash payouts and $0.1 million of restricted shares given to employees terminated in connection with our cost reduction/focused spending plan and $0.1 million in fees associated with our early exit from a portion of our lease in our Boston office. Restructuring and impairment expenses as a percentage of revenue was 42.5% for the twelve months ended December 31, 2015.

Financial Expenses. For the twelve months ended December 31, 2015, financial expenses decreased by 20.9%, or $0.3 million, to $1.1 million, from $1.4 million during the same period in 2014. The decrease in financial expenses resulted from a decrease of $0.4 of interest expenses due to the reduction in principal of our outstanding indebtedness, partially offset by an increase in miscellaneous expenses of $0.1 million. Financial expenses as a percentage of revenue decreased to 47.4% in the twelve months ended December 31, 2015, from 49.1% in the same period in 2014.

Tax Expenses (Income). For the twelve months ended December 31, 2015 there was no material change in tax expenses (income) compared to the same period in 2014.

Net Loss. Our net loss decreased by $9.5 million, or 37.9%, to $15.6 million for the twelve months ended December 31, 2015 from $25.1 million during the same period in 2014. The decrease in net loss resulted primarily from a decrease of $10.2 million in operating expenses primarily associated with lower research and development expenses, due to our cost reduction/focused spending plan, and a decrease of $0.3 million in financial expenses, partially offset by a decrease of $1.0 million in gross profit (see above for explanation).

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2015, as well as net losses and negative operating cash flows in recent years. 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 do not have sufficient resources to fund operations beyond May 2016. 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 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, pursuant to which we received a loan of $10 million, before deduction of issuance costs. Interest on the loan is 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%. Payments under the loan and security agreement are interest only for 9 months, followed by 30 monthly payments of principal and interest through the scheduled maturity date on February 1, 2017. Our obligations under the loan and security agreement are secured by a grant of a security interest in all of our assets (other than our intellectual property). In addition, in connection with the loan and security agreement, we issued the lender a five year warrant to purchase 168,351 shares

of our common stock at a per share exercise price of $2.97.

On October 23, 2013, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC ("MLV"), pursuant to which we may issue and sell shares of our common stock in an aggregate amount up to $40 million from time to time in an "at-the-market" offering as defined in Rule 415 under the Securities Act of 1933, as amended, through MLV as our sales agent. On August 15, 2014, we sold 94,800 shares of our common stock, at $24.00 per share, pursuant to the at-the-market issuance sales agreement with MLV. These sales resulted in net proceeds to us of approximately $2.2 million. We paid MLV compensation at a commission rate of 3% of the gross sales. Prior to these sales, we have not made any sales under this "at-the-market" equity offering program, and, as of December 31, 2015, shares of our common stock having an aggregate value of approximately $37.7 million remained available for sale under this offering program. Such sales were made pursuant to our effective $75 million shelf registration statement filed with the Securities and Exchange Commission in October 2013 (File No. 333-191875). Our securities purchase agreement with purchasers of shares of our common stock and warrants to purchase our common stock, dated March 4, 2015, entered into in connection with the public offering described below, prohibits us from issuing and selling additional shares of our common stock under this "at-the-market" equity offering program until March 9, 2017.

On November 7, 2014, we sold 626,189 shares of our common stock and warrants to purchase 313,100 shares of our common stock in a registered direct offering. The shares of common stock were sold at a negotiated purchase price of $13.00 per share, and each purchaser received a warrant to purchase one-half of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months after the date of issuance and have a term of exercise of 42 months after the date of issuance and an exercise price of $17.50. This offering resulted in net proceeds to us of approximately $7.4 million after deducting placement agent fees and other estimated offering expenses. Such sales were made pursuant to the $75 million shelf registration statement.

On March 9, 2015, we sold 3,436,968 shares of our common stock and warrants to purchase 3,436,968 shares of our common stock in a public offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of exercise of 5 years from the date of issuance and an exercise price of $5.50. This offering resulted in net proceeds to us of approximately $12.4 million after deducting placement agent fees and other estimated offering expenses. Such sales were made pursuant to the $75 million shelf registration statement.

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 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 $0.59. This offering resulted in gross proceeds to us of approximately $1.1 million.

On March 21, 2016, we sold 1,033,051 shares of our common stock and warrants to purchase 516,526 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 $0.59. 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. Such sales were made pursuant to the $75 million shelf registration statement

As of March 28, 2016, shares of our common stock having an aggregate value of approximately $49.7 million remained available for sale under the shelf registration statement, including approximately $37.7 million remaining available for sale under “at-the-market” equity offering program; however, because our current aggregate value of public float is below $75 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months, and as of March 28, 2016, we have no “shelf capacity” under the $75 million shelf registration statement and cannot make further sales pursuant to such shelf registration statement.

Twelve months ended December 31, 2015 compared to the twelve months ended December 31, 2014

General. At December 31, 2015, we had cash and cash equivalents of $3.3 million, as compared to $6.3 million as of December 31, 2014. 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.

Cash used in our operating activities was $11.6 million for the twelve months ended December 31, 2015 and $19.4 million for the same period in 2014. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2015 were a net loss of $15.6 million, as well as an increase in working capital of $0.2 million, offset by $3.1 million in non-cash share based compensation that was largely paid to our directors, chief executive officer and chief operating officer $0.6 million of non-cash expenses related to the impairment of our royalty buyout option (discussed above), $0.3 million of non-cash financial expenses and $0.2 million of depreciation and amortization expenses. The principal reasons for the usage of cash in our operating activities for the twelve months ended December 31, 2014 were a net loss of $25.1 million, offset by $4.1 million in non-cash share-based compensation that was largely paid to our directors and chief executive officer, a decrease in working capital of $0.9 million, $0.4 million of non-cash financial expense and $0.3 million of depreciation and amortization expenses.

Cash used in our investing activities was $23,000 during the twelve months ended December 31, 2015, compared to $86,000 during the same period in 2014. The decrease in cash used in our investing activities resulted primarily from a decrease in purchases of property, plant and equipment.

Cash provided by financing activities for the twelve months ended December 31, 2015 was $8.6 million, compared to $8.3 million during the same period in 2014. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2015 was the issuance of shares and warrants in a public offering for approximately $12.4 million after deducting placement agent fees and other estimated offering expenses, offset by loan repayments of $3.7 million and $0.1 million of payments made by us in satisfaction of tax withholding obligations associated with the vesting of restricted stock held by some of our employees. The principal source of the cash provided by financing activities during the twelve months ended December 31, 2014 relates to funds received from the issuance of shares in a registered direct offering of $7.4 million and funds received from the issuance of at-the-market shares of $2.2 million, offset by the repayment of a loan of $1.2 million.

As of December 31, 2015, our current liabilities exceeded our current assets by a multiple of 1.5. Current assets decreased by $4.7 million during the period and current liabilities decreased by $1.6 million during the period. As a result, our working capital surplus decreased by $3.1 million to a working capital deficit of $2.3 million at December 31, 2015.

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 April, 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update No. 2015-03, “Simplifying the Presentation of Debt Issuance Costs.” The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued 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, 2016. We are currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, “Revenue from Contracts with Customers,” such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

On July 22, 2015, the FASB issued Accounting Standards Update No. 2015-11, “Simplifying the Measurement of Inventory,” which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out and the retail inventory method are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. We are currently evaluating the impact of the standard on its consolidated financial statements.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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

- Report of Kesselman & Kesselman, Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of December 31, 2015 and 2014
- Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014
- Consolidated Statements of Changes in Equity for the Years Ended December 31, 2015 and 2014
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014
- 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, 2015, 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, 2015.

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, 2015. 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, 2015.

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, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

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

Name	Age	Position
Alan Milinazzo	56	President, Chief Executive Officer and Director
Craig Shore	54	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
James Barry, Ph.D.	56	Executive Vice President, Chief Operating Officer and Director
Sol J. Barer, Ph.D.	68	Chairman of the Board of Directors
Isaac Blech	66	Vice Chairman of the Board of Directors
Michael Berman	58	Director
James J. Loughlin	73	Director
Campbell Rogers, M.D.	54	Director
Paul Stuka	61	Director

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. Alan Milinazzo, Sol J. Barer, Ph.D. and Paul Stuka are our Class 1 directors, with their terms of office to expire at our 2018 annual meeting of stockholders. James J. Loughlin and Michael Berman are our Class 2 directors, with their terms of office to expire at our 2016 annual meeting of stockholders. Isaac Blech, Campbell Rogers, M.D. and James Barry, Ph.D. are our Class 3 directors, with their terms of office to expire at our 2017 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.

On March 24, 2016, Mr. Loughlin notified us that he does not intend to stand for re-election to the board of directors at our 2016 annual meeting of stockholders. Mr. Loughlin's decision not to stand for re-election did not result from any disagreement with us or our management.

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.

Alan Milinazzo has served as our president, chief executive officer and director since January 3, 2013, and will serve in such positions until the earlier of June 30, 2016, or the date upon which a new president and/or chief executive officer commences employment. See "Item 11. Executive Compensation—Agreements with Executive Officers—Alan Milinazzo." Mr. Milinazzo served as president and chief executive officer of Orthofix International N.V., a Nasdaq-listed medical device company, until August 2011, a position he was promoted to in 2006 after being hired a year earlier as chief operating officer. He also served as a director of Orthofix International N.V. from December 2006 until June 2012, and currently serves as a director of Flexion Therapeutics (NSDQ: FLXN) and the Musculoskeletal Transplant Foundation. From 2002 to 2005, Mr. Milinazzo was the general manager of Medtronic, Inc.'s coronary and peripheral vascular businesses. Mr. Milinazzo also spent 12 years as an executive with Boston Scientific Corporation in numerous roles, including vice president of marketing for SCIMED Europe. Mr. Milinazzo has over 20 years of experience in management and marketing, including positions with Aspect Medical Systems and American Hospital Supply. As chief executive officer, Mr. Milinazzo'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.

James Barry, Ph.D. has served as a director since January 30, 2012 and as our executive vice president and chief operating officer since July 14, 2014. Dr. Barry has served as executive vice president and chief operating officer at Arsenal Medical Inc., a medical device company focused on local therapy, since September 2011. Dr. Barry also heads his own consulting firm, Convergent Biomedical Group LLC, advising medtech companies on product development, strategy, regulatory challenges 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 sciences functions. Dr. Barry joined Boston Scientific in 1992 and oversaw its efforts in the identification and development of drug, device and biological systems for applications with 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 and the Massachusetts Life Science Center and 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 20 years of experience in leadership roles in the medical device industry and significant medical technology experience, in particular with respect to interventional cardiology products.

Sol J. Barer, Ph.D. has served as a director since July 11, 2011 and has served as our chairman since November 16, 2011. Dr. Barer has over 25 years of experience with publicly traded biotechnology companies. In 1980, when Dr. Barer was with Celanese Research Company, he formed the biotechnology group that was subsequently spun out to form Celgene Corporation. Dr. Barer spent 18 years leading Celgene Corporation as president, chief operating officer and chief executive officer, culminating with his tenure as Celgene Corporation's executive chairman from June 2010 until January 2011and chairman from May 2006 until June 2010 and from January 2011 until his retirement in June 2011. Dr. Barer is also a director of Cerecor, Inc., Edge Therapeutics, Inc., Medgenics, Inc., Centrexion Corporation, RestorGenex Corporation, ContraFect Corporation, Amicus Therapeutics, Inc. and Aegerion Pharmaceuticals, Inc. and serves as a senior advisor to a number of other biotechnology companies. Dr. Barer received a Ph.D. in organic chemistry from Rutgers University. Dr. Barer brings to the board significant scientific and executive leadership experience in the U.S. biotechnology industry and prior service on the board of directors of other publicly-held biopharmaceutical companies, as well as a unique perspective on the best methods of growth for a biotechnology company.

Isaac Blech has served as a director and our vice chairmen since January 22, 2016. Mr. Blech is a renowned biotechnology entrepreneur and investor, who, over the past 32 years, has founded and served on the board of companies which have produced major advances in a broad array of diseases, including the diagnosis of chlamydia, herpes, syphilis and HIV, and the treatment of cystic fibrosis, sexual dysfunction, multiple myeloma and brain cancer. The companies he established include Celgene Corporation (NASDAQ: CELG), ICOS Corporation, Nova Pharmaceutical Corporation, Pathogenesis Corporation and Genetics Systems Corporation. Mr. Blech's current roles include director and founder of Cerecor, Inc. (NASDAQ: CERC), a public company developing new treatments for central nervous system disorders, director of ContraFect Corporation (NASDAQ: CFRX), a public infectious disease company, director of Medgenics, Inc. (NYSE: MDGN), a public company creating new treatments for rare diseases, and vice chairman of Edge Therapeutics, Inc. (NASDAQ: EDGE), a public company that treats life-threatening neurological conditions. He is vice chairman of Centrexion Corporation, a private company which is developing new modalities of pain control, vice chairman of Regenovation, Inc., a private company developing new ways to regenerate human tissue, vice chairman of X4 Pharmaceuticals, a private cancer immunology company, vice chairman of Sapience Therapeutics, a private oncology company and vice chairman of Aridis Pharmaceuticals, a private company with a product to treat pneumonia. He also serves as vice chairman of WaveGuide Corporation, a private company developing the world's smallest NMR machine, vice chairman of root9B Technologies, Inc. (OTC: RTNB), a public cyber security company, and vice chairman of The SpendSmart Payments Company (OTC: SSPC), a public electronic rewards company.

Our board of directors believes that Mr. Blech's broad experiences as a founder, director and major investor in numerous biotechnology companies provide him with the qualifications and skills to serve as a director.

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 2003 as co-founder and a director of Aetherworks II, a medical device incubator, (ii) since 2004 as a co-founder and director of Benechill, Inc., a company developing a therapeutic hypothermia system for the treatment of cardiac arrest, (iii) 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, (iv) since 2005 as a director of PharmaCentra, LLC, which creates customizable marketing programs that help pharmaceutical companies communicate with physicians and patients, (v) since 2011 as a co-founder and director of Rebiotix Inc., a company developing an innovative treatment for C Diff colitis, (vi) since 2011 as a director of AngioSlide Ltd., a medical device company that has developed an embolic capture angioplasty device, (vii) since 2011 as a director of InterValve, Inc., a medical device company developing an aortic valvuloplasty balloon for treatment of calcific aortic stenosis, (viii) since 2013 as a Director of ClearCut Inc., a medical device company that has developed an MRI system for tumor margin assessment, (ix) since 2013 as a director of PulmOne Ltd., a medical device company developing an innovative Pulmonary Function Testing system, (x) since 2014 as a director of Mazor Robotics, Inc., a publicly held company that has developed and markets an innovative system for robotic surgery, (xi) since 2014 as a director of SoniVie, a medical device company and (xii) since 2014 as a venture partner at RiverVest Ventures. Mr. Berman was a member of the Data Sciences International, Inc. board from 2001 until 2012. 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.

James J. Loughlin has served as our director since September 19, 2012. On March 24, 2016, Mr. Loughlin notified us that he does not intend to stand for re-election to the board of directors at our 2016 annual meeting of stockholders. Mr. Loughlin served as the national director of the pharmaceuticals practice at KPMG LLP, and a five-year term as member of the board of directors of KPMG LLP. Additionally, Mr. Loughlin served as chairman of the pension and investment committee of the KPMG LLP board from 1995 through 2001. He also served as partner in charge of human resources, chairman of the personnel and professional development committee, secretary and trustee of the Peat Marwick Foundation and a member of the pension, operating and strategic planning committees. In addition, Mr. Loughlin has served as a member of the board of directors of Celgene Corporation, a global biopharmaceutical company focused on novel therapies for the treatment of cancer and inflammatory diseases, since 2006, including as chairman of the audit committee since June 2008 and a member of the compensation committee since June 2008. Mr. Loughlin served as a member of the board of directors of Alfacell Corporation, a biopharmaceutical company primarily focused on therapeutic drugs for the treatment of cancer and other pathological conditions, until 2008 and Datascope Corp., a medical device company engaged in the interventional cardiology and radiology, cardiovascular and vascular surgery, and critical care fields, until January 2009. Mr. Loughlin brings to the board his valuable experiences as national director of the pharmaceuticals practice at KPMG LLP, an extensive background in accounting and financial reporting, qualifying him as an audit committee financial expert, and prior service on the board of directors of other publicly-held biopharmaceutical companies.

Campbell Rogers, M.D. has served as a director since September 3, 2013. Dr. Rogers has served as 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, Johnson & Johnson, where he was responsible for leading investments and research in cardiovascular devices, from July 2006 to March 2012. 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. 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 served 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.

Messrs. Milinazzo and Shore and Dr. Barry are parties to certain agreements related to their service as executive officers and directors described under “Item 11. 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. During the last year, we undertook a review of the Section 16(a) reports filed on behalf of each individual who served as our director or executive officer during the fiscal year ended December 31, 2015, to determine whether all of their reportable transactions in our common stock were timely reported and to ensure proper reporting of all of their beneficial holdings. The review revealed that there were a number of transactions that were not timely reported and, as these transactions were identified, we undertook to file corrected forms throughout the year. None of these cases involved purchase or sale, but rather non-market transactions such as shares withheld for payment of tax liability incident to the receipt, exercise or vesting of a security, grant or cancellation of restricted stock awards or stock options, amendment to include previously reported indirectly held shares that were inadvertently omitted and adjustment to reflect the one-for-ten reversed stock split of our common stock effected on October 1, 2015.

The following is the number of late reports filed since the beginning of the fiscal year ended December 31, 2015, under Section 16(a) and the number of transactions reflected therein as not reported on a timely basis during such fiscal year or prior fiscal years by such executive officers and directors:

- Mr. Milinazzo filed four late reports, two with respect to one transaction, one with respect to two transactions and one with respect to five transactions
- Dr. Rogers filed three late reports, each with respect to one transaction
- Mr. Loughlin filed two late reports, each with respect to one transaction
- Mr. Shore filed one late report, each with respect to two transactions
- Eli Bar filed one late report, each with respect to two transactions
- Dr. Barer filed two late reports, each with respect to one transaction. In addition, one Form 4 filed in 2014 and one Form 4 filed in 2015 by Dr. Barer inadvertently omitted previously reported indirectly held shares of common stock, which was subsequently reported in an amendment to Form 4 originally filed on January 28, 2016.
- Mr. Berman filed two late reports, each with respect to one transaction
- Dr. Barry filed three late reports, one with respect to three transactions, one with respect to one transaction and one with respect to one transaction

- Mr. Stuka filed two late reports, each with respect to one transaction. In addition, Mr. Stuka filed a Form 4 on March 7, 2016 with respect to three transactions which had not been previously reported (i) one of which involved issuance of shares of common stock in 2013 as a penalty for failure to effect the listing of our common stock on a national securities exchange by December 31, 2012 to purchasers party to that certain securities purchase agreement, dated as of March 31, 2011, (ii) two of which involved issuance of ratchet shares issued in 2013 and 2014 in connection with our granting of certain options to purchase shares of common stock, pursuant to that certain securities purchase agreement, dated as of March 31, 2011.

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. Loughlin and Stuka and Dr. Barer, 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 MKT rules. Mr. Loughlin 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 and Dr. Barer, each of whom qualify as an independent director under Section 803(A) of the NYSE MKT 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 Loughlin and Dr. Barer, each of whom qualify as an independent director under Sections 803(A) and 805(c)(1) of the NYSE MKT 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.inspire-md.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, 2015 and 2014.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Restricted Stock Awards ($)(1)	Option Awards($)(1)	All Other Compensation ($)	Total ($)
Alan Milinazzo President and Chief Executive Officer (2)	2015	225,000(3)	45,833(4)	428,826 (3)	131,221	20,462 (5)	851,342
	2014	450,000	69,105(6)	553,916	736,482	20,460 (5)	1,829,963
Craig Shore Chief Financial Officer, Secretary and Treasurer	2015	224,481(7)	17,349(4)(7)	33,750	33,479	74,318 (7)(8)	383,377 (7)
	2014	214,525	22,331(6)	327,013	322,817	59,276 (8)	945,962
James Barry, Ph.D. Executive Vice President and Chief Operating Officer	2015	300,333(9)	37,500(4)	127,167 (10)	16,740	19,936 (11)	532,093
	2014	183,812(12)	25,914(6)	391,500	802,545 (13)	123,748 (14)	1,527,519

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(1) The amounts reflect the dollar amounts recognized for financial statement reporting purposes with respect to the twelve month periods ended December 31, 2015 and 2014 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” and Note 2-“Significant Accounting Policies” and Note 10-“Equity” of the Notes to the Consolidated Financial Statements for the Twelve Months Ended December 31, 2015 included herein.

(2) Mr. Milinazzo served as our director during the twelve months ended December 31, 2015 and 2014, but did not receive any additional compensation for his services as director.

(3) Pursuant to amendments to employment agreement with Mr. Milinazzo, dated January 5, 2016, and June 29, 2015, Mr. Milinazzo received 50% of his base salary for January 2015 through December 31, 2015, or $225,000, in 31,250 shares of restricted common stock, which was issued on January 26, 2015, and 63,825 shares of restricted common stock, which was issued on December 31, 2015. See “—Agreements with Executive Officers—Alan Milinazzo.”

(4) Bonuses for the 2015 calendar year were approved by the Compensation Committee in July 2015.

(5) Mr. Milinazzo’s other compensation consisted solely of benefits related to health insurance.

(6) Bonuses for the 2014 calendar year were approved by the Compensation Committee in January 2015.

(7) The change in salary from 2014 to 2015 is exclusively due to the difference in the exchange rate for the applicable period. 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 3.769 NIS per dollar and 3.889 NIS per dollar, which were the exchange rates as of June 30, 2015 and December 31, 2014. The average exchange rate for the twelve month period ended December 31, 2015 and 2014 were 3.884 NIS per dollar and 3.58 NIS per dollar, respectively.

(8) Mr. Shore’s other compensation consisted solely of benefits in the twelve months ended December 31, 2015 and 2014. 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.

(9) Includes $26,583 of salary forgone at the election of Dr. Barry, representing 50% of his salary from March 10, 2015 through April 30, 2015 in exchange for 3,692 shares of restricted common stock. See “—Agreements with Executive Officers—James Barry.”

(10) Includes 4,757 shares of restricted common stock we issued to Dr. Barry in lieu of 50% of his base salary pursuant to amendments to employment agreement with Dr. Barry, dated January 5, 2016, and dated February 22, 2015. See “—Agreements with Executive Officers—James Barry.”

(11) Dr. Barry’s other compensation consisted solely of benefits related to health insurance.

(12) Dr. Barry’s salary compensation includes $15,000 of fees earned as a director during the twelve months ended December 31, 2014.

(13) Includes the fair value of options granted to Dr. Barry as a director of $94,909 during the twelve months ended December 31, 2014.

(14) Dr. Barry’s other compensation in the twelve months ended December 31, 2014 consisted of $115,000 of consulting fees and $8,748 of benefits related to health insurance

Agreements with Executive Officers

Alan Milinazzo

On January 3, 2013, we entered into an employment agreement with Alan Milinazzo to serve as our president, chief executive officer and a director, which was first amended on April 24, 2013, and further amended on January 5, 2015, June 29, 2015, and January 21, 2016. The employment agreement, as amended, will continue until the earlier of June 30, 2016 or the date upon which a new president and/or chief executive officer (or executive performing a similar role) commences employment with us (or, if such individual is promoted internally, the date such individual is promoted to the position of president and/or chief executive officer).

Under the employment agreement, as amended, Mr. Milinazzo is entitled to an annual base salary of at least $450,000. 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. Milinazzo, 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). The base salary will be reviewed annually by the board for increase as part of its annual compensation review. Mr. Milinazzo is also eligible to receive an annual bonus of at least $275,000 upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with Mr. Milinazzo on or before the end of the first quarter of the fiscal year to which the bonus relates and, in the event actual performance exceeds the goals, the board may, in its sole discretion, pay Mr. Milinazzo bonus compensation of more than $275,000. The annual bonus amount will be less than $275,000 if the target objectives and performance goals are not met. In addition, Mr. Milinazzo is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion.

On January 5, 2015, we amended Mr. Milinazzo’s employment agreement to provide that, for a limited period of time to be mutually agreed to by us and Mr. Milinazzo, Mr. Milinazzo will receive 50% of his base salary in cash payments, with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock, payable and granted in equal installments in accordance with our normal payroll practices. These shares of restricted stock were to vest immediately and be valued as of the closing price of our common stock on the date of grant. Notwithstanding the foregoing agreement, at Mr. Milinazzo’s request, no shares of restricted common stock were granted to Mr. Milinazzo pursuant to this amendment. Rather, we and Mr. Milinazzo determined that it would be in our mutual best interest to make a single grant of shares of restricted common stock to Mr. Milinazzo having a fair market value, as of the date of grant, equal to 50% of his annual base salary, with such shares vesting on the first anniversary of the date of grant, as opposed to making bi-weekly grants of restricted common stock to Mr. Milinazzo. As such, on January 26, 2015, we issued 31,250 shares of restricted common stock valued at $7.20 per share, representing the fair market value of our common stock as of the market close on January 26, 2015, in lieu of 50% of his base salary for his employment in 2015, to vest on January 26, 2016.

On June 29, 2015, we further amended Mr. Milinazzo's employment agreement to memorialize the payroll adjustment that was made to Mr. Milinazzo's manner of salary payment on January 26, 2015 and to provide certain additional changes. Specifically, this amendment provided that, until we raise an aggregate of $5 million from investors, Mr. Milinazzo will receive (A) with respect to his employment in 2015, 50% of his base salary in cash payments, with the remaining 50% having been paid to Mr. Milinazzo on January 26, 2015, through the issuance of 31,250 shares of restricted common stock as discussed above, which will be subsequently adjusted based upon the volume-weighted average price of our common stock during the calendar year ended December 31, 2015 (or during the period from January 2, 2015 through his termination date if Mr. Milinazzo's employment is terminated upon his death or disability, by Mr. Milinazzo for good reason, or by us without cause prior to December 31, 2015) to represent the equivalent of 50% of Mr. Milinazzo's base salary in 2015. On December 31, 2015, we issued an additional 63,825 shares of restricted common stock as an adjustment pursuant to such amendment, as the value of our common stock declined following the grant to Mr. Milinazzo on January 26, 2015.

On January 21, 2016, we further amended Mr. Milinazzo's employment agreement to provide that, during the remaining term of his employment, Mr. Milinazzo will receive (A) 50% of his base salary in cash payments, for all days that Mr. Milinazzo works during the remaining term of his employment, at the monthly rate of $18,750, payable in accordance with our regular payroll practices, and (B) a lump-sum payment equivalent to 50% of Mr. Milinazzo's base salary through June 30, 2016, at the monthly rate of $18,750, payable within 20 business days from the earlier of (x) us raising an aggregate of $5 million from investors, or (y) June 30, 2016.

In accordance with Mr. Milinazzo's employment agreement, on January 3, 2013, we granted Mr. Milinazzo a nonqualified stock option to purchase 52,593 shares of our common stock, made pursuant to a nonqualified stock option agreement, an incentive stock option to purchase 7,408 shares of our common stock, made pursuant to an incentive stock option agreement, and 40,000 shares of restricted stock, which are subject to forfeiture until the vesting of such shares, made pursuant to a restricted stock award agreement. The options have an exercise price of $40.50, which was the fair market value of our common stock on the date of grant. The options are subject to a three-year vesting period subject to Mr. Milinazzo's continued service with us, with one-thirty-sixth (1/36th) of such awards vesting each month. The shares of restricted stock initially vested monthly over thirty-six months, with 1/36 vesting on February 3, 2013, March 3, 2013 and April 3, 2013. The grant was then amended to vest annually over three years, with 9/36 vesting on January 3, 2014, and one-third vesting on January 3, 2015 and January 3, 2016. On or before December 31 of each calendar year, Mr. Milinazzo will be eligible to receive an additional grant of equity awards equal, in the aggregate, to up to 0.5% of actual outstanding shares of our common stock on the date of grant, provided that the actual amount of the grant will be based on his achievement of certain performance objectives as established by the board, in its reasonable discretion, for each such calendar year. Each additional grant will, with respect to any awards that are options, have an exercise price equal to the fair market value of our common stock, and will be subject to a three-year vesting period subject to Mr. Milinazzo'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. In connection with the equity compensation related to 2013 achievements, on January 29, 2014, Mr. Milinazzo was granted stock options to purchase 8,633 shares of common stock and 8,633 restricted shares. In connection with the equity compensation related to 2014 achievements, on January 26, 2015, Mr. Milinazzo was granted stock options to purchase 5,300 shares of common stock and 5,300 restricted shares.

Mr. Milinazzo's employment agreement, as amended, also contains certain noncompetition, no solicitation, confidentiality, and assignment of inventions requirements for Mr. Milinazzo.

Pursuant to Mr. Milinazzo's employment agreement, as amended, if Mr. Milinazzo's employment is terminated upon his death or disability, by Mr. Milinazzo for good reason (as such term is defined in Mr. Milinazzo's employment agreement, as amended), or by us without cause (as such term is defined in Mr. Milinazzo's employment agreement, as amended), Mr. Milinazzo will be entitled to receive, in addition to other unpaid amounts owed to him (e.g., for base salary and accrued vacation): (i) any unpaid incentive compensation (as such term is defined in the employment agreement, as amended) actually earned or owing as of the termination date; (ii) vesting of 100% of all unvested stock options, restricted stock, stock appreciation rights or similar stock based rights granted to Mr. Milinazzo, and lapse of any forfeiture included in such restricted or other stock grants; (iii) an extension of the exercise period of any outstanding stock options or stock appreciation rights until the earlier of (a) two (2) years 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; and (v) to the fullest extent permitted by our then-current benefit plans, continuation of benefits coverage for the lesser of 12 months after termination or until Mr. Milinazzo obtains coverage from a new employer. If, during the term of the employment agreement, as amended, we terminate Mr. Milinazzo's employment for cause or Mr. Milinazzo voluntarily terminates his employment, Mr. Milinazzo 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.

Mr. Milinazzo 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) Mr. Milinazzo terminates his employment for good reason, or (b) we terminate his employment without cause, the lump sum severance payment to which he is entitled will be equal to 200% of his base salary, and all stock options, restricted stock, stock appreciation rights or similar stock-based rights granted to him will vest in full and be immediately exercisable and any risk of forfeiture included in restricted or other stock grants previously made to him will immediately lapse.

Pursuant to an option cancellation and release agreement, dated January 26, 2016, between us and Mr. Milinazzo, Mr. Milinazzo agreed to cancel options to purchase 160,488 shares of our common stock at exercise prices ranging from $7.20 to $40.50 previously granted to him. In exchange for the cancellation of Mr. Milinazzo's options, we granted to Mr. Milinazzo, 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. Pursuant to the employment agreement, 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. On May 5, 2014, we entered into an amended and restated employment agreement with Mr. Shore. The employment agreement, as amended, has an initial term that ends on April 20, 2017 and will automatically renew for additional one-year periods on April 21, 2017 and on each April 21st thereafter unless either party gives the other party written notice of its election not to extend such employment at least six months prior to the next April 21st renewal date. If a change in control occurs when less than two full years remain in the initial term or during any renewal term, the employment agreement will automatically be extended for two years from the change in control date and will terminate on the second anniversary of the change in control date. Under the terms of the employment agreement, Mr. Shore is entitled to an annual base salary of at least $220,000, retroactive to January 1, 2014. 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 45% 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 and based on the percentages set forth in his employment agreement. 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 corresponding percentages for the goals, as part of our annual compensation review. In addition, Mr. Shore is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion. Mr. Shore will also be considered for grants of equity awards each year as part of the board's annual compensation review, which will be made at the sole discretion of the board of directors. Each grant will, with respect to any awards that are options, have an exercise price equal to the fair market value of our common stock as of the date of grant, and will be subject to a three-year vesting period subject to Mr. Shore's continued service with us, with one-third of each additional grant vesting equally on the first, second, and third anniversary of the date of grant for such awards.

If during the term of the employment agreement, Mr. Shore's employment is terminated upon his death or disability or by us without cause (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 50% of all unvested stock options granted to him; (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 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) Mr. Shore terminates his employment for good reason, or (b) we terminate Mr. Shore's employment without cause, he is entitled to receive the full lump sum severance payment equal to 100% of his base salary and all stock options, stock appreciation rights or similar stock-based rights granted to him will vest in full and be immediately exercisable and any risk of forfeiture included in restricted or other stock grants previously made to him will immediately lapse. Furthermore, 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. We have also agreed orally that, upon Mr. Shore's termination of service as a result of death, disability, resignation for "good reason" or termination by us without "cause," Mr. Shore will also be entitled to receive: (a) 50% vesting of all unvested stock options, restricted stock, restricted stock units, stock appreciation rights or similar stock based rights outstanding at the time of termination of service; and (b) the right to exercise any outstanding stock options or stock appreciation rights for a period equal to the lesser of (x) two years from the date of termination of service, or (y) the period remaining until the original expiration date of any such outstanding stock options or stock appreciation rights.

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, 2014 was $51,615, 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, 2014, Mr. Shore would have been entitled to receive $67,564 in severance under Israeli law, thereby requiring us to pay Mr. Shore $15,949, in addition to releasing the $51,615 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 vacation days accrued.

The employment agreement also contains certain standard noncompetition, no 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 44,350 shares of our common stock at exercise prices ranging from $7.20 to $49.29 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.

James Barry

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 on March 28, 2016. Dr. Barry was previously a director and continues his role as a director. The employment agreement has an initial term that ends on July 14, 2017 and will automatically renew for additional one-year periods on July 17, 2017 and on each July 17 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 July 17 renewal date. If a change in control occurs when less than two full years remain in the initial term or during any renewal term, the employment agreement will automatically be extended for two years from the change in control date and will terminate on the second anniversary of the change in control date.

Under the 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). The base salary will be reviewed annually by the board for increase as part of its annual compensation review. Dr. Barry is also eligible to receive an annual bonus of $225,000 upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with Dr. Barry on or before the end of the first quarter of the fiscal year to which the bonus relates and, in the event actual performance exceeds the goals, the board may, in

its sole discretion, pay Dr. Barry bonus compensation of more than $225,000. In addition, Dr. Barry is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion.

On January 5, 2015, we amended Dr. Barry's employment agreement to provide that, for a limited period of time to be mutually agreed to by us and Dr. Barry, Dr. Barry will receive 50% of his base salary in cash payments, with the remaining 50% to be paid in an equivalent amount of shares of restricted common stock, payable and granted in equal installments in accordance with our normal payroll practices. These shares of restricted stock were to vest immediately and be valued as of the closing price of our common stock on the date of grant. Notwithstanding the foregoing agreement, at Dr. Barry's request, no shares of restricted common stock were granted to Dr. Barry pursuant to this amendment. Rather, we and Dr. Barry determined that it would be in our mutual best interest to make a single grant of shares of restricted common stock to Dr. Barry having a fair market value, as of the date of grant, equal to 50% of his annual base salary, with such shares vesting on the first anniversary of the date of grant, as opposed to making bi-weekly grants of restricted common stock to Dr. Barry. As such, , on January 26, 2015, we issued 19,011 shares of restricted common stock valued at $7.20 per share, representing the fair market value of our common stock as of the market close on January 26, 2015, in lieu of 50% of his base salary for his employment in 2015, to vest on January 26, 2016.

On February 22, 2015, we further amended Dr. Barry's employment agreement to memorialize the payroll adjustment that was made to Dr. Barry's manner of salary payment on January 26, 2015 and to provide certain additional changes. Specifically, this amendment provided that, until the earlier of (1) September 30, 2015 and (2) we raise an aggregate of $5 million from investors, Dr. Barry shall receive 50% of his base salary in cash payments, with the remaining 50% having been paid to Dr. Barry on January 26, 2015, through the issuance of 19,011 shares of restricted stock as discussed above. Notwithstanding the foregoing, with Dr. Barry's consent, Dr. Barry continued to receive only 50% of his base salary in cash from March 9, 2015, the date of the closing of our offering from which we received gross proceeds of approximately $13.7 million, until April 30, 2015. As we commenced full cash payment of Dr. Barry's salary on April 30, 2015, Dr. Barry forfeited 10,562 shares of restricted stock on May 1, 2015, which represented the shares of restricted common stock previously granted to Dr. Barry to cover 50% of his base salary from May 1, 2015 through December 31, 2015. The remaining such shares of restricted stock issued to Dr. Barry on January 26, 2015 in lieu of cash base salary fully vested on January 26, 2016.

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 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.

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 150% 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 50% 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, 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, the lump sum severance payment to which he is entitled will be increased from 150% of his base salary to 250% of his base salary and all stock options, restricted stock units, stock appreciation rights or similar stock-based rights granted to him will vest in full and be immediately exercisable and any risk of forfeiture included in restricted or other stock grants previously made to him will immediately lapse.

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 67,677 shares of our common stock at exercise prices ranging from $7.20 to $78.00 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.

2015 Grants of Plan-Based Awards

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#) (1)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
Alan Milinazzo	01/26/2015	15,209			109,500
President and Chief Executive	01/26/2015	5,300			38,159
Officer	01/26/2015	31,250			225,000
	01/26/2015		5,300	7.2	22,599
	01/26/2015		25,474	7.2	108,622
	12/31/2015	63,825			56,166
Craig Shore	01/26/2015	4,688			33,750
Chief Financial Officer, Secretary and Treasurer	01/26/2015		7,852	7.2	33,479
James Barry, Ph.D.	01/26/2015		3,926	7.2	16,740
Executive Vice President and Chief Operating Officer	01/26/2015	10,793			77,708

(1) On January 26, 2016, we entered into an option cancellation and release agreement with each of the named executive officers included in the table above, pursuant to which the parties agreed to cancel options which their exercise prices is ranging from $7.20 to $78.00 previously granted to each of the named executive officers included in the table above.

Outstanding Equity Awards at December 31, 2015

The following table shows information concerning unexercised options and unvested restricted shares outstanding as of December 31, 2015 for each of our named executive officers.

	Option Awards					Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable (15)		Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($)
Alan Milinazzo	58,334	1,667	(1)	40.5	1/3/2023		
						13,330 (2)	11,730
	19,830	9,915	(3)	20.5	4/23/2023		
						5,995 (4)	5,276
	2,878	5,755	(5)	31.0	1/27/2024		
						5,755 (6)	5.064
	10,445	20,890	(7)	29.7	1/29/2024		
						6,426 (8)	5,655
	-	30,774	(9)	7.2	1/25/2025		
						15,209 (10)	13,384
						5,300 (10)	4,664
						31,250 (11)	27,500
Craig Shore	9,131	-		49.285	2/27/2021		
	7,500	-		32.0	5/24/2022		
	1,667	833	(13)	29.5	5/7/2023		
	2,567	5,133	(5)	31.0	1/27/2024		
						5,133 (6)	4,517
	3,222	6,445	(7)	29.7	1/29/2024		
						1,982 (8)	1,744
	-	7,852	(9)	7.2	1/25/2025		
						4,688 (10)	4,125
James Barry	2,500	-		78.0	1/30/2022		
	1,250	-		31.6	6/17/2022		
	6,667	3,333	(12)	27.5	5/7/2023		
	1,667	3,333	(5)	31.0	1/27/2024		
						10,000 (13)	8,800
	15,000	30,001	(14)	26.1	7/11/2024		
	-	3,926	(9)	7.2	1/25/2025		
						2,344 (10)	2,063
						8,449 (11)	7,435

(1) These options will vest on January 3, 2016.
(2) These restricted shares will vest on January 3, 2016.
(3) These options will vest on April 25, 2016.
(4) These restricted shares will vest on April 25, 2016.
(5) These options vest annually, with one-half vesting on each of January 29, 2016 and January 29, 2017.
(6)

	These restricted shares vest annually, with one-half vesting on each of January 29, 2016 and January 29, 2017.
(7)	These options vest annually, with one-half vesting on each of January 31, 2016 and January 31, 2017.
(8)	These restricted shares vest annually, with one-half vesting on each of January 31, 2016 and January 31, 2017.
(9)	These options vest annually, with one-third vesting on each of January 26, 2016, January 26, 2017 and January 26, 2018.
(10)	These restricted shares vest annually, with one-third vesting on each of January 26, 2016, January 26, 2017 and January 26, 2018.
(11)	These restricted shares will vest on January 26, 2016.
(12)	These restricted shares will vest on May 9, 2016.
(13)	These restricted shares vest annually, with one-half vesting on each of July 14, 2016 and July 14, 2017.
(14)	These options vest annually, with one-half vesting on each of July 14, 2016 and July 14, 2017.
(15)	On January 26, 2016, we entered into an option cancellation and release agreement with each of the named executive officers included in the table above, pursuant to which the parties agreed to cancel options which their exercise prices is ranging from $7.20 to $78.00 previously granted to each of the named executive officers included in the table above.

Option Exercises and Stock Vested

There were no stock options exercised by our named executive officers during the twelve months ended December 31, 2015.

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 500,000 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. A total of 500,000

shares of common stock are reserved for awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan.

The InspireMD, Inc. 2013 Long-Term Incentive Plan is intended 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.

On September 9, 2015, our 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 Plan by 470,000 shares of common stock, to a total of 970,000 shares of common stock.

Director Compensation

The following table shows information concerning our directors, other than Alan Milinazzo and James Barry, Ph.D., during the twelve months ended December 31, 2015.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	**Option Awards [1] ($)**	All Other Compensation ($)	Total ($)
Sol J. Barer, Ph.D.	8,750	—	80,629	—	89,379
Paul Stuka	9,750	—	69,385	—	79,134
James J. Loughlin	10,250	—	71,760	—	82,010
Michael Berman	8,000	—	61,070	—	69,070
Campbell Rogers, M.D.	6,750	—	55,132	—	61,882

(1) The amounts in this column reflect the dollar amounts recognized for financial statement reporting purposes with respect to the twelve months ended December 31, 2015, 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” and Note 2-“Significant Accounting Policies” and Note 9-“Equity” of the Notes to the Consolidated Financial Statements for the Year Ended December 31, 2015 included herein.

Name	Shares Subject to Options		Grant Date	Exercise Price	Vesting Schedule	Expiration	Fair Market Value on Grant Date
Sol J. Barer, Ph.D.	4,162	(1)(6)	January 5, 2015	$ 7.8	Fully vested as of grant date	January 5, 2025	$ 17,380
	9,161	(2)(6)	January 26, 2015	$ 7.2	One-third annually in 2016, 2017 and 2018 on the anniversary of the date of grant, provided that Dr. Barer is providing services to us or our subsidiaries or affiliates on the applicable vesting date.	January 26, 2025	$ 39,059
	4,389	(3)	March 31, 2015	$ 3.2	Fully vested as of grant date	March 31, 2025	$ 7,971
	4,967	(4)	June 30, 2015	$ 2.8	Fully vested as of grant date	June 30, 2025	$ 8,060
	8,155	(5)	September 30, 2015	$ 1.7	Fully vested as of grant date	September 30, 2025	$ 8,159
Paul Stuka	4,637	(1)(6)	January 5, 2015	$ 7.8	Fully vested as of grant date	January 5, 2025	$ 19,366
	5,409	(2)(6)	January 26, 2015	$ 7.2	One-third annually in 2016, 2017 and 2018 on the anniversary of the date of grant, provided that Mr. Stuka is providing services to us or our subsidiaries or affiliates on the applicable vesting date.	January 26, 2025	$ 23,064
	4,891	(3)	March 31, 2015	$ 3.2	Fully vested as of grant date	March 31, 2025	$ 8,882
	5,534	(4)	June 30, 2015	$ 2.8	Fully vested as of grant date	June 30, 2025	$ 8,981
	9,087	(5)	September 30, 2015	$ 1.7	Fully vested as of grant date	September 30, 2025	$ 9,091
James J. Loughlin	4,875	(1)(6)	January 5, 2015	$ 7.8	Fully vested as of grant date	January 5, 2025	$ 20,359
	5,409	(2)(6)	January 26, 2015	$ 7.2	One-third annually in 2016, 2017 and 2018 on the anniversary of the date of grant, provided that Mr. Loughlin is providing services to us or our subsidiaries or affiliates on the applicable vesting date.	January 26, 2025	$ 23,064
	5,142	(3)	March 31, 2015	$ 3.2	Fully vested as of grant date	March 31, 2025	$ 9,338
	5,818	(4)	June 30, 2015	$ 2.8	Fully vested as of grant date	June 30, 2025	$ 9,442
	9,553	(5)		$ 1.7	Fully vested as of grant date		$ 9,558

			September 30, 2015			September 30, 2025	
Michael Berman	3,805	(1)(6)	January 5, 2015	$ 7.8	Fully vested as of grant date	January 5, 2025	$ 15,890
	5,409	(2)(6)	January 26, 2015	$ 7.2	One-third annually in 2016, 2017 and 2018 on the anniversary of the date of grant, provided that Mr. Berman is providing services to us or our subsidiaries or affiliates on the applicable vesting date.	January 26, 2025	$ 23,064
	4,013	(3)	March 31, 2015	$ 3.2	Fully vested as of grant date	March 31, 2025	$ 7,228
	4,541	(4)	June 30, 2015	$ 2.8	Fully vested as of grant date	June 30, 2025	$ 7,369
	7,456	(5)	September 30, 2015	$ 1.7	Fully vested as of grant date	September 30, 2025	$ 7,460
Campbell Rogers, M.D.	3,210	(1)(6)	January 5, 2015	$ 7.8	Fully vested as of grant date	January 5, 2025	$ 13,407
	5,409	(2)(6)	January 26, 2015	$ 7.2	One-third annually in 2016, 2017 and 2018 on the anniversary of the date of grant, provided that Mr. Rogers is providing services to us or our subsidiaries or affiliates on the applicable vesting date.	January 26, 2025	$ 23,064
	3,386	(3)	March 31, 2015	$ 3.2	Fully vested as of grant date	March 31, 2025	$ 6,149
	3,832	(4)	June 30, 2015	$ 2.8	Fully vested as of grant date	June 30, 2025	$ 6,218
	6,291	(5)	September 30, 2015	$ 1.7	Fully vested as of grant date	September 30, 2025	$ 6,294

(1) These options were granted in lieu of the cash compensation that was owed to them for their services as directors for the third and fourth calendar quarters of 2014.

(2) These options were granted as the director's 2015 annual director compensation.

(3) These options were granted in lieu of the cash compensation for their services as directors for the first calendar quarter of 2015.

(4) These options were granted in lieu of the cash compensation for their services as directors for the second calendar quarter of 2015.

(5) These options were granted in lieu of the cash compensation for their services as directors for the third calendar quarter of 2015.

(6) On January 26, 2016, we entered into an option cancellation and release agreement with each of the directors , pursuant to which the parties agreed to cancel options which their exercise prices is ranging from $7.20 to $100.00 previously granted to each of the directors.

For the 2014 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 50,000 shares of our common stock for each board member; and (v) an option to purchase an additional 35,000 shares of our common stock for the chairman of the board.

On January 5, 2015, our compensation committee amended its compensation policy for directors to provide that effective as of July 1, 2014, each director would forego any cash compensation in exchange for such number of immediately vested 10 year stock options having a Black-Scholes value equal to the cash compensation otherwise due to such director under our current director compensation policies. As a result of such amendment, on January 5, 2015, we granted to each of Dr. Barer, Mr. Berman, Mr. Loughlin, Dr. Rogers and Mr. Stuka options to purchase 41,611, 38,045, 48,745, 32,100 and 46,367 shares of common stock, respectively, in lieu of the cash compensation that was owed to them for their services as directors for the third and fourth calendar quarters of 2014 (which was $17,500, $16,000, $20,500, $13,500 and $19,500, respectively). Each of these options has a term of 10 years, an exercise price of $0.78 per share, the closing price of our common stock on the date of the grant, and vested immediately. On January 26, 2016, we entered into an option cancellation and release agreement with the directors, pursuant to which the parties agreed to cancel options which their exercise prices is ranging from $7.20 to $100.00 previously granted to each of the directors.

Directors' and Officers' Liability Insurance

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

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2015, Messrs. Stuka and Loughlin and Dr. Barer served on our compensation committee. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

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

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 28, 2016 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., 321 Columbus Avenue, Boston, MA 02116. As of March 28, 2016, we had 10,726,841 shares outstanding.

Name of Beneficial Owner	Number of Shares Beneficially Owned [1]		Percentage Beneficially Owned [1]	
5% Owners				
Sabby Management LLC. [2]	1,878,871	[3]	16.38	%
Officers and Directors				
Alan W. Milinazzo	172,180	[4]	1.6	%
Craig Shore	15,437	[5]	*	
Sol J. Barer, Ph.D.	2,085,046	[6]	18.13	%
James Barry, Ph.D.	23,605	[7]	*	
Michael Berman	19,011	[8]	*	
James J. Loughlin	97,014	[9]	*	
Campbell Rogers, M.D.	26,221	[10]	*	
Paul Stuka	429,300	[11]	3.94	%
All directors and executive officers as a group (8 persons)	2,867,814		24.39	%

*Represents ownership of less than one percent.

(1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assumes the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 28, 2016. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

(2) Sabby Management LLC's address is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458

(3) Based on our knowledge, including Amendment No. 1 to Schedule 13G filed with the Securities and Exchange Commission on January 12, 2016, comprised of (i) 1,045,698 shares of common stock owned directly by Sabby Healthcare Master Fund, Ltd., (ii) 92,787 shares of common stock owned directly by Sabby Volatility Warrant Master Fund, Ltd., (iii) warrants to purchase 57,693 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2015 owned directly by Sabby Healthcare Volatility Master Fund, Ltd., (iv) warrants to purchase 370,193 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2015 owned directly by Sabby Volatility Warrant Master Fund, Ltd. and (v) warrants to purchase 312,500 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2015 owned directly by Sabby Healthcare Master Fund, Ltd. Sabby Management, LLC serves as the investment manager of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. Hal Mintz serves as manager of Sabby Management, LLC. As such, Sabby Management, LLC and Hal Mintz may be deemed to beneficially own these securities.

(4) Includes warrants to purchase 13,462 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(5) Includes warrants to purchase 75 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(6) Includes options to purchase 90,011 shares of common stock and warrants to purchase 683,345 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(7) Includes warrants to purchase 962 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(8) Includes options to purchase 16,010 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(9) Includes options to purchase 20,513 shares of common stock and warrants to purchase 25,000 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(10) Includes options to purchase 13,509 shares of common stock and warrants to purchase 4,237 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

(11) Paul Stuka is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of the (i) 267,060 shares of common stock and (ii) currently exercisable warrants to purchase 80,228 shares of common stock held by Osiris Investment Partners, L.P., in addition to personally holding options to purchase 19,512 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016 and warrants to purchase 62,500 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2016.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2015 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 (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	677,762		24.2	458,533
Equity compensation plans not approved by security holders	87,722	(1)	68.42	-
Total	765,484		29.26	

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

- In April 2008, we issued options to purchase 147 shares of common stock to a provider of finder services who assisted InspireMD Ltd. in raising funds in 2008. The exercise price of these options is $49.285 per share. These options are fully vested and expire in June 2016.

- Options issued to current director: in November 2011, we issued options to purchase an aggregate of 72,500 shares of common stock to Dr. Barer, the chairman of our board of directors. The exercise price of these options is $78 per share. An option to purchase 18,125 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 18,125 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 36,250 shares of common stock vests 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 vesting on November 30, 2011, provided that Dr. Barer is still providing services to us in some capacity as of each such vesting date.

- Warrant issued to current officer: in March 2011, for work performed in connection with the share exchange transactions and as bonus compensation, we issued Mr. Shore, our chief financial officer, secretary and treasurer, a five-year warrant to purchase up to 75 shares of common stock at an exercise price of $72 per share.

- Options issued to current vice president of global marketing and strategy: in September 2013, we issued options to purchase 15,000 shares of common stock to David Blossom. The exercise price of these options was $22.3 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 September 16, 2023.

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

On November 7, 2014, we closed a registered direct offering of approximately 626,000 shares of common stock and warrants to purchase up to approximately 313,000 million shares of common stock at a price of $13.00 per share, for gross proceeds of $8.1 million, before deducting placement agents' fees and estimated offering expenses. Each purchaser received a warrant to purchase 0.5 of a share of common stock for each share of common stock that it purchased in the offering. The warrants are non-exercisable for six months and have a term of exercise of 42 months from the date of issuance and an exercise price of $17.50. The purchasers in the offering included Dr. Barer, the chairman of our board of directors, who purchased 19,231 shares of common stock and warrants to purchase 9,616 shares of common stock, for a purchase price of $250,000, Mr. Milinazzo, our president and chief executive officer, and Dr. Barry, our executive vice president and chief operating officer, who each purchased 1,924 shares of common stock and warrants to purchase 962 shares of common stock, for a purchase price of $25,000, and Rick Olson, our then-current vice president of global sales and operations of InspireMD Ltd, who purchased 11,539 shares of common stock and warrants to purchase 5,770 shares of common stock, for a purchase price of $150,000.

On March 9, 2015, we closed a public offering of approximately 34.4 million shares of common stock and warrants to purchase up to approximately 34.4 million shares of common stock at a price of $5.5 per share, for gross proceeds of $13.7 million, before deducting placement agents' fees and estimated offering expenses. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the offering. The warrants have a term of exercise of five years from the date of issuance and an exercise price of $5.5. The purchasers in the offering included: Dr. Barer, the chairman of our board of directors, who purchased 250,000 shares of common stock and warrants to purchase 250,000 shares of common stock, for a purchase price of $1,000,000, Osiris Investment Partners, L.P., of which Mr. Stuka, our director, is the principal and managing member, which purchased 62,500 shares of common stock and warrants to purchase 62,500 shares of common stock, for a purchase price of $250,000 and Mr. Milinazzo, our president and chief executive officer, who purchased 12,500 shares of common stock and warrants to purchase 12,500 shares of common stock, for a purchase price of $50,000.

On March 21, 2016, we sold 1,900,000 shares of our common stock and warrants to purchase 950,000 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 $0.59. The purchasers in the offering included Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., for which Sabby Management LLC serves as the investment manager, who purchased an aggregate of 750,000 shares of common stock and warrants to purchase 375,000 shares of common stock, for a purchase price of $442,500.

On March 21, 2016, we closed a private placement of 1,033,051 shares of our common stock and warrants to purchase up to 516,526 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 847,458 shares of common stock and warrants to purchase 423,729 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 127,119 shares of common stock and warrants to purchase 63,560 shares of common stock, for a purchase price of $75,000, Mr. Loughlin, our director, who purchased 50,000 shares of common stock and warrants to purchase 25,000 shares of common stock, for a purchase price of $29,500 and Dr. Rogers, our director, who purchased 8,474 shares of common stock and warrants to purchase 4,237 shares of common stock, for a purchase price of $5,000.

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 Drs. Barer and Rogers and Messrs. Loughlin, Stuka, Berman and Blech satisfy the requirement for independence set out in Section 803 of the NYSE MKT 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 MKT 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, 2015 and 2014 are described below.

Audit Fees

Kesselman billed us audit fees in the aggregate amount of $119,000 and $170,500 for the year ended December 31, 2015 and 2014, respectively. These fees relate to the audit of our annual financial statements and the review of our interim quarterly financial statements.

Audit-Related Fees

Kesselman billed us audit-related fees in the aggregate amount of $47,000 and $67,000 for the year ended December 31, 2015 and 2014, respectively. The fees for the year ended December 31, 2015 mostly related to our prospectus supplement filed with the Securities and Exchange Commission on March 4, 2015.

The fees for the year ended December 31, 2014 related to performance of audit-related services for our registration statement on Form S-8 initially filed with the Securities and Exchange Commission on June 5, 2014 our prospectus supplement initially filed with the Securities and Exchange Commission on November 5, 2014 and in connection with our evaluation of certain abandoned transactions.

Tax Fees

Kesselman billed us tax fees in the aggregate amount of $51,525 and $42,275 for the year ended December 31, 2015 and 2014, 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, 2015 and 2014.

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, 2015 and 2014
- Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014
- Consolidated Statements of Changes in Equity for the Years Ended December 31, 2015 and 2014
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014
- Notes to Consolidated Financial Statements

2. Financial Statement Schedules

None

3. Exhibits

See Index to Exhibits

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INSPIREMD, INC.

Date: March 28, 2016 By: /s/ Alan Milinazzo
Alan Milinazzo
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Alan Milinazzo Alan Milinazzo	President, Chief Executive Officer and Director (principal executive officer)	March 28, 2016
/s/ Craig Shore Craig Shore	Chief Financial Officer, Chief Administrative OfficerSecretary and Treasurer (principal financial and accounting officer)	March 28, 2016
/s/ Sol J. Barer, Ph.D. Sol J. Barer, Ph.D.	Chairman of the Board of Directors	March 28, 2016
/s/ Isaac Blech Isaac Blech	Vice Chairman of the Board of Directors	March 28, 2016
/s/ James Barry, Ph.D. James Barry, Ph.D.	Director	March 28, 2016
/s/ Michael Berman Michael Berman	Director	March 28, 2016
/s/ James J. Loughlin James J. Loughlin	Director	March 28, 2016
/s/ Campbell Rogers, M.D. Campbell Rogers, M.D.	Director	March 28, 2016
/s/ Paul Stuka Paul Stuka	Director	March 28, 2016

Index to Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 1, 2011)
3.3	Certificate of Designation, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
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)
10.1+	Amended and Restated 2011 Umbrella Option Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 4, 2011)
10.2+	Form of Stock Option Award Agreement (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
10.3	Form of $72.00 Warrant (incorporated by reference to Exhibit 10.6 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
10.4	License Agreement, by and between Svelte Medical Systems, Inc. and InspireMD Ltd., dated as of March 19, 2010 (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.5+	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)

10.6+	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)
10.7	Form of Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 22, 2011)
10.8	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)
10.9	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)
10.10+	Stock Award Agreement, dated as of November 16, 2011, by and between InspireMD, Inc. and Sol J. Barer, Ph.D. (Incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 18, 2011)
10.11+	Nonqualified Stock Option Agreement, dated as of November 16, 2011, by and between InspireMD, Inc. and Sol J. Barer, Ph.D. (Incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 18, 2011)
10.12	Form of April 2012 $72.00 Warrant (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2012)
10.13	First Amendment to License Agreement, dated October 20, 2012, by and among Svelte Medical Systems, Inc., InspireMD, Inc. and InspireMD Ltd. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 23, 2012)
10.14+	Second Amendment to the InspireMD, Inc. 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 December 26, 2012)
10.15+	Employment Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.16+	Restricted Stock Award Agreement, dated January 3, 2013, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2013)
10.17	Form of $30.00 Warrant (incorporated by reference to Exhibit 10.76 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 9, 2013)

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10.18	Letter Agreement, dated as of April 15, 2013, by and among InspireMD, Inc. and each holder of Senior Secured Convertible Debentures Due April 15, 2014 (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 15, 2013)
10.19	Form of Amended $30.00 Warrant (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 15, 2013)
10.20+	First Amendment to Employment Agreement, dated April 24, 2013, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2013)
10.21+	First Amendment to Restricted Stock Award Agreement, dated April 24, 2013, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 26, 2013)
10.22	Second Amendment to License Agreement, dated August 22, 2013, by and among Svelte Medical Systems, Inc., InspireMD, Inc. and InspireMD Ltd. (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013)
10.23	Loan and Security Agreement, dated October 23, 2013, by and among InspireMD, Inc., InspireM.D Ltd and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.24	Fixed Charge Debenture, dated October 23, 2013, by and among InspireMD, Inc., Inspire M.D Ltd and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.25	Floating Charge Debenture, dated October 23, 2013, by and among InspireMD, Inc., Inspire M.D Ltd and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.26	Warrant Agreement, dated October 23, 2013, by and between InspireMD, Inc. and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.27	Account Control Agreement, dated October 23, 2013, among InspireMD, Inc., Hercules Technology Growth Capital, Inc. and Bank Leumi USA (incorporated by reference to Exhibit 10.5 to Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2013)
10.28+	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)
10.29+	Consulting Agreement, dated February 25, 2014, by and between InspireMD, Inc. and James Barry (incorporated by reference to Exhibit 10.55 to Transition Report on Form 10-KT filed with the Securities and Exchange Commission on February 26, 2014)

10.30+	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)

10.31+	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)
10.32+	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)
10.33+	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)
10.34+	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)
10.35+	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)
10.36+	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)
10.37+	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)
10.38+	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)
10.39+	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)
10.40+	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)
10.41+	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)
10.42+	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)

10.43	Form of Securities Purchase Agreement in connection with registered direct offering (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2014)
10.44	Form of $17.50 Warrant (incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2014)

10.45+	Second Amendment to Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.46+	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)
10.47+	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)
10.48	Exclusive Distribution Agreement, dated December 1, 2014, by and between InspireMD Ltd. and Cardio Medical Sales L.P. (incorporated by reference to Exhibit 10.73 to Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 12, 2015)
10.49+	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)
10.50	Form of Securities Purchase Agreement in connection with public offering (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
10.51	Form of $5.50 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)
10.52	Placement Agency Agreement, dated as of March 4, 2015, by and among InspireMD, Inc., H.C. Wainwright & Co., LLC and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on March 4, 2015)
10.53+	Third Amendment to Employment Agreement, dated June 29, 2015, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on July 6, 2015)
10.54^	Distribution Agreement, dated August 5, 2015, by and between Penumbra, Inc. and InspireMD, Inc. (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)
10.55+	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)
10.56+	Offer Letter, between InspireMD, Inc. and Isaac Blech, dated January 16, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on January 22, 2016)
10.57+	Fourth Amendment to Employment Agreement, dated January 21, 2016, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January

	22, 2016)
10.58+	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)
10.59+	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)

10.60+	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)
10.61+	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)
10.62+	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)
10.63+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and James Loughlin (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on January 28, 2016)
10.64+	Option Cancellation and Release Agreement, dated January 26, 2016, by and between InspireMD, Inc. and Alan Milinazzo (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed on January 28, 2016)
10.65+	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)
10.66*+	Third Amendment to Employment Agreement, dated March 28, 2016, by and between InspireMD, Inc. and James J. Barry, PhD
10.67	Form of $0.59 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)
10.68	Form of $0.7375 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)
10.69	Form of $0.59 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)
10.70	Form of $0.7375 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)
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
23.1*	Consent of Kesselman & Kesselman, Certified Public Accountants
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002

32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Annual Report on Form 10-K for the twelve months ended December 31, 2015, formatted in XBRL (eXtensible Business Reporting Language), (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Income, (iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Cash Flows, (v) Condensed Consolidated Statement of Stockholders' Equity and (vi) Notes to Consolidated Financial Statements

* Filed herewith.

+ Management contract or compensatory plan or arrangement.

^ Confidential treatment has been granted with respect to certain portions of this exhibit by the Securities and Exchange Commission under a confidential treatment request pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

INSPIREMD, INC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2015

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INSPIREMD, INC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2015

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The amounts are stated in U.S. dollars in thousands

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

InspireMD, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, capital deficiency and cash flows present fairly, in all material respects, the financial position of InspireMD Inc. (the "Company") and its subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the financial statements, the Company has an accumulated deficit as of December 31, 2015, as well as net losses and negative operating cash flows in recent years. The Company's management expects to continue incurring losses and negative cash flows from operations until its products 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's management has determined that the Company does not have sufficient resources to fund operations beyond May, 2016. 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.

Tel-Aviv, Israel /s/ Kesselman & Kesselman
March 28, 2016 Certified Public Accountants (Isr.)
A member firm of
PricewaterhouseCoopers
International Limited

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INSPIREMD, INC.

CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

	December 31,	
	2015	2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$3,257	$6,300
Accounts receivable:		
Trade, net	405	635
Other	142	359
Prepaid expenses	75	150
Inventory	753	1,924
Total current assets	4,632	9,368
NON-CURRENT ASSETS:		
PROPERTY, PLANT AND EQUIPMENT, net	472	622
Deferred issuance costs	85	153
Fund in respect of employee rights upon retirement	502	498
Long-term prepaid expenses		66
Royalties buyout	87	752
Total non-current assets	1,146	2,091
Total assets	$5,778	$11,459

INSPIREMD, INC.

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2015	2014
LIABILITIES NET OF CAPITAL DEFICIENY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$512	$909
Other	2,006	3,576
Advanced payment from customers	167	179
Current maturity of loan	4,234	3,809
Total current liabilities	6,919	8,473
LONG-TERM LIABILITIES:		
Liability for employees rights upon retirement	706	687
Long-term loan	1,099	5,086
Total long-term liabilities	1,805	5,773
COMMITMENTS AND CONTINGENT LIABILITIES		
(Note 9)		
Total liabilities	8,724	14,246
EQUITY (CAPITAL DEFICIENCY):		
Common stock, par value $0.0001 per share; 50,000,000 shares authorized; 7,676,074 and 4,136,852, shares issued and outstanding at December 31, 2015 and 2014, respectively	1	
Additional paid-in capital	120,049	104,624
Accumulated deficit	(122,996)	(107,411)
Total capital deficiency	(2,946)	(2,787)
Total liabilities net of capital deficiency	$5,778	$11,459

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

INSPIREMD, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year Ended December 31,	
	2015	2014
REVENUES	$2,310	$2,818
COST OF REVENUES	2,606	2,034
GROSS PROFIT (LOSS)	(296)	784
OPERATING EXPENSES:		
Research and development	3,642	8,744
Selling and marketing	3,178	6,613
General and administrative	6,387	9,125
Restructuring and impairment	982	
Total operating expenses	14,189	24,482
LOSS FROM OPERATIONS	(14,485)	(23,698)
FINANCIAL EXPENSES, net:		
Interest expenses	1,036	1,409
Other financial expenses (income)	60	(24)
Total financial expenses	1,096	1,385
LOSS BEFORE TAX EXPENSES	(15,581)	(25,083)
TAX EXPENSES	4	12
NET LOSS	$(15,585)	$(25,095)
NET LOSS PER SHARE - basic and diluted	$(2.23)	$(7.09)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	6,976,378	3,539,364

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

INSPIREMD, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares				
	Number of shares	Par value	Additional paid-in capital	Accumulated deficit	Total equity
		U.S. dollars in thousands, except share amounts			
BALANCE AT JANUARY 1, 2014	3,398,297	*	$ 90,956	$ (82,316)	$ 8,640
Net loss				(25,095)	(25,095)
Issuance of shares and warrants, including at the market offering, net of $881 issuance costs	725,927	*	9,645		9,645
Employee and non-employee share-based compensation expenses			4,138		4,138
Vesting of restricted stock	17,196	*			
Taxes withheld in respect of share issuance	(4,568)	*	(115)		(115)
BALANCE AT DECEMBER 31, 2014	4,136,852	*	$ 104,624	$ (107,411)	$ (2,787)
Net loss				(15,585)	(15,585)
Issuance of shares and warrants, net of $1,315 issuance costs	3,436,968	1	12,431		12,432
Employee and non-employee share-based compensation expenses			3,107		3,107
Vesting of restricted stock	141,834	*			
Taxes withheld in respect of share issuance	(39,580)	*	(113)		(113)
BALANCE AT DECEMBER 31, 2015	7,676,074	$ 1	$ 120,049	$ (122,996)	$ (2,946)

***** Represents an amount less than $1

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,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(15,585)	$(25,095)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	241	263
Impairment of royalties buyout	576	
Loss from sale of property, plant and equipment	14	
Change in liability for employees rights upon retirement	19	77
Financial expenses	249	350
Share-based compensation expenses	3,107	4,138
Loss (gains) on amounts funded in respect of employee rights upon retirement, net	3	(18)
Changes in operating asset and liability items:		
Decrease in prepaid expenses	141	39
Decrease in trade receivables	230	1,220
Decrease in other receivables	217	28
Decrease (increase) in inventory	1,171	(331)
Decrease in trade payables	(397)	(659)
Increase (decrease) in other payable and advanced payment from customers	(1,582)	626
Net cash used in operating activities	(11,596)	(19,362)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Decrease in restricted cash		93
Purchase of property, plant and equipment	(16)	(133)
Amounts funded in respect of employee rights upon retirement, net	(7)	(46)
Net cash used in investing activities	(23)	(86)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of shares and warrants	12,432	9,535
Repayment of long-term loan	(3,702)	(1,148)
Taxes withheld in respect of share issuance	(113)	(115)
Net cash provided by financing activities	8,617	8,272
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(41)	(59)
DECREASE IN CASH AND CASH EQUIVALENTS	(3,043)	(11,235)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	6,300	17,535
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$3,257	$6,300
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Income taxes	$13	$14

Interest paid	$863	$1,082
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Anti-dilution rights	-	$110

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

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex coronary and vascular disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures. In October 2014, the Company launched a limited market release of its carotid embolic prevention system (CGuard™ EPS), which combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease. In January 2015, the Company received CE mark approval for the rapid exchange delivery system and launched CGuard in countries in Europe.

The Company's coronary products combining MicroNet and a bare-metal stent (MGuard Prime™ EPS) are 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, 2015, as well as 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™) 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 does not have sufficient resources to fund operations beyond May, 2016. 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.

c. Reverse stock split

On October 1, 2015, the Company effectuated a one-for-ten reverse stock split of its common stock. All related share and per share data have been retroactively applied to the financial statements and their related notes for all periods presented. See Note 10a.

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, royalty buyout 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.

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 are 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 market 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 and risks and rewards for the products are transferred to the customer, collection is reasonably assured and product returns can be reliably estimated.

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

j. Research and development costs

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

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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, net of estimated forfeitures. The Company estimates forfeitures based on historical experience and anticipated future conditions.

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 performance based and dependent upon achieving certain goals. With respect to these 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.

n. Advertising

Costs related to advertising and promotion of products are charged to sales and marketing expense as incurred. Advertising expenses were approximately $0.2 million and $0.8 million for the years ended December 31, 2015 and 2014, respectively.

o. Net loss per share

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

For the years ended December 31, 2015 and 2014, all shares of common stock underlying outstanding options, warrants and restricted stock have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive. The total number of shares of common stock related to outstanding options and warrants and restricted stock excluded from the calculations of diluted loss per share were 5,004,836 and 1,352,326 for the years ended December 31, 2015 and 2014, respectively.

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.

r. Allocation of issuance proceeds

When debt or equity is issued with other components that are subsequently measured at fair value, the proceeds are allocated first to such components (such as warrant liabilities and embedded derivatives in the debt that require bifurcation at their fair values) then the residual amount of the proceeds to the debt or equity. When the other components are classified in equity, the proceeds are allocated based on relative fair values. See Note 7.

s. Recently issued accounting pronouncements

1. In April, 2015, the Financial Accounting Standards Board ("FASB") issued guidance related to the presentation of Debt Issuance Costs. The new guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. The new guidance does not affect the recognition and measurement of debt issuance costs. The new guidance is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The new guidance will be applied on a retrospective basis.

2. In May 2014, the Financial Accounting Standards Board (the "FASB") issued 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, 2016. The Company is currently evaluating the impact, if any, the adoption of this guidance will have on its consolidated financial statements.

On July 9, 2015, the FASB approved a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers, such that it is effective beginning on or after December 15, 2017 for public entities. Reporting entities may choose to adopt the standard as of the original effective date.

3.

On July 22, 2015, the FASB issued Accounting Standards Update 2015-11, Simplifying the Measurement of Inventory, which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Inventory measured using last-in, first-out (LIFO) and the retail inventory method (RIM) are not impacted by the new guidance. The new guidance will be effective for public business entities in fiscal years beginning after December 15, 2016, including interim periods within those years. Prospective application is required. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of the standard on its consolidated financial statements.

NOTE 3 - RESTRUCTURING AND IMPAIRMENT

	December 31, 2015 ($ in thousands)
Employee termination costs [1]	305
Lease settlement [2]	101
Total restructuring	$ 406
Impairment of royalties buyout [3]	576
Total restructuring and impairment	$ 982

During the first quarter of 2015, the board of directors approved to curtail developing and promoting our bare metal stent platform and implementing another cost reduction/focused spending plan. The plan has four components: (i) reducing headcount; (ii) limiting the focus of clinical and development expenses to only carotid and neurovascular products; (iii) limiting sales and marketing expenses primarily to those related to the CGuard EPS stent launch; and (iv) reducing all other expenses (including conferences, travel, promotional expenses, executive cash salaries, director cash fees, rent, etc.).

1. During the year ended December 31, 2015, the company incurred $305,000 of costs associated with reducing the Company's headcount.

2. On November 5, 2015, the Company entered into a second amendment (the "Second Lease Amendment") to the lease agreement for its facilities in the U.S. Pursuant to the Second Lease Amendment and effective January 1, 2016, the Company agreed to reduce its leased space and surrender the released premises. The Company also agreed to pay transaction costs and settlement amount of $101,000.

3. During the year ended December 31, 2015 the Company recorded expenses related to the impairment of the royalties buyout asset amounting to $576,000 due to anticipated lower sales of MGuard Prime in the future resulting from industry preferences for drug eluting stents.

The Company values Level 3 Royalties buyout using an internally developed valuation model, whose inputs include future MGuard Prime EPS sales and the derived royalties payments.

NOTE 4 - FAIR VALUE MEASURMENT

Items Measured at Fair Value on a Recurring Basis

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

	Anti-Dilution Rights ($ in thousands)
Balance as of January 1, 2014	$ 156
Total losses (gains) (realized and unrealized) - included in earnings - Financial expenses (income), net	(46)
Settlement by issuance shares	(110)
Balance as of December 31, 2014	$ -

The Company valued Level 3 Anti- Dilution Rights using an internally developed valuation model, whose inputs include potential equity transactions (such as fund raising and share based awards), probability of completing successful fund raising during the relevant period and stock prices.

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. The fair value of the Loan (as defined in Note 7) approximated its carrying amount since it bears interest at rates that approximate current market rates.

NOTE 5 - PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2015	2014
	($ in thousands)	
Cost:		
Computer equipment	$221	$242
Office furniture and equipment	104	110
Machinery and equipment	961	951
Leasehold improvements	143	194
	1,429	1,497
Less - accumulated depreciation and amortization	(957)	(875)
Net carrying amount	$472	$622

b. Depreciation and amortization expenses totaled approximately $152,000 and $163,000 for the years ended December 31, 2015 and 2014, respectively.

NOTE 6 - 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 $211,000 and $233,000 for the years ended December 31, 2015 and 2014, respectively.

Defined contribution plan expenses were approximately $213,000 and $285,000 for the years ended December 31, 2015 and 2014, respectively.

The Company expects contribution plan expenses in 2016 to be approximately $165,000.

NOTE 7 – loan

I. 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 is prime plus 4%, but shall not be

reduced below 10.5%. Payments under the Loan and Security Agreement are 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 is permitted to prepay all or a portion of the Loan. However, any prepayments of the Loan will be subject to a penalty of (i) 2%, if the prepayment occurs within 12 months of the Loan being requested by the Company and InspireMD Ltd. (the "Advance Date"), (ii) 1%, if the prepayment occurs between 12 and 24 months after the Advance Date, and (iii) 0.5%, if the prepayment occurs more than 24 months after the Advance Date. The Company and InspireMD Ltd. will also 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. In addition, upon the occurrence of a change in control, the Company shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and all unpaid lender's fees and expenses accrued to the date of the repayment (including the End of Term Charge) together with the penalties stated above.

b. Security Documents

On October 23, 2013, InspireMD Ltd. issued the lender a Fixed Charge Debenture and a Floating Charge Debenture (collectively, the "Israeli Security Agreements") in order to create a security interest in all the assets and property of InspireMD Ltd., securing the Company's and InspireMD Ltd.'s obligations under the Loan and Security Agreement. In addition, on October 23, 2013 and November 8, 2013, the Company entered into Deposit Account Control Agreements with the lender and two banking institutions in the US (the "Deposit Account Control Agreements") in order to perfect the lender's security interest in the Company's bank account. Pursuant to the Loan and Security Agreement, the Israeli Security Agreements and the Deposit Account Control Agreement, the Company's obligations to the lender are secured by a first priority perfected security interest in all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd.

The Company is required under the Loan and Security Agreement to maintain at all times in the bank accounts under the Deposit Account Control Agreements, cash and cash equivalents which may include cash collected from Accounts Receivable by Inspire M.D Ltd. and InspireM.D GmbH within the previous 7 days, and cash transferred to Inspire M.D Ltd. for the settlement of Permitted Indebtedness within the following 7 days, in each unrestricted and unencumbered, in an aggregate amount of at least the lesser of (a) an amount equal to one hundred percent of the then outstanding principal amount of the Term Loan Advance and (b) an amount equal to seventy-five percent of the aggregate amount of all of Borrower's worldwide cash and cash equivalents.

As of December 31, 2015, the future principal payments obligation for the Loan were as follows:

	($ in thousands)
Year Ended December 31:	
2016	$ 4,234
2017	776
	$ 5,010

NOTE 8 - RELATED PARTIES TRANSACTIONS

a. CEO

On January 26, 2015, the Company granted the CEO stock options to purchase 30,777 shares of the Company's common stock with an exercise price of $7.2 per share. The fair value of the options using the Black-Scholes option-pricing model was approximately $131,000.

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On January 26, 2015 the Company granted the CEO 20,509 shares of restricted common stock which are subject to forfeiture until vested and which vest in three equal annual installments;

On January 5, 2015, the CEO's employment agreement was amended such that, in lieu of 50% of the CEO's base cash salary, he would be paid an equivalent amount of shares of restricted common stock. On January 26, 2015, the Company issued 31,250 shares of restricted stock subject to a one year service condition, with a fair value of $225,000.

On June 29, 2015, the Company amended the employment agreement with the Company’s CEO in order to, among other things, (i) modify the term of employment to end on June 30, 2016 unless earlier terminated by either party; and (ii) provide that, until the Company raises an aggregate of $5 million from investors, the CEO will receive (A) with respect to his employment in 2015, the 31,250 shares of restricted common stock of the Company, issued on January 26, 2015, as described above, will be subsequently adjusted based upon the volume-weighted average price of the Company’s common stock during the calendar year ended December 31, 2015 (or during the period from January 2, 2015 through his termination date if his employment is terminated upon his death or disability, by the CEO for good reason, or by the Company without cause prior to December 31, 2015) to represent the equivalent of 50% of the CEO’s base salary in 2015, and (B) with respect to his employment in 2016, 50% of his base salary from January 1, 2016 through June 30, 2016 to be paid in shares of restricted common stock of the Company valued at the fair market value of the Company’s common stock as of the market close on January 2, 2016. The amendment also amends those certain provisions in the Employment Agreement related to payments on termination of employment.

On December 31, 2015, 63,825 shares of restricted stock were issued to the CEO, based on the adjusting formula stipulated in the amended agreement, as described above.

See note 13b with respect to the fourth amendment to the CEO's employment agreement, entered into subsequent to December 31, 2015.

The share based compensation arrangement with the Company's CEO was initially classified as an equity award, and was reclassified to a liability award on June 29, 2015 following the second amendment to the CEO's employment agreement, given the adjusting formula described above. On this date, the amount accumulated in additional paid in capital was reclassified as a liability, which was subsequently remeasured at fair value up to the date of its settlement.

On December 31, 2015, the fair value of the liability just prior to such date, in the amount of $84,000, was carried to additional paid in capital.

The Company recognized a total compensation expense of $84,000 in connection with the CEO's non-cash portion of his annual 2015 salary.

During the year ended December 31, 2014, the Company granted the CEO stock options to purchase 39,968 shares of the Company's common stock with an exercise price of $29.70-$31.00 per share, and 18,273 shares of restricted stock, which vests in three equal annual installments. The fair value of the above options and restricted shares, using the Black-Scholes option-pricing model, was approximately $736,000 and $554,000, respectively.

The CEO has an option to deliver a number of shares with an aggregate fair market value that equals or exceeds (to avoid the 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, 2015 and 2014, 32,811 and 4,569 shares were withheld by the Company to satisfy tax withholding obligations. The payment, amounting to $81,000 and $115,000, was deducted from equity.

On or before December 31 of each calendar year, the CEO will be eligible to receive an additional grant of equity awards equal, in the aggregate, to up to 0.5% of the Company’s actual outstanding shares of common stock on the date of grant, provided that the actual amount of the grant will be based on his achievement of certain performance objectives as established by the board, in its reasonable discretion, for each such calendar year. In connection with the equity compensation related to 2013 achievements, on January 29, 2014 the CEO was granted stock options to purchase 8,633 shares of the Company's common stock and 8,633 restricted shares, (included in total options and restricted shares granted to the CEO during 2014). In connection with the equity compensation related to 2014 achievements, on January 26, 2015 the CEO was granted stock options to purchase 5,300 shares of the Company's common stock and 5,300 restricted shares.

On January 28, 2015, the Company’s board of directors approved an annual bonus for 2014 to the CEO in the amount of $69,105.

In July 2015, the Company’s board of directors approved an annual bonus for 2015 to the CEO in the amount of $45,833.

b. During the years ended December 31, 2015 and 2014, the Company granted stock options to directors to purchase a total of 138,541 and 33,500 shares of the Company’s common stock, respectively. The options have exercise prices of $1.7 - $7.8 and $31, per share, respectively, which were the fair market value of the Company’s common stock on the date of each respective grant. The options granted in 2014 are subject to a three-year vesting period with one-third of such awards vesting each year. Of the 138,541 options granted in 2015, 107,744 options were in lieu of cash compensation that was owed to them for their services as directors for the third and fourth quarters of 2014 and the first through third quarter of 2015 and are fully vested as of their grant date and the remaining options are subject to a three-year vesting period, with one-third of such awards vesting each year.

The fair value of the above options using the Black-Scholes option-pricing model, was approximately $338,000 and $636,000, respectively.

c. Balances with related parties:

	December 31, 2015	2014
	($ in thousands)	
Current liabilities:		
Other accounts payable	$132	$241

d. Transactions with related parties:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Total expenses	$ 1,892	$ 3,269

NOTE 9 - COMMITMENTS AND CONTINGENT LIABILITIES

a. Lease commitments:

1) On December 13, 2011, the Company entered into a lease agreement for a facility in Israel, which expired in December 2014. The Company had the option, under the agreement, to extend the agreement for two additional two year periods, for a total of four years. The Company extended the agreement for two additional years.

In December 2013, the Company entered into a lease agreement for its facilities in the U.S which expires in February 2018. The Company has the right to terminate the lease agreement effective Febuary 1, 2017 upon 9 months prior written notice, as stipulated in the agreement.

In August 2014, the Company entered into an amendment (the “First Lease Amendment”) to the lease agreement for its facilities in the U.S. Pursuant to the First Lease Amendment, amongst other things, the Company agreed to lease additional space and extend the expiration of the agreement to February 2019.

On November 5, 2015, the Company entered into a second amendment (the “Second Lease Amendment”) to the lease agreement for its facilities in the U.S. See Note 3.

On September 1, 2015 the Company signed a sublease agreement for part of its U.S. facilities. The agreement will terminate on August 31, 2017.

Rent expense included in the consolidated statements of operations totaled approximately $383,000 and $388,000 for the years ended December 31, 2015 and 2014, respectively. The rent expense for the year ended December 31, 2015 excludes $101,000, which is recorded under “Restructuring and impairment” in the consolidated statements of

operations. See Note 3.

As of December 31, 2015, the aggregate future minimum lease obligations for office rent under non-cancelable operating lease agreements were as follows:

	($ in thousands)
Year Ended December 31:	
2016	$ 320
2017	5
	$ 325

2) The Company leases its motor vehicles under operating lease agreements. As of December 31, 2015, the aggregate non-cancelable future minimum lease obligations for motor vehicles were approximately $6,000.

b. License Agreement:

On August 22, 2013, the Company, InspireMD Ltd. and a licensor entered into an amendment to the License Agreement, pursuant to which the Company and the Licensor agreed to amend the royalty fee from 2.9% of all net sales during the term of the agreement to (i) 2% of the first $10.56 million of net sales from July 1, 2013 through June 30, 2015, provided that the Company makes an advance royalty payment of $192,000 on the date of the amendment, (ii) 2.5% of net sales in excess of $10.56 million from July 1, 2013 through June 30, 2015, payable within 45 days of June 30, 2015, and (iii) 2.9% of all net sales beginning on July 1, 2015. The above referenced advance royalty payment has been included in long term prepaid expenses.

During the year ended December 31, 2015 the Company recorded expenses related to the impairment of the royalties buyout asset amounting to $576,000 due to anticipated lower sales of MGuard Prime in the future resulting from industry preferences for drug eluting stents. The expense is recorded under “Restructuring and impairment” in the consolidated statements of operations.

Royalties expenses for the years ended December 31, 2015 and 2014 amounted to approximately $149,000 and $148,000, respectively.

c. Liens and pledges

1) The Company’s obligations under the Loan and Security Agreement were secured by the Israeli Security Agreements and the Deposit Account Control Agreements on all of the assets and properties of the Company and InspireMD Ltd., other than the intellectual property of the Company and InspireMD Ltd. See Note 7.

d. Litigation:

In July 2012, a purported assignee of options in InspireMD Ltd. submitted a statement of claim against the Company, InspireMD Ltd., and the Company’s former CEO and President for a declaratory and enforcement order that it is entitled to options to purchase 8,364 shares of the Company’s common stock at an exercise price of $7.60 per share. In

December 2014 the court accepted a motion to dismiss the former CEO and president from the lawsuit. On May 27, 2015 the Company and the assignee of options accepted a settlement agreement pursuant to which the claim was removed and the plaintiff waived his entire claim against the Company, in consideration of the Company's consent to allow him to exercise 5,855 options of the Company's shares of common stock.

In December 2012, a former service provider of InspireMD GmbH filed a claim with the Labor Court in Buenos Aires, Argentina in the amount of $193,378 plus interest (6% in dollars or 18.5% in pesos), social benefits, legal expenses and fees (25% of the award) against InspireMD Ltd. and InspireMD GmbH. The Company's management, after considering the views of its legal counsel as well as other factors, recorded a provision of $250,000 in the financial statements for the quarter ended December 31, 2012. In March 2015, the interest rate made by the Court of Appeal in Argentina was increased retroactively, which resulted in the provision increasing to $340,000. The related expense for the increase of $90,000 was recorded to “General and administrative” within the Consolidated Statements of Operations. The Company settled with the plaintiff in the amount of $80,000 plus $20,000 for legal fees, which was approved by the Labor Court and paid by the Company in March 2016 resulting in the provision decreasing to $100,000. The related decrease in provision amounting to $240,000 was recorded to “General and administrative” within the Consolidated Statements of Operations.

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

In November 2015, the Company received written communication from a service provider to remit payment amounting to $1,965,000. Given the preliminary stage, the Company’s management and legal counsel cannot estimate the outcome of any legal proceedings or settlements, however believes that neither a court loss nor settlement are probable.

NOTE 10 – EQUITY

a. Share capital

On September 9, 2015, the stockholders approved the authorization of the board of directors, in its discretion, to amend the Amended and Restated Certificate of Incorporation of the Company to effect a reverse stock split of the Company’s common stock at a ratio of one-for-ten and to reduce the number of authorized shares of the Company’s common stock from 125 million shares to 50 million shares. The Company’s common stock is listed on the NYSE MKT.

On September 30, 2015, 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-ten reverse stock split of its common stock, par value $0.0001 per share (the “Reverse Stock Split”), effective as of October 1, 2015, which decreased the number of issued and outstanding shares of common stock and restricted shares of common stock from 78 million shares to 7.8 million shares. The Company’s authorized common stock was decreased from 125 million

shares to 50 million shares. Accordingly, as of December 31, 2015, the Company has authorized 55,000,000 shares of capital stock, par value $0.0001 per share, of which 50,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock.

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

Pursuant to the terms of 2011 SPA that provided these investors with certain anti-dilution protections until March 31, 2014. The Company issued the purchasers or their assigns an aggregate of 84,289 shares of common stock through 2014. The related expense has been recorded to “Financial expenses (income), net” within the consolidated statements of operations in the relevant periods.

On August 15, 2014, the Company sold 94,800 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with MLV & Co. LLC. These sales resulted in net proceeds to the Company of approximately $2.2 million.

On November 7, 2014, the Company sold 626,189 shares of its common stock and warrants to purchase 313,100 shares of common stock in a registered direct offering (the “2014 Offering”). The common stock was sold at a negotiated purchase price of $13 per share, and each purchaser received a warrant to purchase 0.5 of a share of common stock for each share of common stock that it purchased in the offering. The warrants, which are classified in equity, are non-exercisable for six months and have a term of exercise of 42 months from the date of issuance and an exercise price of $17.5. This offering resulted in net proceeds to the Company of approximately $7.4 million after deducting placement agent fees and other estimated offering expenses.

On March 9, 2015, the Company sold 3,436,968 shares of its common stock and warrants to purchase 3,436,968 shares of common stock in a registered direct offering. Each purchaser received a warrant to purchase one share of common stock for each share of common stock that it purchased in the 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 $5.50. This offering resulted in net proceeds to the Company of approximately $12.4 million after deducting placement agent fees and other offering expenses.

b. Share-Based Compensation

1. On March 28, 2011, the board of directors and stockholders of the Company adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan (the “Umbrella Plan”) which expires on March 27, 2021. Under the Umbrella Plan, as subsequently amended, the Company reserved 500,000 shares of common stock as awards to employees, consultants, and service providers. As of December 31, 2015, the Company had reserved 18,603 shares of common stock for issuance under the plans as described above.

On December 16, 2013, the board of directors and stockholders of the Company adopted and approved the InspireMD, Inc. 2013 Long-Term Incentive Plan (the “2013 Plan”). Under the 2013 Plan, the Company reserved 500,000 shares of common stock for awards to employees, officers, directors, consultants, and service providers. On September 9, 2015, 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 Plan by 470,000 shares of common stock, to a total of 970,000 shares of common stock (the "Plan Amendment"). As of December 31, 2015, the Company had reserved 439,930 shares of common stock for 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.

U.S. federal income tax consequences relating to the transactions described under the Umbrella Plan are set forth in Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and treasury regulations in 2004 to regulate all types of deferred compensation.

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).

2. During the years ended December 31, 2015 and 2014, the Company granted stock options to the CEO, employees and directors to purchase a total of 214,499 and 184,652 shares of the Company's common stock, respectively. The options have exercise prices ranging from $1.70-$8.30 and $11.40-$32.30 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 these options, using the Black-Scholes option-pricing model, was approximately $660,000 and $3,279,000, respectively. Of the 214,499 stock options granted in 2015, 107,744 options are fully vested as of their grant date and the remaining options are subject to a three-year vesting period with one-third of such awards vesting each year. The options granted in 2014 are subject to a three-year vesting period with one-third of such awards vesting each year See also Note 8a for stock options grants to the CEO and directors.

Out of the 184,652 stock options granted during the year ended December 31, 2014, 45,001 stock options were granted to the COO of the Company, who also serves as one of the Company's directors.

3. During the year ended December 31, 2015 and 2014, the Company granted to the CEO, employees and directors 196,178 and 65,076 restricted shares of the Company's common stock, respectively. The fair value of these restricted shares was approximately $1,157,000 and $1,916,000. Of the 196,178 restricted shares granted during the year ended December 31, 2015, 43,300 restricted shares are subject to a one-year vesting period, 9,250 restricted shares are fully vested as of their grant date and are subject to a 6 month lock up period, 63,825 restricted shares are fully vested as of their grant date, 32,914 restricted shares are subject to a six-month vesting period and 46,889 restricted shares are subject to a three-year vesting period, with one-third of such awards vesting each year. The 65,076 restricted shares granted during the year ended December 31, 2014 are subject to a three-year vesting period with one-third of such awards vesting each year. Out of the 65,076 restricted shares mentioned above, 15,000 restricted shares were granted to the COO of the Company, who also serves as one of the Company's directors.

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

	Year ended December 31, 2015		2014	
	Number of warrants and options	**Weighted average exercise price**	Number of warrants and options	**Weighted average exercise price**
Outstanding - beginning of period	537,018	$ 40.10	368,818	$ 45.50
Granted	214,499	$ 5.31	184,652	$ 29.10
Forfeited	(37,830)	$ 30.68	(16,452)	$ 39.00
Outstanding -end of period	713,687	$ 30.10	537,018	$ 40.10
Exercisable at the end of the period	344,787	$ 46.37	229,201	$ 54.80

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

	Year ended December 31, 2015		**2014**	
	Number of warrants and options	**Weighted average exercise price**	Number of warrants and options	Weighted average exercise price
Outstanding - beginning of period	139,902	$ 44.80	154,315	$ 45.70
Forfeited	(5,608)	$ 30.67	(14,413)	$ 54.40
Outstanding - end of period	134,294	$ 45.37	139,902	$ 44.80
Exercisable at the end of the period	133,888	$ 45.36	139,140	$ 44.70

5. The following table summarizes information about restricted shares to employees:

	Year ended December 31,	
	2015	**2014**
	Number of restricted shares	Number of restricted shares
Outstanding - beginning of period	103,016	54,654
Granted	196,178	65,076
Forfeited	(10,145)	(718)
Vested	(141,834)	(15,996)
Outstanding - end of period	147,215	103,016

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

	Outstanding as of December 31, 2015		
Exercise price	Warrants and options outstanding	Weighted average remaining contractual life (years)	Warrants and options exercisable
$0-$8.3	251,637	8.19	38,709
$19.7-$29.8	227,249	7.80	117,081
$30.5-$34	87,202	7.67	43,065
$40.5-$49.285	93,283	5.78	91,210
$60-$78	172,360	2.92	172,360
$80-$100	16,250	5.42	16,250
	847,981	6.64	478,675

The weighted average of the remaining contractual life of total vested and exercisable warrants and options as of December 31, 2015 was 5.04 years.

The aggregate intrinsic value of the total exercisable warrants and options as of December 31, 2015 was approximately $25,563.

The weighted average fair value of warrants and options granted was approximately $3.11 and $17.80 for the years ended December 31, 2015 and 2014, respectively. The weighted average fair value of warrants and options granted was estimated using the Black-Scholes option-pricing model.

1. 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, 2015 and 2014:

	Year ended December 31,	
	2015	2014
Expected life	5-6.5 years	5.5-6.5 years
Risk-free interest rates	1.41%-1.71 %	1.64%-2.18 %
Volatility	62.68%-71.12%	62.89%-68 %
Dividend yield	0 %	0 %

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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 Company estimates its forfeiture rate based on its employment termination history, and will continue to evaluate the adequacy of the forfeiture rate based on analysis of employee turnover behavior and other factors (for non-employees the forfeiture rate is nil). 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 a blended volatility, based on its historical data and that of a peer group of public companies.

2. As of December 31, 2015, the total unrecognized compensation cost on employee and non-employee stock options and restricted shares, related to unvested stock-based compensation, amounted to approximately $1.75 million. This cost is expected to be recognized over a weighted-average period of approximately 0.82 years. This expected cost does not include the impact of any future stock-based compensation awards.

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

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Cost of revenues	$ 8	$ 13
Research and development	716	534
Sales and marketing	179	446
General and administrative	2,145	3,145
Restructuring and impairment	59	
	$ 3,107	$ 4,138

c. At-the-Market Agreement

On October 23, 2013, the Company entered into an at-the-market issuance sales agreement, or the Sales Agreement, with MLV & Co. LLC pursuant to which The Company may issue and sell shares of the Company common stock having an aggregate offering price of up to $40 million directly on the NYSE MKT or sales made to or through a market maker other than on an exchange. With the Company's prior written consent, sales may also be made in negotiated transactions and/or any other method permitted by law. MLV & Co. LLC will receive a 3% commission from the gross proceeds of any sales. Subject to the terms and conditions of the Sales Agreement, MLV & Co. LLC will use its commercially reasonable efforts to sell the shares of the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other parameters or conditions that the Company may impose). The Company is not obligated to make any sales of common stock under the Sales Agreement and no assurance can be given that the Company will sell any shares under the Sales Agreement, or, if the Company does, as to the price or amount of shares that the Company will sell, or the dates on which any such sales will take place. The Sales Agreement may be terminated by either party at any time upon 10 days' notice to the other party, or by MLV & Co. LLC at any time in certain circumstances, including the occurrence of a material adverse effect to the Company. In addition, the Sales Agreement will automatically terminate upon the sale of all common stock subject to the Sales Agreement. During the year ended December 31, 2014, the Company sold 94,800 shares of its common stock pursuant to its at-the-market issuance sales agreement with MLV & Co. LLC. These sales resulted in net proceeds to the Company of approximately $2.2 million. Following the 2014 Offering, the Company is prohibited from entering into any variable rate transactions which may impair its ability to make sales under our at-the-market issuance sales agreement absent the consent of the investors in the 2015 Offering until March 9, 2017.

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 is 34%.

Taxation in Israel

InspireMD Ltd. is taxed under the Israeli Income Tax Ordinance as a corporate tax rate of 26.5%.

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%.

Taxation in UK

InspireMD UK is taxed according to the tax laws in the UK. Accordingly, the applicable tax rate is a corporate tax rate of 20%.

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

1. 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 years of a reduced tax rate of 25% 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 five 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.

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 25% on the amount distributed. 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.

2. 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.

The Company opted not to apply for Preferred Enterprise status.

c. Carry forward tax losses

As of December 31, 2015, InspireMD Ltd. had a net carry forward tax loss of approximately $52 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 $29 million. Under U.S. tax laws, the Company’s tax losses can be utilized two years back and twenty years forward. As such the Company's carry forward tax losses will begin to expire on December 31, 2031.

d. Loss before income taxes

The components of loss before income taxes are as follows:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Profit (loss) before taxes on income:		
InspireMD, Inc.	$ (6,131)	$ (11,671)
Subsidiaries	(9,450)	(13,412)
	$ (15,581)	$ (25,083)

Current taxes on income

The following is a reconciliation of the theoretical tax expense, assuming all income was taxed at the regular tax rates applicable to the Company in the U.S. and the actual tax expense:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Loss before taxes on income, as reported in the statements of operations	$ 15,581	$ 25,083
Theoretical tax benefit	(5,297)	(8,529)
Decrease in tax benefit resulting from permanent differences	273	390
Increase (decrease) in taxes on income resulting from the computation of deferred taxes at a rate which is different from the theoretical rate, and other	716	2,038
Difference between income reported for tax purposes and income for financial reporting purposes — net	50	1,100
Decrease in theoretical tax benefit resulting from subsidiaries different tax rate	(53)	(73)
Change in corporate tax rates		-
Change in valuation allowance	4,315	5,086
	$ 4	$ 12

As of December 31, 2015 and 2014, the Company determined that it was more likely than not that the benefit of the operating losses would not be realized and consequently, management concluded that full valuation allowances should be established regarding the Company’s deferred tax assets.

The changes in the valuation allowance for the year ended December 31, 2015 and 2014 were as follows:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Balance at the beginning of the year	$ 24,655	$ 19,569
Changes during the year	4,315	5,086
Balance at the end of the year	$ 28,970	$ 24,655

e. Accounting for Uncertain Tax position

The Company has no uncertain tax positions as of December 31, 2015.

All of the above amounts of unrecognized tax benefits would affect the effective tax rate if recognized.

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

Jurisdiction	**Years**
U.S.	2012-2015
Israel	2012-2015
Germany	2010-2015
United Kingdom	2014-2015

f. Deferred income tax:

	December 31,	
	2015	2014
	($ in thousands)	
Short-term:		
Allowance for doubtful accounts	$74	$89
Provision for vacation and recreation pay	105	59
	179	148
Long-term:		
R&D expenses	1,326	1,738

Share-based compensation	3,737	2,990
Carry forward tax losses	23,674	19,729
Accrued severance pay, net	54	50
	28,791	24,507
Less-valuation allowance	(28,970)	(24,655)
	$-	$-

NOTE 12 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

a. Accounts receivable:

The changes in "Allowance for doubtful accounts" during the years ended December 31, 2015 and 2014 are as follows:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
Balance at beginning of period	$ 337	$ 405
Additions during the period	72	35
Deductions during the period	(49)	(57)
Exchange rate differences	(14)	(46)
Balance at end of period	$ 346	$ 337

b. Inventories:

	December 31,	
	2015	2014
	($ in thousands)	
Finished goods	$301	$1,273
Work in process	307	326
Raw materials and supplies	145	325
	$753	$1,924

For the years ended December 31, 2015 and 2014, the Company recorded expenses for slow moving inventory in the amounts of $588,000 and $129,000, respectively.

c. Voluntary Field Corrective Action

On April 30, 2014, the Company initiated a voluntary field corrective action ("VFA") of its MGuard Prime EPS to address the issue of stent retention following reports of MGuard Prime stent dislodgements. On June 18, 2014, the Company received approval from the European regulatory agency to resume the manufacturing of the MGuard Prime stent with a modified stent securement process. The Company also received approval to modify and re-deploy existing MGuard Prime stents that were sent to the Company by clinical and commercial sites worldwide. These products have been modified and shipped to direct hospital customers and the majority of its distributor partners, who have begun shipping modified product back into hospital accounts. The Company began shipping products to new customers in the Company's direct markets in Western Europe in October 2014. The VFA had an adverse impact on both the commercial and clinical activities relating to the MGuard Prime EPS from the date of initiation through December 31, 2014.

The expenses associated with the modifications that were performed as a result of the VFA are approximately $377,000. These expenses were recorded in “Cost of revenues” through the end of 2015.

In addition, as a result of the VFA, the Company suspended enrollment in the MASTER II trial, which had been previously launched to support its investigational device exemption application for MGuard Prime EPS with the U.S. Food and Drug Administration (“FDA”), pending a review by the FDA of the manufacturing improvements to the MGuard Prime EPS. The FDA approved the re-commencement of the MASTER II trial in October 2014.

Notwithstanding FDA approval to re-commence enrollment of the Master II trial, in light of current market conditions moving toward the use of drug-eluting stents (DES) over bare-metal stents, the Company elected not to resume enrollment in the MASTER II trial. As a result of this change, the MASTER II trial will no longer be an FDA registration trial.

d. Accounts payable and accruals-other:

	December 31,	
	2015	2014
	($ in thousands)	
Employees and employee institutions	$412	$1,022
Accrued vacation and recreation pay	377	410
Accrued clinical trials expenses	582	1,016
Provision for sales commissions	80	120
Accrued expenses	552	993
Taxes payable	3	15
	$2,006	$3,576

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,	
	2015	2014
	($ in thousands)	

Germany	$519	$286
Italy	415	96
Brazil	238	95
Belarus	226	285
Middle East	94	792
Other	818	1,264
	$2,310	$2,818

By product:

	Year ended December 31,	
	2015	2014
	($ in thousands)	
MGuard*	1,607	2,797
CGuard	703	21
	$2,310	$2,818

*Includes revenue from sales of both MGuard Prime and MGuard.

By principal customers:

	Year ended December 31,	
	2015	2014
Customer A	11 %	7 %
Customer B	10 %	10 %
Customer C		21 %

All tangible long lived assets are located in Israel.

NOTE 14 – SUBSEQUENT EVENTS

On January 16, 2016, the Board of Directors appointed a new director as a Vice Chairman of the Board, effective as of January 22, 2016, with a term expiring at the Company's 2017 annual meeting of stockholders. In connection with his appointment, the new director will be granted an option to purchase 780,000 shares of the Company's common stock on April 30, 2016 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 195,000 shares of Common Stock vest and become exercisable immediately upon the time of grant, and, until all 780,000 options shall have vested, options to purchase 195,000 shares of common stock will vest and 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, will be 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 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 Plan), the options shall vest immediately in full. The options have a term of 10 years from the date of grant and may be exercised for either cash or on a cashless basis.

On January 21, 2016, the Company and the Company's CEO, entered into a fourth amendment to the CEO's Employment Agreement dated as of January 3, 2013, as first amended on April 24, 2013, and further amended on January 5, 2015, and on June 29, 2015, by and between the Company and the CEO, in order to, among other things, (i) modify the term of the CEO's employment to end on the earlier of June 30, 2016 or the date upon which a new president and/or chief executive officer (or executive performing a similar role) commences employment with the Company (or, if such individual is promoted internally, the date such individual is promoted to the position of president and/or chief executive officer); and (ii) provide that, during the remaining term of his employment, the CEO will receive (A) 50% of his base salary in cash payments, for all days that the CEO works during the remaining term of his employment, at the monthly rate of $18,750, payable in accordance with the Company's regular payroll practices, and (B) a lump-sum payment equivalent to 50% of the CEO's base salary through June 30, 2016, at the monthly rate of $18,750, payable within 20 business days from the earlier of (x) the Company raising an aggregate of $5 million from investors, or (y) June 30, 2016.

On January 26, 2016 the Company entered into an option cancellation and release agreement with certain directors, the CEO and CFO ("the Optionholders"), pursuant to which the parties agreed to cancel options to purchase an aggregate of 422,443 shares of common stock of the Company at exercise prices ranging from $7.20 to $100.00 previously granted to each of the Optionholders.

On March 21, 2016, the Company sold 1,900,000 shares of its common stock and warrants to purchase 950,000 shares of common stock in an underwritten public offering. The common stock was sold at a price of $0.59 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 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 $0.59. This offering resulted in gross proceeds to the Company of approximately $1.1 million.

On March 21, 2016, the Company sold 1,033,051 shares of its common stock and warrants to purchase 516,526 shares of common stock in an underwritten private offering. The common stock was sold at a price of $0.59 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 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 $0.59. This offering resulted in gross proceeds to the Company of approximately $0.6 million.

These sales of securities on March 21, 2016 resulted in aggregate net proceeds to the Company of approximately $1.4 million after deducting underwriting discount, placement agent fees and other offering expenses.