Avinger Inc
Form 10-K
March 08, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2015

or

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

Commission File Number: 001-36817

AVINGER, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8873453**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

400 Chesapeake Drive

Redwood City, California 94063

(Address of principal executive offices and zip code)

(650) 241-7900

(Telephone number, including area code)

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

Title of Each Class:	**Name of Each Exchange on which Registered**
Common Stock, par value $0.001 per share	The NASDAQ Global Market

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 o 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 o 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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 o

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. o

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 o	Accelerated filer o	Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant s common stock on June 30, 2015 as reported by the NASDAQ Global Market on such date was approximately $158.0 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 7, 2016, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 12,692,189.

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AVINGER, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

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Avinger, Ocelot, Pantheris, and Lumivascular are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this Annual Report on Form 10-K are our property. Other trade names, trademarks and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this Annual Report on Form 10-K appear without the symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and trade names. Certain market and industry data used in this Annual Report on Form 10-K, where noted, is attributable to Millennium Research Group, Inc. Millennium Research Group asserts copyright protection over the use of such information and reserves all rights with respect to its use. This information has been reprinted with Millennium Research Group s permission and the reproduction, distribution, transmission or publication of such information is prohibited without its consent.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipate, assume, believe, contemplate, continue, could, due, estimate, expec may, objective, plan, predict, potential, positioned, seek, should, target, will, would and other similar expressions that are p indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the outcome of our clinical studies and plans to conduct further clinical studies;
- our plans to modify our current products, or develop new products, to address additional indications;
- the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;

- our ability to identify and develop new and planned products and acquire new products;

- our financial performance;

- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally; and

- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management s beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed in Part I, Item 1A under Risk Factors and elsewhere in this Annual Report on Form 10-K. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the SEC as exhibits to the Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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PART I

ITEM 1. BUSINESS

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to dramatically improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select European markets. Our current products include our Lightbox imaging console, as well as our Wildcat, Kittycat, and the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device, designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris, and in March 2016 received FDA approval for an enhanced version of Pantheris, and promptly thereafter we commenced sales of Pantheris in the U.S. and in select European countries. We believe that Pantheris will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures.

According to an article published in The Lancet, the global prevalence of PAD was estimated at 202 million people in 2010. The prevalence of PAD in the United States alone was estimated at 18 million people in 2010 and is projected to grow to 21 million people by 2020 according to the Sage Group. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including coronary artery disease, or CAD, in part because many PAD patients are asymptomatic or dismiss their symptoms as normal signs of aging. Despite the relative undertreatment of PAD, Millennium Research Group estimates that over 570,000 catheter-based PAD procedures in the pelvis and legs were performed in the United States in 2013, which corresponded to a $1.0 billion market. Millennium Research Group also estimates that the number of catheter-based PAD procedures will grow to almost 700,000 in 2017, representing a $1.3 billion market in the United States. Higher diagnosis and intervention rates resulting from greater physician and patient awareness of PAD, as well as higher prevalence, may significantly expand the market opportunity for PAD treatments, according to the Millennium Research Group.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments include stents, angioplasty, and atherectomy devices, which are catheter-based products for the removal of plaque. These treatments also have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina, or EEL.

Our Lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivascular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding healthy portions of

the artery.

In March 2015, we completed enrollment of 134 patients in VISION, a clinical trial designed to support our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and effectiveness endpoints. We believe the data from VISION will also allow us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the EEL, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. We have recently commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select European countries after obtaining the required marketing authorizations.

We have assembled a team with extensive medical device development and commercialization capabilities, including our founder, John B. Simpson, Ph.D., M.D., who founded Advanced Cardiovascular Systems, FoxHollow Technologies and Perclose, among other vascular medical device companies. We began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $10.7 million in 2015, $11.2 million in 2014 and $13.0 million in 2013.

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Overview of Peripheral Arterial Disease

Atherosclerosis is a progressive, degenerative condition in which plaque, consisting of lipids, cholesterol, calcium and other substances found in the blood stream, accumulates on the arterial wall. The accumulation of plaque can result in the narrowing of an artery, which may lead to serious health problems. Plaque can occur in many areas of the body and may vary in composition, density and size. These blockages sometimes contain hard areas, characterized as calcified plaque, as well as softer deposits consisting of fibrous or fatty tissue. As plaque continues to accumulate, it can completely block the artery, making it particularly difficult for physicians to treat.

Comparison of a normal artery to an atherosclerotic artery

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PAD is atherosclerosis in the arteries that supply blood to areas other than the heart, particularly the pelvis and legs, and may lead to serious symptoms such as pain, fatigue or numbness. Genetic predisposition, diabetes, smoking, hypertension, physical inactivity, high cholesterol, obesity and aging all increase the risk of developing PAD. In extreme cases, PAD can lead to critical limb ischemia, or CLI, which, if left untreated, can result in ulceration, infection, or gangrene in the feet and legs and eventually limb amputation or death. The Transatlantic Intersociety Consensus for the Management of Peripheral Arterial Disease, or TASC II, estimates that 55% of CLI patients will undergo amputation or die within one year after the diagnosis.

Current Treatments for PAD and Their Limitations

Physicians have several options available to treat PAD. For mild cases, lifestyle changes or drug therapy may slow or stabilize progression of the disease and alleviate symptoms. For more advanced cases of PAD, a physician may employ minimally-invasive endovascular procedures, or surgical interventions such as bypass or amputation.

Medical Management

The large majority of cases of diagnosed PAD in the United States are medically managed, according to the Society of Interventional Radiology. For this population, lifestyle changes, including improved diet, regular exercise and smoking cessation, as well as drug treatment are often prescribed. Although these measures can be effective, many people are unable to sustain them. In addition, these measures may reduce the symptoms, but do not treat the underlying causes of the disease. Physicians may also prescribe medications that lower cholesterol and reduce blood pressure. These drug therapies are generally prescribed for the life of the patient and do not treat the obstruction, making them an ineffective treatment for many patients. As a result, many of these patients will ultimately require more aggressive treatments.

Surgery

Bypass Surgery. More severe cases of PAD may be treated by surgeons with bypass surgery. This procedure entails using a synthetic graft or harvesting a healthy vessel from another area of the body and grafting it around a blocked portion of an artery. This procedure diverts blood flow around the occluded area to ensure that the tissue supplied by these arteries receives sufficient blood flow. Given its invasive nature, bypass surgery is performed by physicians in an operating room with the patient under general anesthesia. Bypass surgery involves multi-day hospital stays for healing and rehabilitation. General anesthesia and the potential for surgical infections make this approach less suitable for patients with conditions such as high blood pressure, heart failure, chronic obstructive pulmonary disease or poor kidney function. We estimate there were over 150,000 lower extremity bypass surgeries performed in the United States in 2013.

Amputation. CLI is a serious form of PAD caused by severe lack of blood flow to the legs and often results in pain at rest and tissue breakdown. Physicians may recommend full or partial amputation of the leg or foot for patients with CLI. TASC II estimates that 30% of patients with CLI will require an amputation within one year of diagnosis, and

15% of patients who undergo amputation of one leg will undergo amputation of the other leg within two years of the first amputation. According to TASC II, the mortality rate for patients with CLI is 25% at one year from the development of the condition. The Sage Group estimates that approximately 200,000 amputations occur annually as a result of CLI.

Endovascular Interventions

In recent years, technologies and techniques have improved such that many forms of PAD can now be treated by physicians with endovascular approaches. We believe PAD endovascular interventions will continue to increase due to improved safety and effectiveness of endovascular procedures relative to surgical alternatives, together with greater physician and patient awareness of the disease. The most common endovascular treatments include balloon angioplasty, stenting and atherectomy. These procedures involve a physician feeding a catheter over a guidewire through a small incision, typically while using fluoroscopy, or x-ray, as a visual guide. In the event that the patient has a CTO, the physician may require a specialized guidewire, support catheter or other device to cross the CTO prior to treatment consisting of balloon angioplasty, stenting, atherectomy or some combination thereof.

Fluoroscopy is the primary imaging tool currently used during endovascular treatments but delivers limited information to physicians. This technology provides an external view of the artery and does not allow physicians to differentiate between plaque and healthy arterial structures. Additionally, fluoroscopy exposes physicians, hospital staff and patients to radiation, which can lead to cataracts, cancer and abnormal blood cell counts. In addition, physicians frequently perform angiography in combination with fluoroscopy to assess the location and severity of the blockage. Angiography requires the use of contrast dye, which can increase the risk of kidney damage and may lead to acute kidney failure.

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Importance of the External Elastic Lamina. Scientific research has identified the importance of minimizing vascular injury during an endovascular intervention, and specifically the disruption of the membrane between the outer most layers of the artery, which is referred to as the external elastic lamina, or EEL. A study by the Sanford Burnham Institute concluded that disruption of the area around the EEL creates an inflammatory response significantly greater than when the EEL is not injured, ultimately leading to accelerated narrowing of the artery. This narrowing of the artery is known as restenosis, which can lead to the restriction of blood flow. EEL disruption can be caused by wire-based CTO crossing, dissection from balloon angioplasty, stent placement, or an atherectomy device cutting through this area.

Image of the EEL using our visualization compared to a cross sectional view of an artery.

A study from New York s Mount Sinai Medical Center, published in the Journal of Endovascular Therapy in 2015, demonstrated the correlation between restenosis rates and vascular injury during directional atherectomy procedures. Specifically, the study examined the composition of the tissue removed during treatment of 116 patients and assessed restenosis rates after one year. The study found that in 53% of the patients, the extracted tissue contained evidence of vascular injury. In this group of patients the restenosis rate, one-year after treatment, was 97%, while in the group of patients without evidence of vascular injury, the restenosis rate was only 11%.

The data from the Mount Sinai Medical Center study are summarized in the following chart:

Atherectomy Procedures Restenosis Rates at 1-Year

We believe balloon angioplasty, stenting and current atherectomy procedures often result in vascular injury, limiting their safety and efficacy, and increase restenosis rates associated with these treatments.

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Balloon Angioplasty. In an angioplasty procedure, a miniature balloon attached to the tip of the treatment catheter opens the blood vessel by expanding the vessel and compressing plaque against the arterial wall. While angioplasty catheters are relatively easy to use, they stretch the arterial wall, often leading to dissections of, and damage to, the EEL. Furthermore, angioplasty does not actually remove the plaque, which remains in the artery. Different variations of balloon catheters have been developed for the treatment of PAD, claiming additional benefits compared to standard angioplasty. These include cutting or scoring balloons designed to treat blockages with lower inflation pressures, as well as drug-coated balloons designed to suppress the inflammatory response to minimize restenosis. According to TASC II, 35% of angioplasty treatments result in restenosis at one year and 52% at three years. Millennium Research Group estimates that 500,000 PAD angioplasty procedures in the pelvis and legs were performed in the United States in 2013, 62% of which required the additional use of a stent.

Stenting. A stent is a wire-mesh tube that acts as a scaffold inside the artery to maintain adequate blood flow. Stents are currently available in bare metal and drug-coated varieties, with the latter designed to inhibit restenosis. Since stents rely on a similar expansion mechanism as balloons, we believe they also cause injury to the arterial wall and damage healthy arterial structures during placement. According to TASC II, 27% of PAD stent treatments result in restenosis at one year and 36% at three years. Additionally, according to a study in the Journal of the American College of Cardiology, stents placed in the legs fracture in approximately 25% of cases and, in such cases, have one-year patency, or absence of restenosis, rates of 41%, compared to 84% in cases with no stent fractures. Stents placed in the legs are often longer than coronary stents due to the diffuse nature of the lesions and the arterial anatomy, and longer stents have significantly higher fracture rates. Once a stent is implanted, it cannot be removed, which may limit future treatment options such as angioplasty, additional stenting, atherectomy and bypass surgery. Millennium Research Group estimates that 370,000 PAD stent procedures in the pelvis and legs were performed in the United States in 2013.

Atherectomy. Atherectomy is a procedure in which plaque is cleared from the arterial walls using a catheter-based technology with a mechanism to remove or displace diseased tissue. There are several types of atherectomy devices, including directional, rotational and laser, each with different mechanisms of action to remove or displace plaque. Except for Pantheris, currently available atherectomy devices rely on fluoroscopy rather than on- board imaging to provide visual guidance throughout the entire procedure. These atherectomy treatments frequently require the use of a stent or balloon to achieve the desired outcome and cannot selectively target the removal of only diseased tissue. As a result, traditional atherectomy technologies can damage the blood vessel being treated, which we believe increases the risk of restenosis. According to an article published in the Journal of Invasive Cardiology reviewing published clinical data, one-year restenosis rates for existing atherectomy technologies range from 22% to 46%. According to Millennium Research Group, there were 80,000 atherectomy procedures performed in the pelvis and legs in the United States in 2013, 86% of which required the use of a stent or balloon.

Our Solution

Our pioneering Lumivascular platform combines best-in-class interventional devices with optical coherence tomography, or OCT, a high resolution, light-based, radiation-free intravascular imaging technology. Our Lumivascular platform provides physicians with real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first products to offer intravascular visualization during CTO crossing and atherectomy, respectively.

Visualization using our Lumivascular technology compared to standard fluoroscopy imaging

We believe the combination of enhanced visualization and the ability to precisely target the diseased portion of an artery will allow physicians to access difficult-to-treat areas and significantly improve the safety and efficacy of endovascular procedures for patients. Market acceptance of our Lumivascular platform products may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products as compared to alternative procedures such as angioplasty, stenting, bypass surgery or other atherectomy procedures. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. We believe that our Lumivascular platform provides the following benefits to physicians, hospitals and patients, as compared to balloons, stents and other atherectomy procedures:

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- ***Improved efficacy through reduced risk of restenosis.*** Clinical evidence supports the proposition that more desirable outcomes in treating PAD are achieved by minimizing injury to the vessel wall during treatment, thereby reducing the risk of restenosis. Our Lumivascular platform is designed to provide physicians with a clear picture from inside the artery during treatment. In addition, the directional nature of our catheters is designed to enable physicians to accurately target the diseased area, resulting in less damage to arterial structures and allowing for the precise removal of plaque. Our VISION clinical trial demonstrated that the average percent area of adventitial component was only 1% of the total tissue section from histopathological analysis of 162 lesion specimens in the primary cohort. We believe that the low level of adventitia excision means less EEL disruption and will correlate to lower restenosis rates and improved long-term outcomes for patients treated with Pantheris. Additionally, a study conducted at Mount Sinai Medical Center, New York involving 116 patients found one-year restenosis rates of 97% and 17% in patients with and without evidence of EEL disruption, respectively. The Mount Sinai Medical Center study was not conducted using our products. Although we believe that our products would achieve similar results to those achieved with existing atherectomy devices in which no EEL disruption occurred, we can provide no assurance that this would have been the case.

- ***Safety of endovascular procedures.*** Serious adverse events such as perforations and dissections may be reduced during endovascular procedures using our Lumivascular platform. The results of our CONNECT II trial showed the benefit of our Lumivascular platform, as demonstrated by the 98% safety rates in CTO cases using Ocelot, and there were no clinically significant perforations or dissections caused by Pantheris in our VISION trial.

- ***Expanded patient population eligible for endovascular treatment of PAD.*** Our Lumivascular platform is designed to allow physicians to treat complex PAD cases where a traditional guidewire may not be successful due to the high CTO crossing success rates of Ocelot in such cases. There are 150,000 peripheral bypass procedures and 200,000 amputations performed each year in the United States. We believe these procedures are frequently performed as a result of an inability to cross a CTO with endovascular techniques. In our CONNECT II trial, Ocelot demonstrated a 97% CTO crossing rate in cases where a traditional guidewire was not successful. This crossing effectiveness enables the endovascular treatment of patients who may have previously been required to undergo bypass surgery or amputation. In addition, due to improved safety of our Lumivascular platform products, we believe physicians will be more likely to use our products to treat patients who would otherwise be medically managed.

- ***Decreased radiation exposure for physicians and patients.*** In current endovascular treatments for PAD, physicians use fluoroscopy as the primary means of imaging and navigating to the target vessel and assessing results of the treatment. This standard practice exposes physicians, hospital staff and patients to harmful x-ray radiation for a significant period of time. Radiation exposure can be especially high for physicians and hospital staff who may perform multiple endovascular PAD procedures per day. Our Lumivascular platform, which utilizes radiation-free OCT imaging, provides real-time visualization from the inside of the artery. When using our Lumivascular platform, physicians may elect to use less fluoroscopy during a procedure as a result of having an additional means of visualization that does not involve radiation.

- ***Reduced use of balloons and stents and preservation of future treatment options.*** Pantheris is designed to enable physicians to successfully perform atherectomy procedures and remove plaque blockages in PAD patients using fewer balloons and stents. Current atherectomy procedures often require the use of balloons and stents, which may result in restenosis and limit future treatment options. In our VISION trial, balloon angioplasty was used following Pantheris in less than half of the lesions treated, and stents were used in just 4% of treated lesions. By avoiding the use of stents in atherectomy procedures, we believe that Pantheris better preserves future treatment options. We believe our Lumivascular platform can replace other endovascular technologies, lower restenosis rates and reduce overall healthcare costs.

- ***Lumivascular platform designed for ease of adoption by physicians and hospitals.*** Our Lumivascular platform products, while providing image-guided assistance to physicians, are used in a similar fashion to traditional catheters. Consequently, we believe the more than 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States that are trained in endovascular techniques can generally adopt our Lumivascular platform and products without extensive training. We are designing future products to be compatible with our Lumivascular platform, which we expect will enhance the value proposition for hospitals to invest in our technology. We also believe that Pantheris qualifies for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

Risks of using the Lumivascular platform include the risks that are common to endovascular procedures and generally may include perforation, dissection, embolization, bleeding, infection, restenosis and limb loss. We are aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption, including that in procedures using Pantheris,

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some physicians may prefer to have a technician or second physician assisting with the operation of the catheter and that training for technicians and physicians will be required to enable them to effectively operate our Lumivascular platform products. Our current products are contraindicated, and therefore should not be used, in the iliac, coronary, cerebral, renal and carotid arteries.

Our Strategy

Our goal is to become the leading provider of image-guided medical devices for physicians to treat vascular diseases. The key elements of our strategy are to:

- ***Increase the installed base and penetration of our Lumivascular platform.*** Our current sales efforts focus on establishing new Lumivascular platform sites by marketing our products to physicians and hospital administrators through our direct sales force in the United States. Additionally, we seek to increase the use of our Lumivascular platform products by our current customers through case coverage, clinical training and other programs. We expect to continue to grow our sales force in order to better support current customers and attract new users of our Lumivascular platform products. We believe that expanding our U.S. commercial infrastructure and establishing distributor relationships in select regions outside the United States will drive further adoption of our Lumivascular platform.

- ***Perform additional post-market studies to demonstrate the clinical and economic benefits of our Lumivascular platform***. We intend to initiate post-market studies that will examine clinical outcomes of our Lumivascular platform products. We plan to conduct observational registry studies as well as randomized trials comparing the safety, efficacy and cost of our Lumivascular platform products to other endovascular treatments for PAD. We may also conduct studies to support additional clinical indications.

- ***Assist hospitals in raising awareness of our Lumivascular platform for patients suffering from PAD***. We are focused on increasing the awareness of our Lumivascular platform and the benefits it offers to patients and physicians. We work with our hospital customers to build a Lumivascular platform-based program through clinical training, public relations and physician education. The main focus of our clinical value proposition is to demonstrate how the Lumivascular platform allows physicians to avoid injury to the healthy arterial structures during intervention, while addressing the other limitations of competing endovascular approaches. We plan to continue working with our customers to position our Lumivascular platform as an offering they can use to demonstrate their commitment to using the most advanced technologies in caring for their patients.

- ***Leverage our technology platform to develop new products and further enhance our intellectual property portfolio***. We intend to continue to invest in initiatives to improve the safety, efficacy and ease of use of our Lumivascular platform, as well as to reduce costs and procedure times. We have also identified a number of future

expansion opportunities designed to position our Lumivascular platform as the standard of care for vascular disease. We expect our Pantheris atherectomy device to be an important addition to our Lumivascular platform. We also intend to explore the feasibility of seeking new indications for our Lumivascular platform to address unmet clinical needs within the CAD market. We believe we have a strong intellectual property portfolio and will continue to enhance this portfolio as we develop new technologies.

- ***Optimize our manufacturing operations to achieve cost and production efficiencies while maintaining quality***. We design, develop and manufacture all of our products in-house at our headquarters in Redwood City, California using some components and sub-assemblies provided by third-party suppliers. We believe that controlling the manufacturing and assembly of our products allows us to innovate more quickly and produce higher quality products than if we outsourced manufacturing. We have the capacity to significantly increase our manufacturing volume within our current facilities. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce unit costs and increase our gross margins. To further reduce costs, we may seek to manufacture certain of our products or subassemblies outside the United States or through third-party contract manufacturers.

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Our Products

Our current products include our Lightbox console and our various catheters used in PAD treatment. Each of our current products is, and our future products will be, designed to address significant unmet clinical needs in the treatment of vascular disease.

LUMIVASCULAR PRODUCTS

Name	Clinical Indication	Size (Length, Diameter)	Regulatory Status	Original Clearance Date
Lightbox(1)	OCT Imaging	N/A	FDA Cleared CE Mark	November 2012 September 2011
Pantheris 8F	Atherectomy	110cm, 8 French (F)	FDA Cleared CE Mark	October 2015 June 2015
Pantheris 7F	Atherectomy	110cm, 7F	FDA Cleared CE Mark	March 2016 June 2015
Ocelot(2)	CTO Crossing	110cm, 6F	FDA Cleared CE Mark	November 2012 September 2011
Ocelot MVRX(2)	CTO Crossing	110cm, 6F	FDA Cleared	December 2012
Ocelot PIXL(2)	CTO Crossing	135/150cm, 5F	FDA Cleared CE Mark	December 2012 October 2012

(1) Lightbox is cleared for use with compatible Avinger products.

(2) The Ocelot system is intended to facilitate the intra-luminal placement of conventional guidewires beyond stenotic lesions including sub and chronic total occlusions in the peripheral vasculature prior to further percutaneous interventions using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy and provides images of vessel lumen and wall structures. The Ocelot system is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.

NON-IMAGING PRODUCTS

Name	Indication	Size (Length, Diameter)	Regulatory Status	Original Clearance Date
Wildcat(1)	Guidewire Support CTO Crossing	110cm, 6F 110cm, 6F	FDA Cleared FDA Cleared CE Mark	February 2009(3) August 2011 May 2011
Kittycat 2(2)	CTO Crossing	150cm, 5F	FDA Cleared CE Mark	October 2011 September 2011

(1) The Wildcat catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat catheter is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature. The Wildcat catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast.

(2) The Kittycat 2 catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including sub and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat 2 catheter is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.

(3) This original clearance date is for the 7F version of Wildcat. The commercially available version of Wildcat is listed and was cleared in August 2010.

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Lumivascular Platform Overview

Our Lumivascular platform integrates OCT visualization with interventional catheters and is the industry s only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. Our Lumivascular platform consists of a capital component, Lightbox, and a variety of disposable catheter products, including Ocelot, Ocelot PIXL, Ocelot MVRX and Pantheris.

Lightbox

Lightbox is our proprietary imaging console, which enables the use of Lumivascular catheters during PAD procedures. The console contains an optical transceiver that transmits light into the artery through an optical fiber and displays a cross-sectional image of the vascular tissue to the physician on a high definition monitor during the procedure. Lightbox is configured with two monitors, one for the physicians, and one for the Lightbox technician.

Lightbox

OCT image, showing layered structures (artery wall) on the right and non-layered structures (atherosclerotic plaque) on the left.

Lightbox displays a cross-sectional view of the vessel, which provides physicians with detailed information about the orientation of the catheter and the surrounding artery and plaque. Layered structures represent relatively healthy portions of the artery and non-layered structures represent the plaque that is blocking blood flow in the artery. Navigational markers allow the physician to orient the catheter toward the treatment area, helping to avoid damage to the black line during a procedure. Lightbox received FDA 510(k) clearance in November 2012 and CE Mark in Europe in September 2011.

Pantheris

We believe Pantheris is the first atherectomy catheter to incorporate real-time OCT intravascular imaging. Pantheris may be used alone or following a CTO crossing procedure using Ocelot or other products. Pantheris is a single-use product and will provide physicians with the ability to see a cross-sectional view of the artery throughout the procedure. The device restores blood flow by shaving thin strips of plaque using a high-speed directional cutting mechanism that specifically targets the portion of the artery where the plaque resides while minimizing disruption to healthy arterial structures. The excised plaque is deposited in the nosecone of the device and removed from the artery. We believe Pantheris represents a meaningful advancement in the treatment of PAD and will expand the existing treatable market.

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Pantheris positioned prior to a cut

Pantheris excising plaque

To perform atherectomy procedures using Pantheris, physicians advance Pantheris to the diseased portion of the vessel using fluoroscopy prior to activating the cutting tip. The OCT image provides the physician with a cross-sectional view of the treatment site and the relative orientation of the cutter. Visual cues are used to orient the cutting mechanism to target diseased sections of the artery and the plaque is removed by activating the cutter and advancing the catheter through the blockage. A balloon beneath the cutter is inflated to move the catheter closer to the plaque, enabling the physician to stabilize the device and adjust the cut depth into the plaque as necessary. Multiple cuts can be made with the same device until sufficient plaque has been removed to restore adequate blood flow in the artery. In July 2014, FDA granted us an investigational device exemption, or IDE, for Pantheris and we commenced enrollment of our 133-patient VISION trial. We completed enrollment of the VISION trial in March 2015 and we submitted for 510(k) clearance from FDA in August 2015. In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We have made minor modifications to Pantheris since the VISION trial and have recently commenced U.S. sales following receipt of FDA approval this enhanced version of Pantheris in March, 2016. We received CE Mark for Pantheris in June 2015 and in August 2015 for the enhanced version of Pantheris.

Ocelot, Ocelot PIXL and Ocelot MVRX

Ocelot is the first ever CTO crossing catheter to incorporate real-time OCT imaging, which allows physicians to see the inside of an artery during a CTO crossing procedure. Physicians have traditionally relied solely on fluoroscopy and tactile feedback to guide catheters through complicated blockages. Ocelot allows physicians to accurately navigate through CTOs by utilizing the OCT images to precisely guide the device through the arterial blockage, while minimizing disruption to the healthy arterial structures.

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Ocelot crossing a chronic total occlusion, or CTO *Lightbox visualization*

Ocelot has a corkscrew-like tip that rotates to facilitate advancement of the catheter through a CTO. Marker bands are displayed on the OCT image and allow the tip of the catheter to be steered towards the blockage and away from the arterial wall as it moves through the blockage. Once through the blockage, a guidewire can be extended and Ocelot is removed, leaving the wire in place for additional therapies such as the use of an atherectomy catheter like Pantheris. We received CE Mark for Ocelot in September 2011 and received FDA 510(k) clearance in November 2012.

We also offer Ocelot PIXL, a lower profile CTO-crossing device for below-the-knee arteries and Ocelot MVRX, which offers a different tip design for above-the-knee arteries. We received CE Mark for Ocelot PIXL in October 2012 and received FDA 510(k) clearance in December 2012. We received FDA 510(k) clearance for Ocelot MVRX in December 2012.

Other Products

Our first-generation CTO-crossing catheters, Wildcat and Kittycat 2, employ a proprietary design that uses a rotational spinning technique, allowing the physician to switch between passive and active modes when navigating across a CTO. Once across the CTO, Wildcat and Kittycat 2 allow for placement of a guidewire and removal of the catheter while leaving the wire in place for additional therapies. Both products require the use of fluoroscopy rather than our Lumivascular platform for imaging. Wildcat was our first commercial product and has received both FDA 510(k) clearance in the United States and CE Mark in Europe for crossing peripheral artery CTOs. Kittycat 2 has FDA 510(k) clearance in the United States and CE Mark clearance in Europe for the treatment of peripheral artery CTOs.

Clinical Development

We have conducted several clinical trials to evaluate the safety and efficacy of our products and we received FDA clearance for Wildcat and Ocelot for CTO crossing in 2011 and 2012, respectively, and for Pantheris in October 2015.

CONNECT (Wildcat)

Our clinical trial for the Wildcat catheter, known as the CONNECT trial, was a prospective, multi-center, non-randomized trial that evaluated the safety and efficacy of Wildcat in crossing CTOs in arteries of the upper leg. The CONNECT trial enrolled 88 patients with CTOs at 15 centers in the United States. Patients were followed for 30 days post-procedure and an independent group of physicians verified the results to determine crossing efficacy and safety endpoints. The CONNECT trial demonstrated that Wildcat was able to cross 89% of CTOs following unsuccessful attempts to cross with standard guidewire techniques. The trial demonstrated a 95% freedom from major adverse events, or MAEs. In the CONNECT trial, MAEs were defined as clinically significant perforations or embolizations and/or Grade C or greater dissections occurring within 30 days of the procedure. These results represent the second-highest reported CTO crossing rate of any published CTO clinical trial, exceeded only by our subsequent CONNECT II clinical trial results.

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CONNECT II (Ocelot)

Our clinical trial for Ocelot, known as CONNECT II, was a prospective, multi- center, non-randomized trial that evaluated the safety and efficacy of Ocelot in crossing CTOs in arteries of the upper leg using OCT intravascular imaging. The CONNECT II trial enrolled 100 patients with CTOs at 14 centers in the United States and two centers in Europe. Patients were followed for 30 days post-procedure and an independent group of physicians verified the results to confirm the primary efficacy and safety endpoints. Results from the CONNECT II trial demonstrated that Ocelot surpassed its primary efficacy endpoint by successfully crossing the CTO in 97% of the cases following unsuccessful attempts to cross with standard guidewire techniques. Ocelot achieved these rates with 98% freedom from MAEs.

VISION (Pantheris)

VISION was our pivotal, non-randomized, prospective, single-arm trial to evaluate the safety and effectiveness of Pantheris across 20 sites within the United States and Europe. The objective of the clinical trial was to demonstrate that Pantheris can be used to effectively remove plaque from diseased lower extremity arteries while using on-board visualization as an adjunct to fluoroscopy. Two groups of patients were treated in VISION: (1) optional roll-ins, which are typically the first two procedures at a site, and (2) the primary cohort, which are the analyzable group of patients. The data for these two groups was reported separately in our 510(k) submission to FDA. Based on final enrollment, the primary cohort included 130 patients. In March 2015, we completed enrollment of patients in the VISION clinical trial and we submitted for 510(k) clearance from the FDA in August 2015. In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We have made minor modifications to Pantheris subsequent to the completion of VISION and received 510(k) clearance on the enhanced version of Pantheris in March 2016.

VISON s primary efficacy endpoint requires that at least 87% of lesions treated by physicians using Pantheris have a residual stenosis of less than 50%, as verified by an independent core laboratory. The primary safety endpoint required that less than 43% of patients experience an MAE through six-month follow-up as adjudicated by an independent Clinical Events Committee, or CEC. MAEs as defined in VISION included cardiovascular-related death, unplanned major index limb amputation, clinically driven target lesion revascularization, or TLR, heart attack, clinically significant perforation, dissection, embolus, and pseudoaneurysm. Results from the VISION trial demonstrated that Pantheris surpassed its primary efficacy and safety endpoints; residual restenosis of less than 50% was achieved in 96.3% of lesions treated in the primary cohort, while MAEs were experienced in 17.6% of patients.

Although not mandated by the FDA to support the market clearance of Pantheris, the protocol for the VISION trial allowed for routine histopathological analysis of the tissue extracted by Pantheris to be conducted. This process allowed us to determine the amount of adventitia present in the tissue, which in turn indicated the extent to which the external elastic lamina had been disrupted during Pantheris procedures. We completed histopathological analysis on tissue from 129 patients in the primary cohort, representing 162 lesions and determined that the average percent area of adventitia was only 1.0% of the total excised tissue. We believe the low level of EEL disruption will correlate to lower restenosis rates and improved long-term outcomes for patients treated with Pantheris, but we do not intend to make any promotional claims to that effect based on the data from this study. We published the results of the histopathological analysis in conjunction with the primary safety and efficacy endpoint data from the VISION trial.

Final VISION trial data is summarized in the table below.

	Roll-In Cohort	Primary Cohort	Total
Patients Treated	28	130	158
Lesions treated	34	164	198
Primary Efficacy Endpoint			
Lesions analyzed by core lab	34	164	198
Lesions meeting primary efficacy endpoint criterion of residual restenosis of less than 50% by core lab	100%	96.3%	97%
	(34/34)	(158/164)	(192/198)
Primary Safety Endpoint (MAEs through 6 months)			
Total MAEs Reported	3	22	25
Reported MAEs as a percentage of patients enrolled	11.5%	17.6%	16.6%
	(3/26)	(22/125)	(25/151)
Histopathology Results (Non-Endpoint Data)			
Lesions with histopathology results	34	162	196
Average percent area of adventitia in all lesions with histopathology results	0.56%	1.02%	0.94%

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Sales and Marketing

We focus our sales and marketing efforts primarily on the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States that are potential users of our Lumivascular platform products. Our marketing efforts are focused on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders based on their knowledge of our products, clinical expertise and reputation. We also use continuing medical education programs and other opportunities to train interventional cardiologists, vascular surgeons, and interventional radiologists in the use of our Lumivascular platform products and educate them as to the benefits of our products as compared to alternative procedures such as angioplasty, stenting, bypass surgery or other atherectomy procedures. In addition, we work with physicians to help them develop their practices and with hospitals to market themselves as centers of excellence in PAD treatment by making our products available to physicians for treating patients.

Our sales team consists of a vice president, directors, regional managers, sales representatives and clinical specialists. Our sales representatives are divided into two primary roles, one focused on sale and use of our disposable catheters and the other focused on sale and service of our Lightbox console. We have an extensive hands-on sales training program, focused on our technologies, Lumivascular image interpretation, case management, sales processes, sales tools and implementing our sales and marketing programs and compliance with applicable federal and state laws and regulations. Our sales team is supported by a highly specialized marketing team, which is divided into three areas of focus: clinical education, marketing program implementation and technology awareness and product development. We also have a small team of field engineers responsible for installation, service and maintenance of our Lightbox consoles.

As of December 31, 2015, we had 70 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 2015, 2014 and 2013 were $29.2 million, $18.5 million and $25.8 million, respectively.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations and other factors relating to our industry. Because of the market opportunity and the high growth potential of the PAD treatment market, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

Our products compete with a variety of products or devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon market segments include Abbott Laboratories, Boston Scientific, Cardinal Health, Cook Medical, CR Bard and Medtronic. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic, Philips and Spectranetics. Some competitors have attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on-board visualization into their products in the future. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our solution.

Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels and broader product offerings, and have established stronger and deeper relationships with target customers.

To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments on the basis of:

- procedural safety and efficacy;
- acute and long-term outcomes;
- ease of use and procedure time;
- price;
- size and effectiveness of sales force;
- radiation exposure for physicians, hospital staff and patients; and
- third-party reimbursement.

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Intellectual property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights.

It is our policy to require our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using the proprietary rights of third parties in their work for us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

As of December 31, 2015, we held six issued U.S. patents and had 20 U.S. utility patent applications and 3 PCT applications pending. As of December 31, 2015, we also had 10 issued patents from outside of the United States. As of December 31, 2015, we had 39 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. As we continue to research and develop our Pantheris technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our atherectomy devices. Our issued patents expire between the years 2028 and 2032.

Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

As of December 31, 2015, we held three registered U.S. trademarks and two pending U.S. trademark applications, one of which has been allowed. In Europe we hold two registered trademarks. In addition, we held one International Registration under the Madrid Protocol with pending extensions to China, Europe, Japan, and Korea.

Research and Development

Our ongoing research and development activities are primarily focused on improving and enhancing our Lumivascular platform, specifically our core competency of integrating OCT intravascular imaging onto therapeutic catheters. Our research objectives target areas of unmet clinical need, increase the utility of the Lumivascular platform and adoption of our products by healthcare providers.

- ***Product line improvements and extensions.*** We are developing improvements to our Lumivascular platform, including additional catheters for use in different clinical applications. For example, we are developing versions of Pantheris designed to treat smaller vessels and with enhanced cutting capability. We are also developing a next-generation CTO crossing device to target both the peripheral and coronary CTO markets.

- ***Additional treatment indications.*** We intend to seek additional regulatory clearances from FDA to expand the indications for which our products can be marketed within PAD, as well as in other areas of the body. This includes both expanding the marketed indications for our current products, as well as development of new products.

- ***Next-generation console.*** We are focusing our console development efforts on miniaturization, equipment integration and increased processing power in anticipation of future catheter products. We may also develop a version of our Lumivascular platform that integrates OCT imaging into existing catheterization lab and operating room imaging systems.

- ***Improved software and user interface.*** We are actively improving our software to provide more information and control to our end users during a procedure. We use physician and staff feedback to improve the features and user functionality of our Lumivascular platform.

As of December 31, 2015, we had 25 employees focused on research and development. In addition to our internal team, we retain third-party contractors from time to time to provide us with assistance on specialized projects. We also work closely with experts in the medical community to supplement our internal research and development resources. Research and development expenses for the years ended December 31, 2015, 2014 and 2013 were $15.7 million, $11.2 million and $16.0 million, respectively.

Manufacturing

Prior to the introduction of our Lumivascular platform, our non-imaging catheter products were manufactured by a third-party. All of our products are now manufactured in-house using components and sub-assemblies manufactured both in-house at our facilities in Redwood City, California and by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2017. We assemble all of our products at our manufacturing facility but certain critical processes such as coating and sterilization are done by outside vendors.

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Our manufacturing operations are subject to regulatory requirements of 21 CFR part 820 of the Federal Food, Drug and Cosmetic Act, or FFDCA; the Quality System Regulation, or QSR, for medical devices sold in the United States, which is enforced by FDA; the Medical Devices Directive 93/42/EEC, which is required for doing business in the European Union; and applicable requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances, and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. We cannot ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims by or injury to employees or the public.

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components or subassemblies.

We rely on single and limited source suppliers for several of our components. For example, we rely on one vendor for, among other components, our torque shaft and drive cable. These components are critical to our products and there are relatively few alternative sources of supply for them. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of the components used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our product and could therefore harm our business, financial condition and results of operations.

Our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components would limit our ability to manufacture our product and could have a material adverse effect on our business, financial condition and results of operations.

We have registered with FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDRH. We and our component suppliers are required to manufacture our products in compliance with FDA s QSR in 21 CFR part 820 of the FFDCA. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. Since we began manufacturing onsite, our Quality System has undergone 14 external audits, the last of which occurred on July 7 through July 9, 2015 and resulted in zero non-conformances.

Our failure or the failure of our component suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. Our Redwood City facilities meet the requirements set forth by ISO 13485:2003 Medical devices Quality management systems Requirements for regulatory purposes and MDD 93/42/EEC European Union Council Medical Device Directive.

Government Regulation

In general, medical device companies must navigate a challenging regulatory environment. The FDA regulates the medical device market to ensure the safety and efficacy of these products. The FDA allows for two primary pathways for a medical device to gain approval for commercialization: a successful pre-market approval, or PMA application or 510(k) clearance. A completely novel product must go through the more rigorous PMA process, or premarket approval, if it cannot receive authorization through a 510(k). The FDA has established three different classes of medical devices that indicate the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy. Level I and Level II devices are considered lower risk and often can gain approval for commercial distribution by submitting a notification request to the FDA, generally known as the 510(k) process. The devices regarded as the highest risk by the FDA are designated Class III status and generally require the submission of a PMA application for approval to commercialize a product. These generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA.

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The 510(k) clearance path can be significantly less time-consuming and arduous than PMA approval, making this route preferable for a medical device company. Through a 510(k), a company must provide documentation that its device is substantially equivalent to a technology already approved through a 510(k) or in distribution before May 28, 1976 for which the FDA has not yet required a PMA submission. The FDA has 90 days from the date of the premarket equivalence submission to authorize or decline commercial distribution of the device. However, similar to the PMA process, approval may take longer than this three-month window, as the FDA can request additional data. If the FDA resolves that the product is not substantially equivalent to a predicate device, then the device acquires a Class III designation. All of our currently marketed products have received commercial clearance and associated indications for use through the 510(k) regulatory pathway with the FDA, some with the support of clinical data.

A PMA application must be accompanied by substantial data that supports the safety and efficacy of the device, which includes the provision of preclinical, clinical, technical, manufacturing and labeling information. If the FDA deems the application acceptable to pass through the first level of scrutiny, it has 180 days to review the submission, but it can typically take longer (up to several years) as this regulatory body can request additional information or clarifications. The FDA may also impose additional regulatory hurdles for a PMA, including the institution of an outside advisory panel of experts to assess the application or provide recommendations as to whether to approve the device. Although the FDA in the end approves or disapproves the device, in nearly all cases the FDA follows the recommendation from the independent panel concerning approvability of the new device. As part of this process, the FDA will also inspect the manufacturing operations of the company requesting approval to verify compliance with quality control regulations. Significant changes in the fabrication of a device, or alterations in the labeling or design of a product require new PMA applications or PMA supplements for a product originally approved under a PMA. This creates substantial regulatory risk for devices undergoing the PMA route.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- The FDA s QSR which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;

- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance or PMA approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with the determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require a new 510(k) clearance or premarket approval. The FDA could also require a manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or premarket approval is obtained. Also, in these circumstances, it may be subject to significant regulatory fines, penalties, and warning letters.

The MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. BSI, our European Notified Body, inspected our facility in 2013 and 2015 and

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found zero non-conformances. Our current facility was inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. In the latest FDA audit, there were no findings that involved a material violation of regulatory requirements, and no non-conformances were noted. Our responses to these observations noted in 2009 and 2011 were accepted by the FDA, and we believe that we are in substantial compliance with the QSR.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

Regulatory System for Medical Devices in Europe

The European Union consists of 25 member states and has a coordinated system for the authorization of medical devices. The E.U. Medical Devices Directive, or MDD, sets out the basic regulatory framework for medical devices in the European Union. This directive has been separately enacted in more detail in the national legislation of the individual member states of the European Union.

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for CE mark varies

according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive federal protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities: health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures. HIPAA requires Covered Entities to obtain a written assurance of compliance from individuals or organizations who provide services to Covered Entities involving the use or disclosure of protected health information (Business Associates).

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009. HITECH amends HIPAA and, among other things, expands and strengthens HIPAA, creates new targets for enforcement, imposes new penalties for noncompliance and establishes new breach notification requirements for Covered Entities and Business Associates. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule, or the Omnibus Rule. The Omnibus Rule contained significant changes for Covered Entities and Business Associates with respect to permitted uses and disclosures of Protected Health Information.

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Under HITECH s new breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services, or the Secretary. Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and in some cases, they must be reported through local and national media, depending on the size of the breach. We are currently subject to the HIPAA regulations. We are subject to audit under the U.S. Department of Health and Human Services, or HHS, HITECH-mandated audit program. We may also be audited in connection with a privacy complaint. We are subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To avoid penalties under the HITECH breach notification provisions, we must ensure that breaches of protected health information are promptly detected and reported within the company, so that we can make all required notifications on a timely basis. However, even if we make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In addition to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations in all jurisdictions, both state and federal. However, we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security, could result in civil and/or criminal penalties and could have a material adverse effect on our business.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions.

In addition to federal privacy regulations, there are a number of state laws governing confidentiality of health information that are applicable to our operations. New laws governing privacy may be adopted in the future as well. We have taken steps to comply with health information privacy requirements that are applicable to us.

Federal, State and Foreign Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. In March 2010, the Recipient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act, was enacted in the United States. The provisions of the Affordable Care Act are effective on various dates. The Affordable Care Act expands the government s investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the Anti-Kickback Statute and the False Claims Act, to make it easier to bring suit under these statutes. The Affordable Care Act also allocates additional resources and tools for the government to police healthcare fraud, with expanded subpoena power for HHS, additional funding to investigate fraud and abuse across the healthcare system and expanded use of recovery audit contractors for enforcement.

Anti-Kickback Statutes. The federal healthcare programs Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

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The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General, or OIG, of HHS to issue a series of regulations known as safe harbors. These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Act. Another development affecting the healthcare industry is the increased use of the federal False Claims Act, and in particular, action brought pursuant to the False Claims Act s whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act, and many of these state laws apply where a claim is submitted to any third-party payor and not just a federal healthcare program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 and $11,000 for each separate instance of false claim. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Sunshine Act. The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Affordable Care Act, requires all entities that operate in the United States and manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children s Health Insurance Program to report annually to the Secretary of HHS: (i) payments or other transfers of value made by that entity, or by a third-party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician ownership and investment interests in the entity. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. The final rule implementing the Sunshine Act required data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, was due March 31, 2014. The statute requires the federal government to make reported information available to the public starting September 2014, which it has. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

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Foreign Corrupt Practices Act. The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

International Laws. In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act of 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The Act contains a number of provisions that impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal healthcare programs and reimbursement changes.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payors. While in general it is too early to predict specifically what effect the Affordable Care Act and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Third-Party Reimbursement

Payment for patient care in the United States is generally made by third-party payors, including private insurers and government insurance programs, such as Medicare and Medicaid. The Medicare program, the largest single payor in the United States, is a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services, or CMS, and covers certain medical care expenses for eligible elderly and disabled individuals. Because a large percentage of the population with PAD includes Medicare beneficiaries, and private insurers may follow the coverage and payment policies of Medicare, Medicare s coverage and payment policies are significant to our operations.

Medicare pays PAD treatment facilities, including hospitals and physician office-based labs, pre-determined amounts for each procedure performed. These payment amounts differ based on a variety of factors, including:

- Type of procedure performed angioplasty, stent or atherectomy;
- Patient-specific complexities and comorbidities;
- Type of facility hospital, teaching hospital or office-based lab;
- Inpatient or outpatient status; and
- Geographic region.

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We receive payment from the treatment facility for our products, and the Medicare reimbursement to the facility is intended to cover the overall cost of treatment, including the cost of products used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. For procedures performed in hospitals, the physician who performs the procedure is reimbursed separately under the Medicare physician fee schedule. Claims for PAD procedures are typically submitted by the treatment facility and physician to Medicare or other health insurers using established billing codes. These codes identify the procedures performed and are relied upon to determine third-party payor reimbursement amounts.

Medicare reimbursement levels for fiscal year 2016 went into effect as of October 1, 2015. National average Medicare payment rates for PAD procedures for fiscal year 2016 are $10,175 - $19,410 for inpatient procedures and, $4,592 - $14,612 for outpatient procedures. These amounts include the cost of disposable catheters such as Ocelot and Pantheris. While reimbursement varies based on the type of procedure performed (i.e., angioplasty, stent or atherectomy), additional device-specific reimbursement is not available. The amount of reimbursement can vary substantially by geographical region and by facility. Payment rates of other third-party payors may follow Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. Because of the wide variability, it is not possible to identify an average rate for third-party payors other than Medicare.

Employees

As of December 31, 2015, we had 186 employees, including 52 in manufacturing and operations, 69 in sales and marketing, 25 in research and development, 17 in clinical affairs, regulatory affairs, and quality assurance and 23 in finance, general administrative and executive administration. All 186 employees are full time employees. None of our employees are represented by a labor union or are parties to a collective bargaining agreement and we believe that our employee relations are good.

Corporate and other Information

We were incorporated in Delaware on March 8, 2007. Our principal executive offices are located at 400 Chesapeake Drive, Redwood City, California 94063, and our telephone number is (650) 241-7900. Our website address is *www.avinger.com*. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC s on-line database, which is located at *www.sec.gov*. Our common stock is traded on the NASDAQ Global Market under the symbol AVGR .

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure

obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes. Please also see Cautionary Notes Regarding Forward-Looking Statements.

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Risks Related to Our Business

Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our common stock.

Our quarterly and annual results of operations, including our revenues, profitability and cash flow, may vary significantly in the future and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuation in quarterly and annual results may decrease the value of our common stock. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, particularly Pantheris, which we commenced commercialization in March 2016;

- market acceptance of our Lumivascular platform;

- the availability of reimbursement for our Lumivascular platform products;

- our ability to attract new customers and grow our business with existing customers;

- results of our clinical trials;

- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;

- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;

- changes in our pricing policies or those of our competitors;
- general economic, industry and market conditions;
- the regulatory environment;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

We have a history of net losses and we may not be able to achieve or sustain profitability.

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $47.3 million in 2015, $32.0 million in 2014 and $39.9 million in 2013. As of December 31, 2015, we had an accumulated deficit of approximately $196.3 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

We expect our costs and expenses to increase in the future due to anticipated increases in cost of revenues, sales and marketing expenses, research and development expenses and general and administrative expenses and, therefore, we expect our losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

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Our limited commercialization experience and number of approved products makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

We were incorporated in 2007, began commercializing our initial non-Lumivascular platform products in 2009 and introduced our first Lumivascular platform products in the United States in late 2012. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries. These risks and uncertainties include the risks inherent in clinical trials and increasing and unforeseen expenses as we continue to attempt to grow our business.

Our short commercialization experience and limited number of approved products also make it difficult for us to forecast our future financial performance and growth and such forecasts are limited and subject to a number of uncertainties, including our ability to obtain FDA clearance for new versions of Pantheris and other Lumivascular platform products we intend to commercialize in the United States. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

Our success depends in large part on a limited number of products, particularly Pantheris, all of which have a limited commercial history. If these products fail to gain, or lose, market acceptance, our business will suffer.

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of Pantheris and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA approval to market an enhanced version of Pantheris in March 2016. As such, increased acceptance among physicians of these products may not occur. Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. If demand for Pantheris and our other Lumivascular platform products do not increase as we anticipate and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not

increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

We are also aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption. For example, in procedures using Pantheris, some physicians may prefer to have a technician or second physician assisting with the operation of the catheter as well as a separate technician to operate the Lightbox, making the procedure less financially attractive for physicians and their hospitals. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications, or obtain any additional and necessary regulatory clearances for such modifications. Also, although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our Lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye, particularly with Pantheris. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it will require training for technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. These or other characteristics and features of our Lumivascular platform may cause our products not to be widely adopted and harm our business, financial condition and results of operation.

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We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

We believe that the net proceeds from the follow-on offering we intend to conduct whereby we may issue and sell shares of common stock having an aggregate value of up to $50.0 million, together with our cash and cash equivalents at December 31, 2015 and expected revenues from operations and debt financing currently available under our Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds, or CRG, will be sufficient to satisfy our capital requirements and fund our operations for at least the next 12 months. We can provide no assurance that we will be successful in raising funds pursuant to our follow-on offering or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. We will likely need additional funds through our intended follow-on offering or in separate financing to meet our operational needs and capital requirements for product development, clinical trials and commercialization.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings and our initial public offering, or IPO. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary business technology or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;

- the costs and expenses of expanding our sales and marketing infrastructure and our manufacturing operations;

- the costs and timing of developing variations of our Lumivascular platform products, especially Pantheris, and, if necessary, obtaining FDA clearance of such variations;

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris;

- the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;

- the number and types of future products we develop and commercialize;

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

- the extent and scope of our general and administrative expenses.

We may raise funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of December 31, 2015, we had $29.6 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG. Our debt with CRG is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, incur debt, grant liens, make investments, make acquisitions, make certain restricted payments and sell assets, in each case subject to certain exceptions. We are also subject to standard event of default provisions under the Loan Agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. We used the initial net proceeds under the Loan Agreement to repay and terminate our credit facility with

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PDL Biopharma, Inc., or PDL, however, our obligation to continue to make royalty payments to PDL out of our quarterly revenues through April 18, 2018 remain in effect. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The existing collateral pledged under the Loan Agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions.

Our ability to compete is highly dependent on demonstrating the benefits of our Lumivascular platform to physicians, hospitals and patients.

In order to generate sales, we must be able to clearly demonstrate that our Lumivascular platform is both a more effective treatment system and more cost-effective than the alternatives offered by our competitors. If we are unable to convince physicians that our Lumivascular platform leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse events during treatment than those using competing technologies, our business will suffer. In order to use Pantheris or our Ocelot family of catheters, hospitals must make an investment in our Lightbox. Accordingly, we must convince hospitals and physicians that our Lumivascular platform results in significantly better patient outcomes at a competitive overall cost. For example, we may need to demonstrate that the investment hospitals must make when purchasing our Lightbox and the incremental costs of having a technician or a second physician operate Pantheris can be justified based on the benefits to patients, physicians and hospitals. If we are unable to develop robust clinical data to support these claims we will be unable to convince hospitals and third-party payors of these benefits and our business will suffer.

Our value proposition to physicians and hospitals is largely dependent upon our contention that the rate of arterial damage when physicians are using our products is lower than with competing products. If minimizing arterial damage does not significantly impact patient outcomes, meaning either (i) that restenosis is often triggered without disrupting healthy arterial structures, or (ii) arteries can be damaged during treatment without triggering restenosis, then we may be unable to demonstrate our Lumivascular platform s benefits are any different than competing technologies. Furthermore, physicians may find our imaging system difficult to use and we may not be able to provide physicians with adequate training to be able to realize the benefits of our Lumivascular platform. If physicians do not value the benefits of on-board imaging and the enhanced visualization enabled by our products during an endovascular intervention as compared to our competitor s products, or do not believe that such benefits improve clinical outcomes, our Lumivascular platform products may not be widely adopted.

The use, misuse or off-label use of the products in our Lumivascular platform may result in injuries that lead to product liability suits, which could be costly to our business.

We require limited training in the use of our Lumivascular platform products because we market primarily to physicians who are experienced in the interventional techniques required to use our device. If demand for our Lumivascular platform continues to grow, less experienced physicians will likely use the devices, potentially leading to more injury and an increased risk of product liability claims. The use or misuse of our Lumivascular platform products has in the past resulted, and may in the future result, in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims. Our Lumivascular platform products are contraindicated for use in the carotid, cerebral, coronary, iliac, or renal arteries. Our sales force does not promote the use of our products for off-label indications, and our U.S. instructions for use specify that our Lumivascular platform products are not intended for use in the carotid, cerebral, coronary, iliac or renal arteries. However, we cannot prevent a physician from using our Lumivascular platform products for these off-label applications. The application of our Lumivascular platform products to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a more narrow location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the

brain, leading to a stroke. If our Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management s attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our Lumivascular platform products.

We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

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Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of our Lumivascular platform products. Medical malpractice carriers are also withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our Lumivascular platform products and potential customers may opt against purchasing our Lumivascular platform products due to the cost or inability to procure insurance coverage.

Our ability to compete depends on our ability to innovate successfully.

The market for medical devices in general, and in the PAD market in particular, is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. There are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with ours. Demand for our Lumivascular platform products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our Lumivascular platform products could become obsolete and our revenues would decline as our customers purchase our competitors products.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could harm sales of our products. Our products could be rendered obsolete because of future innovations in the treatment of PAD. In order to remain competitive, we must continue to develop new product offerings and enhancements to our existing Lumivascular platform products. Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop products, applications or features due to certain constraints, such as insufficient cash resources, inability to raise sufficient cash in future equity or debt financings, high employee turnover, inability to hire sufficient research and development personnel or a lack of other research and development resources, we may miss market opportunities. Furthermore, many of our competitors expend a considerably greater amount of funds on their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to our competitors research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration, increasing our revenues or becoming profitable.

Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, Boston Scientific, Cardinal Health, Cook Medical, CR Bard and Medtronic. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic, Philips and Spectranetics. Some competitors have previously attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on-board visualization into their products in the future and may remain competitive with us in marketing traditional technologies. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our products. Many of our competitors have significantly greater financial and other resources than we do and have well-established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

Our ability to compete effectively depends on our ability to distinguish our company and our Lumivascular platform from our competitors and their products, and includes such factors as:

- procedural safety and efficacy;
- acute and long-term outcomes;
- ease of use and procedure time;
- price;
- size and effectiveness of sales force;
- radiation exposure for physicians, hospital staff and patients; and
- third-party reimbursement.

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In addition, competitors with greater financial resources than ours could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenues to decline and would harm our business.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late-stage clinical trials.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including:

- negative or inconclusive results that may cause us to decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;

- trial results that do not meet the level of statistical significance required by the FDA or other regulatory authorities;

- findings by the FDA or similar foreign regulatory authorities that the product is not sufficiently safe for investigational use in humans;

- interpretations of data from preclinical testing and clinical testing by the FDA or similar foreign regulatory authorities that may be different from our own;

- delays or failure to obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;

- delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;

- findings by the FDA or similar foreign regulatory authorities that our or our suppliers manufacturing processes or facilities are unsatisfactory;

- changes in the review policies of the FDA or similar foreign regulatory authorities or the adoption of new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;

- trouble in managing multiple clinical sites;

- delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and

- the suspension or termination by us, or regulators, of our clinical trials because the participating patients are being exposed to unacceptable health risks.

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Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials, and any failure of those parties to fulfill their obligations could increase costs and cause delays.

From time to time, we engage consultants to help design, monitor, and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to help facilitate the clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, commonly referred to as good clinical practices. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances that we need to commercialize our products.

We have no long-term data regarding the safety and efficacy of our Lumivascular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivascular platform may not be positive or consistent with our short-term data, which would harm our ability to obtain clearance to market and sell our products.

Our Lumivascular platform is a novel system, and our success depends on its acceptance by the medical community as being safe and effective, and improving clinical outcomes. Important factors upon which the efficacy of our Lumivascular platform products, including Pantheris, will be measured are long-term data on the rate of restenosis following our procedure, and the corresponding duration of patency, or openness of the artery, and publication of that data in peer-reviewed journals. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the use of our Lumivascular platform products. The long-term clinical benefits of procedures that use our Lumivascular platform products, including Pantheris, are not known.

The results of short-term clinical experience of our Lumivascular platform products, including Pantheris, do not necessarily predict long-term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long-term restenosis and reintervention for procedures using our Lumivascular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long-term rates of restenosis and reintervention do not meet physicians expectations, our Lumivascular platform products may not become widely adopted and physicians may recommend alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivascular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivascular platform products are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of our product may suffer and our business would be harmed. Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician s actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high-volume users of our Lumivascular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

Our ability to market our current products in the United States is limited to use in peripheral vessels, and if we want to market our products for other uses, we will need to file for FDA clearances or approvals and may need to conduct trials to support expanded use, which would be expensive, time-consuming and may not be successful.

Our current products are cleared in the United States only for crossing sub-total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These clearances prohibit our ability to market or advertise our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off-label uses of medical devices are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. We are not allowed to actively promote or advertise our products for off-label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot or Pantheris in the United States for use in coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues.

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The continuing development of many of our products, including Pantheris, depends upon maintaining strong working relationships with physicians.

The development, marketing, and sale of our products, including Pantheris, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry s relationship with physicians is under increasing scrutiny by the OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business.

If we fail to grow our sales and marketing capabilities and develop widespread brand awareness cost effectively, our growth will be impeded and our business may suffer.

We plan to continue to expand and optimize our sales infrastructure in order to grow our customer base and our business. Identifying and recruiting qualified personnel and training them in the use of our Lumivascular platform, and on applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. It could take several months before any new sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenues. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues.

Our ability to increase our customer base and achieve broader market acceptance of our Lumivascular platform will depend to a significant extent on our ability to expand our marketing operations. We plan to dedicate significant financial and other resources to our marketing programs. Our business will be harmed if our marketing efforts and expenditures do not generate an increase in revenue.

In addition, we believe that developing and maintaining widespread awareness of our brand in a cost-effective manner is critical to achieving widespread acceptance of our Lumivascular platform and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenues, and even if they do, any increase in revenues may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our Lumivascular platform.

If we are unable to manage the anticipated growth of our business, our future revenues and operating results may be harmed.

Any growth that we experience in the future could provide challenges to our organization, requiring us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. We expect to continue to grow our sales force and manufacturing

infrastructure. Rapid expansion in personnel could mean that less experienced people produce and sell our products, which could result in inefficiencies and unanticipated costs and disruptions to our operations.

We have limited experience manufacturing our Lumivascular platform products in commercial quantities, which could harm our business.

Because we have only limited experience in manufacturing our Lumivascular platform products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

- we intend to significantly expand our manufacturing capacity, and our production processes may have to change to accommodate this growth;

- key components and sub-assemblies of our Lumivascular platform products are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

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- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities;

- we have limited experience in complying with the FDA s QSR, which applies to the manufacture of our Lumivascular platform products; and

- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for our manufacturing operations.

If we are unable to keep up with demand for our Lumivascular platform products, our revenues could be impaired, market acceptance for our Lumivascular platform products could be harmed and our customers might instead purchase our competitors products. Our inability to successfully manufacture our Lumivascular platform products would materially harm our business.

Our manufacturing facilities and processes and those of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain, or not fully comply with the requirements of, a quality system could result in regulatory authorities initiating enforcement actions against us and our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, or our electronic systems are compromised, our ability to manufacture and sell our Lumivascular platform products and to pursue our research and development efforts may be jeopardized.

We currently manufacture and assemble our Lumivascular platform products in-house. Our products are comprised of components sourced from a variety of contract manufacturers, with final assembly completed at our facility in Redwood City, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding and power outages. Further, our electronic systems may experience service interruptions, denial-of-service and other cyber-attacks, computer viruses or other events. Any of these may render it difficult or impossible for us to manufacture products, pursue our research and development efforts or otherwise run our business for some period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products.

We depend on third-party vendors to manufacture some of our components and sub-assemblies, which could make us vulnerable to supply shortages and price fluctuations that could harm our business.

We currently manufacture some of our components and sub-assemblies at our Redwood City facility and rely on third-party vendors for other components and sub-assemblies used in our Lumivascular platform. Our reliance on third-party vendors subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier s operations;

- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier s failure to consistently produce quality components;

- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;

- difficulty identifying and qualifying alternative suppliers for components in a timely manner;

- inability of the manufacturer or supplier to comply with QSR as enforced by the FDA and state regulatory authorities;

- inability to control the quality of products manufactured by third parties;

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- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and

- delays in delivery by our suppliers due to changes in demand from us or their other customers.

Any significant delay or interruption in the supply of components or sub-assemblies, or our inability to obtain substitute components, sub-assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business.

We depend on single and limited source suppliers for some of our product components and sub-assemblies, and if any of those suppliers are unable or unwilling to produce these components and sub-assemblies or supply them in the quantities that we need, we would experience manufacturing delays.

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber and drive cables that are key components of our catheters, and we rely on a single vendor for our data acquisition card in Lightbox. These components are critical to our products and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of the components or sub-assemblies used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components or sub-assemblies incorporated into our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

Our future growth depends on physician adoption of our Lumivascular platform products, which may require physicians to change their current practices.

We intend to educate physicians on the capabilities of our Lumivascular platform products and advances in treatment for PAD patients. We target our sales efforts to interventional cardiologists, vascular surgeons and interventional radiologists because they are often the physicians diagnosing and treating both coronary artery disease and PAD. However, the initial point of contact for many patients may be general practitioners, podiatrists, nephrologists and endocrinologists, each of whom commonly treat patients experiencing complications or symptoms resulting from PAD. If these physicians are not made aware of our Lumivascular platform products, they may not refer patients to interventional cardiologists, vascular surgeons and interventional radiologists for treatment using our Lumivascular platform procedure, and those patients may instead be surgically treated or treated with an alternative interventional procedure. In addition, there is a significant correlation between PAD and coronary artery disease, and many physicians do not routinely screen for PAD while screening for coronary artery disease. If we are not successful in educating physicians about screening for PAD and about the capabilities of our Lumivascular platform products, our ability to increase our revenues may be impaired.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. In particular, our founder and Executive Chairman, Dr. John Simpson, is the visionary behind many of our product development activities and he actively supports our clinical trials and physician education and training efforts. If Dr. Simpson was no longer working at our company, our industry credibility, product development efforts and physician relationships would be harmed. We do not currently maintain key person life insurance policies on any of our employees, including Dr. Simpson.

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales executives. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

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We do not currently intend to devote significant additional resources in the near-term to market our Lumivascular platform internationally, which will limit our potential revenues from our Lumivascular platform products.

Marketing our Lumivascular platform outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into select European markets, but we do not currently intend to devote significant additional resources to market our Lumivascular platform internationally in order to focus our resources and efforts on the U.S. market. Our decision to market our products primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our Lumivascular platform products or other products internationally.

Our ability to utilize our net operating loss carryforwards may be limited.

As of December 31, 2015, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $171.2 million and $161.2 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2015 for state purposes. We may use these NOLs to offset against taxable income for U.S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 ownership change generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. This offering or future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause an ownership change. If an ownership change occurs, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes, which could harm our profitability.

The forecasts of market growth included in this Annual Report on Form10-K may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, if at all.

Growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. The forecasts in this Annual Report on Form 10-K relating to, among other things, the expected growth in PAD prevalence, diagnosis and endovascular PAD procedures and the markets therefor and increased awareness, higher diagnosis, and intervention rates, may prove to be inaccurate.

Even if these markets experience the forecasted growth described in this Annual Report on Form 10-K, we may not grow our business at similar rates, or at all. Our growth is subject to many factors, including whether the market for PAD treatments continues to grow, our ability to successfully commercialize Pantheris, the rate of market acceptance of our Lumivascular platform products versus the products of our competitors and our success in implementing our business strategies, each of which is subject to many risks and uncertainties. Accordingly, the forecasts of market growth included in this Annual Report on Form 10-K should not be taken as indicative of our future growth.

We may acquire other companies or technologies, which could divert our management s attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our Lumivascular platform, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth in our business has been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

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Risks Related to Our Intellectual Property

We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our Lumivascular platform products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties trade secrets. Additionally, our products include hardware and software components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third-party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party s patent or trademark or of misappropriating a third-party s trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our Lumivascular platform products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our Lumivascular platform products or using product names, which would have a significant adverse impact on our business.

Additionally, we may need to commence proceedings against others to enforce our patents or trademarks, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may not be able to stop a competitor from marketing and selling products that are the same or similar to our products or from using product names that are the same or similar to our product names, and our business may be harmed as a result.

We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivascular platform products.

We are aware of patent families related to catheter positioning, optical coherence tomography, occlusion cutting and atherectomy owned by third parties. With regard to atherectomy patents, one of our founders, Dr. John Simpson, founded FoxHollow Technologies prior to founding our company. FoxHollow Technologies developed an atherectomy device that is currently sold by Medtronic, and Dr. Simpson and our Chief Technology Officer, Himanshu Patel, are listed as inventors on patents covering that device that are now held by Medtronic. We are not currently aware of any claims Medtronic has made or intends to make against us with respect to Pantheris or any other product or product under development. Because of a doctrine known as assignor estoppel, if any of Dr. Simpson s earlier patents are asserted against us by Medtronic, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Medtronic has significantly greater financial resources than we do to pursue patent litigation and could assert these patent families against us at any time. Adverse determinations in any such litigation could prevent us from manufacturing or selling Pantheris or other products or products under development, which would significantly harm our business.

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Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2015, we held six issued U.S. patents and had 20 U.S. utility patent applications and 3 PCT applications pending. As of December 31, 2015, we also had 10 issued patents outside of the United States. As of December 31, 2015, we had 39 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business.

We use certain open source software in Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re-engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and operating results.

Risks Related to Government Regulation

Failure to comply with laws and regulations could harm our business.

Our business is subject to regulation by various federal, state, local and foreign governmental agencies, including agencies responsible for monitoring and enforcing employment and labor laws, workplace safety, environmental laws, consumer protection laws, anti-bribery laws, import/export controls, federal securities laws and tax laws and regulations. In certain jurisdictions, these regulatory requirements may be more stringent than those in the United States and in other circumstances these requirements may be more stringent in the United States. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, mandatory recalls, enforcement actions, adverse publicity, disgorgement of profits, fines, damages, civil and criminal penalties or injunctions and administrative actions. If any governmental sanctions, fines or penalties are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results and financial condition could be harmed. In addition, responding to any action will likely result in a significant diversion of management s attention and resources and substantial costs. Enforcement actions and sanctions could further harm our business, operating results and financial condition.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our Lumivascular platform products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.

Our Lumivascular platform products are medical devices that are subject to extensive regulation by FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;

- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;

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- premarketing clearance or approval;

- record keeping;

- product marketing, promotion and advertising, sales and distribution; and

- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for, an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval from FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market Pantheris, our image-guided atherectomy device, and our Ocelot family of catheters for crossing sub and total occlusions in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we are required to timely file various reports with the FDA, including reports required by the MDRs that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. For example, to date we have submitted to the FDA five MDRs regarding our Ocelot family of catheters, which included four perforations and one related to removal of the guidewire coating.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publically available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

Material modifications to our Lumivascular platform products may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our Lumivascular platform products until clearances are obtained.

Material modifications to the intended use or technological characteristics of our Lumivascular platform products will require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on published FDA guidelines, the FDA requires device manufacturers to initially make and document a

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determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer s decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our Lumivascular platform products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our Lumivascular platform products in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our Lumivascular platform products as modified, which could harm our operating results and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. We plan to make further modifications to the design of Pantheris to enhance cutting efficiency and access smaller vessels. Future versions of Pantheris incorporating these enhancements may require additional regulatory clearances or approvals.

If we or our suppliers fail to comply with the FDA s QSR, our manufacturing operations could be delayed or shut down and Lumivascular platform sales could suffer.

Our manufacturing processes and those of our third-party suppliers are required to comply with the FDA s QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our Lumivascular platform products. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenues to decline.

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. BSI, our European Notified Body, inspected our facility in 2013 and in 2015 and found zero non-conformances. We can provide no assurance that we will continue to remain in compliance with the QSR. If the FDA, CDHS or BSI inspect our facility and discover compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility we may be unable to produce our Lumivascular platform products, which would harm our business.

Our Lumivascular platform products may in the future be subject to product recalls that could harm our reputation.

FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our Lumivascular platform products would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement

would negatively affect our stock price.

Changes in coverage and reimbursement for procedures using our Lumivascular platform products could affect the adoption of our Lumivascular platform and our future revenues.

Currently, our Lumivascular platform procedure is typically reimbursed by third-party payors, including Medicare and private healthcare insurance companies, under existing reimbursement codes. These payors may change their coverage and reimbursement policies, as well as payment amounts, in a way that would prevent or limit reimbursement for our products, which would significantly harm our business. Also, healthcare reform legislation or regulation may be proposed or enacted in the future, which may adversely affect such policies and amounts. We cannot predict whether and to what extent existing coverage and reimbursement will continue to be available. If physicians, hospitals and other providers are unable to obtain adequate coverage and reimbursement for procedures performed using our Lumivascular platform products, they are significantly less likely to use our Lumivascular platform products and our business would be harmed.

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Healthcare reform measures could hinder or prevent our planned products commercial success.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Effective January 1, 2016, the excise tax of 2.3% on the sale of medical devices has been suspended for two years.

It remains unclear whether changes will be made to the Affordable Care Act. We cannot assure you that the Affordable Care Act, as currently enacted or as amended in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that will affect how we operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children s Health Insurance Program to report annually to the HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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- HIPAA, as amended by the HITECH Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. In addition, our research and development and manufacturing operations produce biological waste materials, such as human and animal tissue, and waste solvents, such as isopropyl alcohol. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third part property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Regulations related to conflict minerals may force us to incur additional expenses, may result in damage to our business reputation and may adversely impact our ability to conduct our business.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC promulgated final rules regarding disclosure of the use of certain minerals, known as conflict minerals, that are mined from the Democratic Republic of the Congo and adjoining countries, as well as procedures regarding a manufacturer s efforts to prevent the sourcing of such minerals and metals produced from those minerals. These disclosure requirements require ongoing due diligence efforts and disclosure obligations. There are costs associated with complying with these disclosure requirements, including for diligence in regards to the sources of any conflict minerals used in our products, in addition to the cost of remediation and other changes to products, processes, or sources of supply as a consequence of such verification activities. In addition, our ongoing implementation of these rules could adversely affect the sourcing, supply, and pricing of materials used in our products. We may face reputational harm if we determine that certain of our components contain minerals not determined to be conflict free or if we are unable to alter our processes or sources of supply to avoid using such materials. Reputational harm could adversely affect our business, financial condition or results of operations.

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Risks Related to Ownership of Our Common Stock

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has fluctuated since our IPO and is likely to continue to fluctuate substantially. As a result of this price fluctuation, investors may experience losses on their investments in our stock. In addition, the development stage of our operations may make it difficult for investors to evaluate the success of our business to date and to assess our future viability. The market price for our common stock may be influenced by many factors, including:

- the results of our clinical trials;
- changes in analysts estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts estimates;
- quarterly variations in our or our competitors results of operations;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;

- lawsuits threatened or filed against us;
- the announcement of new products or product enhancements by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

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We maintain a shelf registration statement on Form S-3, or the Registration Statement, with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $150.0 million of our common stock, preferred stock, depositary shares, warrants, units, subscription rights or debt securities. We have also established, and may in the future establish, at-the-market offerings pursuant to which we may offer and sell shares of our common stock pursuant to the Registration Statement. The Registration Statement has not yet been declared effective by the SEC. In addition, pursuant to our Securities Purchase Agreement with CRG, the Registration Statement also registers for resale 348,262 shares of common stock held by CRG. Once the Registration Statement is declared effective by the SEC, shares held by CRG may be sold freely in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Sales of newly issued securities under the Registration Statement will result in dilution of our stockholders and could cause our stock price to fall.

We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

Our directors, officers and their affiliates have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of February 29, 2016, our directors, officers and their affiliates collectively control approximately 30.5% of our outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

We previously identified and remediated a material weakness in our internal control over financial reporting. We may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with US generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our IPO, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our IPO, we determined that we had a material weakness in our internal control over financial reporting as of December 31, 2013 and 2012. The material weakness we identified related to not maintaining sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

The actions we have taken to remediate the material weakness are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have remediated this weakness, we cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness or significant deficiency could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

The requirements of being a public company may strain our resources, divert management s attention and affect our ability to attract and retain executive management and qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of The NASDAQ Global Market and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an emerging growth company. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial

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reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management s attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified executive officers and members of our board of directors, particularly to serve on our audit committee and compensation committee.

As a result of disclosure of information in this Annual Report on Form 10-K and in filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile or decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;

- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder s notice;

- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;

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- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;

- allowing stockholders to remove directors only for cause;

- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;

- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;

- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;

- limiting the forum for certain litigation against us to Delaware; and

- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or bylaws (iv) any action to interpret apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We maintain our principal executive offices, comprising 44,200 square feet in two buildings in Redwood City, California, under a lease agreement that expires in November 2019. We have the option to extend the lease through November 2022. Our facility houses our research and development, sales, marketing, manufacturing, finance and administrative activities. We believe that our current facilities are adequate for our current and anticipated future needs through at least 2017.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. From time to time we may be involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

MARKET INFORMATION FOR COMMON STOCK

Our common stock began trading on The NASDAQ Global Market on January 30, 2015 and trades under the symbol AVGR . Prior to January 30, 2015, there was no public market for our common stock. In our IPO, our common stock priced at $13.00 per share on January 29, 2015. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

	Low	High
Fiscal Year ending December 31, 2015		
First Quarter (beginning January 30, 2015)	$ 10.00	$ 13.32
Second Quarter	$ 10.50	$ 13.15
Third Quarter	$ 12.52	$ 16.45
Fourth Quarter	$ 14.67	$ 24.75

On March 7, 2016, the last reported sale price of our common stock as reported on The NASDAQ Global Market was $12.96 per share.

HOLDERS OF RECORD

As of March 7, 2016, there were 12,692,189 shares of our common stock held by 236 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

STOCK PRICE PERFORMANCE GRAPH

The following stock performance graph compares our total stock return with the total return for (i) the NASDAQ Composite Index and the (ii) the NASDAQ Medical Equipment Index for the period from January 30, 2015 (the date our common stock commenced trading on the NASDAQ Global Market) through December 31, 2015. The figures represented below assume an investment of $100 in our common stock at the closing price of $13.50 on January 30, 2015 and in the NASDAQ Composite Index and the NASDAQ Medical Equipment Index on January 30, 2015 and the reinvestment of dividends into shares of common stock. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed soliciting material

or be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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$100 investment in stock or index	Ticker	January 30, 2015	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Avinger, Inc.	AVGR	$ 100.00	$ 82.15	$ 95.63	$ 108.96	$ 168.22
NASDAQ Composite Index	IXIC	$ 100.00	$ 106.00	$ 108.15	$ 100.49	$ 109.24
NASDAQ Medical Equipment	NQUSB4535T	$ 100.00	$ 108.12	$ 105.82	$ 97.45	$ 108.78

DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business and to finance the growth and development of our business. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our Loan Agreement with CRG prohibits us from paying any dividends or making any other distribution or payment on account of our common stock.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

All of our equity compensation plans have been approved by our stockholders. The equity compensation plans are described in Notes 12 and 13 to our financial statements included in this Annual Report on Form 10-K. The following table provides information as of December 31, 2015, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (2)	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securites

				Reflected in Column (a))
Equity compensation plans approved by stockholders (1)	5,643,434	$	9.53	884,509

(1) Includes the following plans: our 2009 Stock Plan, our 2015 Equity Incentive Plan and our 2015 Employee Stock Purchase Plan. Our 2015 Equity Incentive Plan provides that on the first day of each fiscal year commencing in fiscal year 2016, the number of shares authorized for issuance under the 2015 Plan is automatically increased by a number equal to the lesser of (i) 1,690,000 shares of common stock, (ii) 5.0% of the aggregate number of shares of common stock outstanding on the last day of the preceding fiscal year, or (iii) such number of shares that may be determined by our board of directors. Our 2015 Employee Stock Purchase Plan provides that on the first day of each fiscal year commencing in fiscal year 2016 the number of shares authorized for issuance under our 2015 Employee Stock Purchase Plan is automatically increased by a number equal to the lesser of (i) 493,000 shares of common stock, (ii) 1.5% of the aggregate number of shares of common stock outstanding on such date, or (iii) an amount determined by our board of directors or a duly authorized committee of our board of directors.

(2) The weighted average exercise price does not take into account outstanding restricted stock, or RSUs, which have no exercise price.

RECENT SALES OF UNREGISTERED SECURITIES

There were no sales of unregistered securities during fiscal 2015 other than those transactions previously reported to the SEC on our Current Reports on Form 8-K.

USE OF PROCEEDS FROM PUBLIC OFFERING OF COMMON STOCK

Our IPO of 5,000,000 shares of common stock was effected through a registration statement on Form S-1 (File No. 333-201322), which was declared effective on January 29, 2015. Our IPO closed on February 4, 2015 and resulted in net proceeds of approximately $56.9 million, after deducting underwriting discounts and commissions of approximately $4.5 million and other expenses of approximately $3.6 million. No payments for such expenses were made directly or indirectly to any of our officers or directors or to persons owning 10% or more of our common stock.

Canaccord Genuity Inc., Cowen and Company, LLC, Oppenheimer & Co. Inc., BTIG, LLC and Stephens Inc. acted as the underwriters. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on January 30, 2015 pursuant to Rule 424(b) of the Securities Act.

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PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 6. SELECTED FINANCIAL DATA

You should read the following selected financial data together with the section of this Annual Report on Form 10-K entitled Management s discussion and analysis of financial condition and results of operations and our financial statements and the related notes included in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future or any other period.

Statements of Operations Data:

	Year Ended December 31,			
	2015	2014	2013	2012
	(in thousands, except per share data)			
Revenues	$ 10,713	$ 11,213	$ 12,964	$ 8,560
Cost of revenues	6,478	6,513	8,205	4,151
Gross profit	4,235	4,700	4,759	4,409
Operating expenses:				
Research and development	15,694	11,224	15,973	15,416
Selling, general and administrative	29,231	18,503	25,758	22,848
Total operating expenses	44,925	29,727	41,731	38,264
Loss from operations	(40,690)	(25,027)	(36,972)	(33,855)
Interest income (expense), net	(5,127)	(6,014)	(2,923)	19
Other income (expense), net	(1,527)	(909)	5	(19)
Loss before provision for income taxes	(47,344)	(31,950)	(39,890)	(33,855)
Provision for income taxes		14	11	9
Net loss and comprehensive loss	(47,344)	(31,964)	(39,901)	(33,864)
Adjustment to net loss resulting from convertible preferred stock modification	(2,384)			
Net loss and comprehensive loss attributable to common stockholders	$ (49,728)	$ (31,964)	$ (39,901)	$ (33,864)
Net loss attributable to common stockholders per share, basic and diluted	$ (4.38)	$ (132.63)	$ (170.52)	$ (162.03)
Weighted average common shares used to compute net loss per share, basic and	11,362	241	234	209

diluted

Balance Sheets Data:

	As of December 31,			
	2015	2014	2013	2012
	(in thousands)			
Cash and cash equivalents	$ 43,059	$ 12,316	$ 12,221	$ 20,617
Working capital	43,576	9,917	15,734	22,462
Total assets	54,104	24,437	24,508	30,324
Long-term borrowings	29,565	18,228	19,622	
Convertible notes and accrued interest		8,609	13,661	
Convertible preferred stock		132,260	99,654	99,659
Accumulated deficit	(196,261)	(146,533)	(114,569)	(74,668)
Total stockholders equity (deficit)	15,589	(143,868)	(112,782)	(73,644)

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this Annual Report on Form 10-K entitled Selected financial data and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report on Form 10-K entitled Risk factors.

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to area away from the heart, particularly the pelvis and legs. Our mission is to dramatically improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select European markets. Our current products include our Lightbox imaging console, as well as our Wildcat, Kittycat, and the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris, and we received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the U.S. and select European countries promptly thereafter. We believe that Pantheris will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION will also allow us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. We have recently commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select European countries, after obtaining the required marketing authorizations.

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians because they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. We are designing future products to be compatible with our Lumivascular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. We also believe that Pantheris will qualify for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our

products.

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Prior to the introduction of our Lumivascular platform our non-imaging catheter products were manufactured by third parties. All of our products are now manufactured in-house at our facilities in Redwood City, California using components and sub-assemblies manufactured both in-house and by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2017. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors.

We began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $10.7 million in 2015, $11.2 million in 2014 and $13.0 million in 2013. During the years ended December 31, 2015, 2014 and 2013, our net loss was $47.3 million, $32.0 million and $39.9 million, respectively. We have not been profitable since inception and as of December 31, 2015, our accumulated deficit was $196.3 million. Since inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering, or IPO, of 5.0 million shares. As a result of our IPO, which closed in February 2015, we received net proceeds of approximately $56.9 million, after underwriting discounts and commissions of approximately $4.5 million and other expenses associated with our IPO of approximately $3.6 million.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we may borrow up to $50.0 million on or before March 29, 2017. We borrowed $30.0 million on September 22, 2015. Upon FDA approval of our 510(k) for Pantheris we became eligible to borrow an additional $10.0 million, on or prior to June 30, 2016. We may also borrow an additional $10.0 million, on or prior to March 29, 2017, contingent on achieving certain revenue milestones, among other conditions. Contemporaneous with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of $14.357 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the securities purchase agreement, we were obligated to file a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into a Sales Agreement with Cowen and Company, or Cowen, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement has not yet been declared effective by the SEC and no shares of common stock have been sold under the agreement with Cowen to date.

During the third and fourth quarters of 2013, we effected a reduction in force, lowering our total headcount from 168 employees at June 30, 2013 to 115 employees at December 31, 2013. We implemented this reduction to better align resource utilization with our corporate strategy as we transitioned our focus from non-imaging products to Lumivascular platform products, including Pantheris.

Components of Our Results of Operations

Revenues

All of our revenues are currently derived from sales of our Lightbox console and our various PAD catheters and related services in the United States and select European markets. We expect our revenues to increase as we continue to expand our sales and marketing infrastructure and introduce new Lumivascular platform products including Pantheris. No single customer accounted for more than 10% of our revenues during 2015, 2014 or 2013.

We expect our revenues to increase in 2016 as we commence sales of Pantheris in the United States. However, revenues may fluctuate from quarter-to-quarter due to a variety of factors including capital equipment purchasing patterns that are typically heavier towards the end of the calendar year and lighter in the first quarter. In addition, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients.

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Cost of Revenues and Gross Profit

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for leased equipment held by customers and certain direct costs such as those incurred for shipping our products. We expect cost of revenues to increase in absolute dollars to the extent our revenues grow and as we continue to invest in our operational infrastructure to support anticipated growth.

We calculate gross margin as gross profit divided by revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and as we spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. In the future, we may seek to manufacture certain of our products outside the United States to further reduce costs. Our gross margin will likely fluctuate from quarter to quarter as we continue to introduce new products and sales channels, and as we adopt new manufacturing processes and technologies.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses allocated to R&D programs, consulting, related travel expenses and facilities expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. However, we expect R&D expenses as a percentage of revenues to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

Selling, General and Administrative Expenses

Our sales organization is divided into two primary roles, one focused on sale and use of our disposable catheters and the other focused on sale and service of our Lightbox console. Our current sales efforts focus on establishing new Lumivascular platform sites by marketing our products to physicians and hospital administrators. Additionally, we seek to increase the use of our Lumivascular platform products by our current customers through case coverage, clinical training and other programs.

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human

resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, a 2.3% tax on U.S. sales of medical devices, general corporate expenses and allocated facilities-related expenses. Effective January 1, 2016, the excise tax of 2.3% on U.S sales of medical devices has been suspended for two years. We expect to continue to grow our sales force in order to support current customers and attract new users of our Lumivascular platform products. We believe that expanding our U.S. sales infrastructure and establishing distributor relationships in select regions outside the United States will drive further adoption of our Lumivascular platform. We expect SG&A expenses to continue to increase in absolute dollars but decrease as a percentage of revenues through at least 2016, as we expand our infrastructure to drive and support anticipated growth in revenues.

Interest Income (Expense), net

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our various debt agreements.

Other Income (Expense), net

Other income (expense), net primarily consisted of gains and losses resulting from the remeasurement of the fair value of our common stock warrant liability and the compound embedded derivative instrument associated with our convertible promissory notes, or the notes, which were repaid in full in September 2015, and the loss on the extinguishment of the notes. We continued to record adjustments to the estimated fair value of the common stock warrants until the Series E preferred stock issuance in September 2014, upon which the common stock warrant exercise price was fixed at $12.60 per share. At that time we re-evaluated the terms of the common stock warrants and determined that the common stock warrants issued with the convertible notes met the requirements for equity classification and the fair value of the warrant liability was reclassified to additional paid-in capital. We continued to record adjustments to the estimated fair value of the compound embedded derivative instrument associated with the notes until the notes were repaid in September 2015. Upon extinguishment of the notes, the associated current fair value of the embedded derivative asset was expensed to other income (expense), net. Additionally, for the year ended December 31, 2015, other income (expense), net includes charges to reflect the carrying value of our ongoing royalty obligation to PDL Biopharma, or PDL.

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Results of Operations:

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Revenues	$ 10,713	$ 11,213	$ 12,964
Cost of revenues	6,478	6,513	8,205
Gross profit	4,235	4,700	4,759
Gross margin	40%	42%	37%
Operating expenses:			
Research and development	15,694	11,224	15,973
Selling, general and administrative	29,231	18,503	25,758
Total operating expenses	44,925	29,727	41,731
Loss from operations	(40,690)	(25,027)	(36,972)
Interest income (expense), net	(5,127)	(6,014)	(2,923)
Other income (expense), net	(1,527)	(909)	5
Loss before provision for income taxes	(47,344)	(31,950)	(39,890)
Provision for income taxes		14	11
Net loss and comprehensive loss	$ (47,344)	$ (31,964)	$ (39,901)

Comparison of Years Ended December 31, 2015 and 2014

Revenues. Revenues decreased $0.5 million, or 4%, to $10.7 million during the year ended December 31, 2015, compared to $11.2 million during the year ended December 31, 2014. For the year ended December 31, 2015, sales of our Lightbox imaging console increased by 6% to $4.1 million while sales of our disposable catheters decreased by 10% to $6.6 million. The decrease in disposable catheter revenues in 2015 and changes in revenue mix related to our continuing commercial focus on our Lumivascular programs to broaden physician exposure to optical coherence tomography, or (OCT, image interpretation and building the installed base of the Lightbox imaging console prior to the commercial launch of Pantheris, which began in March 2016.

Cost of Revenues and Gross Margin. Cost of revenues of $6.5 million during the year ended December 31, 2015, were unchanged compared to the year ended December 31, 2014. Gross margin for the year ended December 31, 2015 was 40%, compared to 42% during the year ended December 31, 2014. This decrease was primarily attributable to increases in manufacturing overhead costs as we invested in operational infrastructure to support anticipated growth and the commercial launch of Pantheris.

Research and Development Expenses. R&D expenses increased $4.5 million, or 40%, to $15.7 million during the year ended December 31, 2015, compared to $11.2 million during the year ended December 31, 2014. This increase was primarily due to a $3.8 million increase in personnel-related expenses and an increase of $1.0 million in outside

services, partially offset by a decrease of $0.4 million in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $2.5 million compared to $0.2 million for the year ended December 31, 2015 and 2014, respectively. The remaining increase in personnel-related expenses and increase in outside services were attributable to our VISION clinical trial.

Selling, General and Administrative Expenses. SG&A expenses increased $10.7 million, or 58%, to $29.2 million during the year ended December 31, 2015, compared to $18.5 million during the year ended December 31, 2014. This increase was primarily due to a $7.7 million increase in personnel-related expenses and an increase of $3.0 million in consulting, legal and professional fees. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of $3.1 million compared to $0.4 million for the year ended December 31, 2015 and 2014, respectively. Increases in our consulting, legal and professional fees were associated with the audit and reviews of our financial statements and other costs associated with operating as a public company.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.9 million, or 15%, to an expense of $5.1 million during the year ended December 31, 2015, compared to an expense of $6.0 million during the year ended December 31, 2014. This decreased expense was attributable to the conversion of certain of our then-outstanding notes into shares of Series E preferred stock during the third and fourth quarter of 2014.

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Other Income (Expense), Net. Other income (expense), net increased $0.6 million, or 68%, to an expense of $1.5 million during the year ended December 31, 2015, compared to an expense of $0.9 million during the year ended December 31, 2014. Other expense for the year ended December 31, 2015, was primarily attributable to the reversal of the current fair value of the embedded derivative asset of $1.1 million upon the repayment of our notes in September 2015, expense of $0.9 million to reflect the carrying value of our ongoing royalty obligation to PDL and non-cash charges related to the amortization of debt discount and issuance costs associated with the notes and the credit agreement upon their repayment in September 2015, partially offset by the remeasurement of the fair value of the derivative instruments associated with our notes through the date of their repayment. During the year ended December 31, 2014, other expense was primarily attributable to the $1.2 million loss on the extinguishment of certain of our then-outstanding notes that were converted into Series E preferred stock in September 2014, partially offset by the remeasurement of the fair value of our common stock warrant liability through the issuance of the Series E preferred stock in September 2014, and the derivative instruments associated with such notes which were accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

Comparison of Years Ended December 31, 2014 and 2013

Revenues. Revenues decreased $1.8 million, or 14%, to $11.2 million during the year ended December 31, 2014, compared to $13.0 million during the year ended December 31, 2013. For the year ended December 31, 2014, sales of our Lightbox imaging console increased by $1.1 million, or 37%, to $3.9 million while sales of our disposable catheters decreased by $2.8 million, or 28%, to $7.3 million. The decrease in total revenues in 2014 and changes in revenue mix related to strategic decisions made in the fourth quarter of 2013 to focus commercial efforts on its Lumivascular programs to broaden physician exposure to OCT image interpretation and build the installed base of the Lightbox imaging console.

Cost of Revenues and Gross Margin. Cost of revenues decreased $1.7 million, or 21%, to $6.5 million during the year ended December 31, 2014, compared to $8.2 million during the year ended December 31, 2013. This decrease was attributable to the decrease in revenues from sales of our Wildcat and Kittycat non-imaging catheters, as well as a decrease in personnel-related expenses associated with our headcount reduction during the third and fourth quarters of 2013. Gross margin for the year ended December 31, 2014 was 42%, up from 37% during the year ended December 31, 2013. This increase was primarily attributable to the growth in sales of our Lightbox imaging console.

Research and Development Expenses. R&D expenses decreased $4.8 million, or 30%, to $11.2 million during the year ended December 31, 2014, compared to $16.0 million during the year ended December 31, 2013. This decrease was primarily due to a $2.2 million decrease in personnel-related expenses associated with our headcount reduction during the third and fourth quarters of 2013, a decrease of $1.5 million in product development materials and related costs and a reduction of $1.1 million in outside services and, as we focused our research and development efforts on our Lumivascular platform products, particularly Pantheris.

Selling, General and Administrative Expenses. SG&A expenses decreased $7.3 million, or 28%, to $18.5 million during the year ended December 31, 2014, compared to $25.8 million during the year ended December 31, 2013. This decrease was primarily due to a $6.1 million decrease in personnel-related expenses associated with our headcount reduction during the third and fourth quarters of 2013 and a reduction of $1.4 million in consulting, legal and professional fees, associated with our reduction in headcount and cost reduction actions taken in the second half of 2013 partially offset by an increase of $0.3 million in tradeshow and travel-related expenses.

Interest Income (Expense), Net. Interest income (expense), net increased $3.1 million, or 106%, to an expense of $6.0 million during the year ended December 31, 2014, compared to an expense of $2.9 million during the year ended December 31, 2013. This increased expense was attributable to interest expense incurred on our credit agreement with PDL, entered into during the second quarter of 2013, and the notes issued during the fourth quarter of 2013, and non-cash interest related to the amortization of debt discount and issuance costs associated with the notes and the credit agreement.

Other Income (Expense), Net. Other income (expense), net decreased to an expense of $0.9 million during the year ended December 31, 2014, compared to income of $5,000 during the year ended December 31, 2013. The increase in other expense was primarily attributable to the $1.2 million loss on the extinguishment of our notes that were converted into Series E preferred stock in September 2014, partially offset by the remeasurement of the fair value of our common stock warrant liability through the issuance of the Series E preferred stock in September 2014, and the derivative instruments associated with our notes which are accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

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Liquidity and Capital Resources

As of December 31, 2015, we had cash and cash equivalents of $43.1 million and an accumulated deficit of $196.3 million, compared to cash and cash equivalents of $12.3 million and an accumulated deficit of $146.5 million as of December 31, 2014. We currently believe our existing cash and cash equivalents, expected revenues, debt financing currently available under our Loan Agreement with CRG and the net proceeds from the follow-on offering we intend to conduct whereby we may issue and sell shares of common stock having an aggregate value of up to $50.0 million, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity, through our follow-on offering or in separate financings, or sell additional debt securities or obtain an additional credit facility. Further, because of the risk and uncertainties associated with the commercialization of our existing products as well as products in development, we may need additional funds to meet our needs sooner than planned. To date, our primary sources of capital were private placements of preferred stock, debt financing agreements and our IPO. In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to $50.0 million, of which $30.0 million was immediately available and drawn down by us. Of the remaining $20.0 million, $10.0 million is currently available to us until June 30, 2016 and the remaining $10.0 million is contingent on the achievement of certain net revenue milestones prior to December 31, 2016, and if such milestones are achieved, the remaining amount may be drawn down until March 29, 2017. As of December 31, 2015, we had $29.6 million outstanding under the Loan Agreement. See section titled Contractual Obligations.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into a Sales Agreement with Cowen, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $50.0 million in an at-the-market offering. The shelf registration statement has not yet been declared effective by the Securities and Exchange Commission, or SEC. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. The common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold.

If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which diverts resources from other activities. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and scale back our business and operations.

Cash Flows

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (40,883)	$ (21,801)	$ (40,655)

Investing activities	(322)	(117)	(496)
Financing activities	71,948	22,013	32,755
Net (decrease) increase in cash and cash equivalents	$ 30,743	$ 95	$ (8,396)

Net Cash Used in Operating Activities

Net cash used in operating activities for 2015 was $40.9 million, consisting primarily of a net loss of $47.3 million and an increase in net operating assets of $3.3 million, partially offset by non-cash charges of $9.7 million. The increase in net operating assets was primarily due to an increase in inventories and in prepaids and other current assets, decreases in accrued expenses and other current liabilities due to timing of payments relating to our IPO costs, and decreases in other liabilities related to the repayment of accrued interest on our notes, partially offset by an increase in accrued compensation. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with PDL and its repayment, and the reversal of the current fair value of the embedded derivative asset upon repayment of the notes, partially offset by the change in fair value of the embedded compound derivative associated with the notes through the repayment date.

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Net cash used in operating activities for 2014 was $21.8 million, consisting primarily of a net loss of $32.0 million, partially offset by a decrease in net operating assets of $3.6 million and by non-cash charges of $6.6 million. The decrease in net operating assets was primarily due to decreases in inventory, and an increase in accrued expenses and other current liabilities related to interest payable to PDL and transaction fees related to our Series E financing. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense related to our credit agreement with PDL, and losses on the extinguishment of our notes.

Net cash used in operating activities for 2013 was $40.7 million, consisting primarily of a net loss of $39.9 million and an increase in net operating assets of $4.3 million, partially offset by non-cash charges of $3.6 million. The increase in net operating assets was primarily due to the expansion of our sales and marketing organizations to support the ongoing commercialization of our Lumivascular platform resulting in increases in accounts receivable and inventory as well as a decrease in accounts payable and accrued expenses and other current liabilities due to timing of payments. Non-cash charges consisted primarily of depreciation, stock-based compensation, and non-cash interest expense related to our credit agreement with PDL.

Net Cash Used in Investing Activities

Net cash used in investing activities in 2015 was $0.3 million consisting of purchases of property and equipment of $0.6 million, partially offset by $0.3 million from the release of a restriction against our cash. Net cash used in investing activities in 2014 and 2013 was $0.1 million and $0.5 million, respectively, consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in 2015 was $71.9 million, consisting of net proceeds of $58.7 million from the issuance of common stock related to our IPO, net proceeds of $6.2 million from the issuance of our Series E preferred stock, net proceeds of $5.5 million from the issuance of our common stock and net proceeds of $29.1 million from the debt financing under the Loan Agreement with CRG, partially offset by the payment of $27.6 million to retire our debt with PDL and outstanding notes. As of December 31, 2014, cash paid for deferred IPO costs was $1.8 million.

Net cash provided by financing activities in 2014 was $22.0 million, consisting of net proceeds of $4.7 million from the issuance of convertible notes and net proceeds of $19.2 million from the issuance of our Series E preferred stock. Cash paid for deferred IPO costs was $1.8 million.

Net cash provided by financing activities in 2013 was $32.8 million, consisting primarily of net proceeds of $19.3 million under our credit agreement with PDL and net proceeds of $13.4 million from the issuance of convertible notes.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

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Contractual Obligations

Our principal obligations consist of the operating lease for our facilities, capital leases related to office equipment, our ongoing royalty obligations with PDL, our Loan Agreement with CRG and non-cancellable purchase commitments. The following table sets out, as of December 31, 2015, our contractual obligations due by period (in thousands):

	Payments Due by Period				
	Less Than 1 Year	1 - 3 Years	3-5 Years	More Than 5 Years	Total
Operating lease obligations	$ 1,060	$	$	$	$ 1,060
Capital lease obligations	19	22			41
Ongoing royalty obligations with PDL	1,220	1,693			2,913
CRG Loan			26,199	8,733	34,932
Noncancellable purchase commitments	4,347				4,347
	$ 6,646	$ 1,715	$ 26,199	$ 8,733	$ 43,293

In March 2016, we amended our facility operating lease to extend the lease term for a period of three years from December 1, 2016, until November 30, 2019. Under the terms of the amended facility lease agreement, we are obligated to pay approximately $5.7 million in lease payments through November 2019 over the term of the amended agreement.

Our contractual obligations have not otherwise significantly changed from December 31, 2015.

CRG

In September 2015, we entered into a Loan Agreement with CRG, under which we may borrow up to $50.0 million in principal amount from CRG on or before December 31, 2016. We borrowed $30.0 million on September 22, 2015. Upon FDA approval of our 510(k) for Pantheris, we became eligible to borrow an additional $10.0 million in principal amount, on or prior to June 30, 2016. We may borrow the final $10.0 million, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions. Under the Loan Agreement, the first sixteen quarterly payments are interest only payments, and the last eight quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 12.5% per annum. We make quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, we may elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind, or PIK, for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the loan. To date we have elected the PIK option to the extent available and have made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

We may voluntarily prepay the loan in full, with a prepayment premium beginning at 5% and declining by 1% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the principal amount borrowed. In addition, a facility fee equal to 7.0% of loan principal borrowed plus any PIK is payable at the end of the term or when the loan is repaid in full. The term loan is collateralized by a security interest in substantially all of our assets.

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of $7.0 million in 2015, with the target minimum revenue increasing in each year thereafter until reaching $70,000,000 in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include our failure to make timely payments of amounts due under the Loan Agreement, the failure to adhere to the covenants set forth in the Loan Agreement, our insolvency or upon the occurrence of a material adverse change. We were in compliance with the covenants under the Loan Agreement as of December 31, 2015.

We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding debt with PDL and to retire the principal and accrued interest underlying our outstanding notes, which are described below.

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Convertible Promissory Notes

On October 29, 2013, we entered into a Note and Warrant Purchase Agreement, or the Convertible Note Agreement, with certain existing preferred stockholders, third-parties and employees for the issuance of convertible notes up to an aggregate principal amount of $25.0 million. Under the terms of the Convertible Note Agreement, we issued convertible notes, or the notes, in October and November 2013 for total proceeds of $13.5 million and in May and July 2014 for total proceeds of $4.7 million. We are required to pay interest under the notes at a rate equal to 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20% per annum. The principal and accrued interest thereon was to mature on the earlier of: (i) October 29, 2018, (ii) an event of default or (iii) a change of control event.

In September 2015, in connection with the consummation of the Loan Agreement, we repaid all principal and accrued interest outstanding under the notes.

Lease Agreement

We lease our headquarters in Redwood City, California pursuant to a lease agreement with HCP LS Redwood City dated July 30, 2010, as amended by the First Amendment to Lease dated September 30, 2011 and the Second Amendment to Lease dated March 4, 2016, collectively, the Amended Lease. The Amended Lease has a rental commencement date of December 1, 2011, a term of eight years and expires in November 2019. We have an additional option to extend the lease term for a period of three years. The option must be exercised no more than 12 months and no less than nine months prior to the expiration of the applicable term. The Amended Lease is for an aggregate of approximately 44,200 rentable square feet.

PDL Credit and Security Agreements

On April 18, 2013, we, as the borrower, entered into a credit agreement with PDL, as the lender and agent. The credit agreement provided for an aggregate term loan facility of up to $40.0 million, available in two tranches of up to $20.0 million each. We borrowed $20.0 million as a term loan under tranche one of the credit agreement on April 18, 2013. We also paid closing fees to PDL of approximately $200,000, which were deducted from the tranche one funds we received, plus legal and brokerage fees. Tranche two of the credit agreement, the availability of which was conditioned on our satisfaction of certain milestones, never became available to us as we did not reach those milestones. The proceeds from tranche one were used for working capital, capital expenditures and general corporate purposes.

In September 2015, in connection with the consummation of the Loan Agreement with CRG, we repaid all amounts outstanding under the credit agreement with PDL. The payoff amount of $21.4 million included accrued interest through the repayment date of $0.6 million and $0.2 million as an end-of-term final payment fee.

Following the retirement of the PDL debt, our royalty obligations under the PDL credit agreement continue and are payable through the maturity date at the higher of a reduced rate of 0.9% of our quarterly revenues or certain minimum amounts, starting at $65,000 per quarter in 2013 and increasing annually to $310,000 per quarter in 2018. Additionally, until there are no further obligations to periodically pay to PDL a percentage

of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. We were in compliance with the covenants under the credit agreement as of December 31, 2015.

Critical Accounting Policies and Estimates

Management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

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Revenue Recognition

All of our revenues are currently derived from sales of our Lumivascular platform products, various non-imaging PAD catheters and related services in the United States and select European markets. We recognize revenues when the following revenue recognition criteria are met:

- Persuasive evidence of an arrangement exists. We consider this criterion satisfied when we have an agreement or contract in place with the customer.

- Delivery has occurred or services have been rendered. We principally determine this criterion to be satisfied as follows:

- Lightbox console: upon our receipt of a form executed by the customer acknowledging that the training and installation process is complete.

- PAD catheters: when the product has been shipped and risk of loss and title has passed to the customer.

- Service: recognized ratably over the term of the service period. To date service revenues have been insignificant.

- The fee is fixed or determinable and collectability is reasonably assured. We determine the satisfaction of these criteria based on our judgment regarding the nature of the fee charged for products, contractual agreements entered into, and the collectability of those fees under any contract or agreement.

We offer our customers the ability to purchase or lease our Lightbox. When a customer leases the Lightbox, we recover the cost of providing the system by charging that customer a premium on sales of the Ocelot family of catheters. When a Lightbox is leased, we retain title to the equipment and it remains capitalized on our balance sheet under property and equipment. The costs to maintain these leased Lightboxes held by customers are charged to cost of revenues as incurred.

We evaluate our lease agreements and account for these contracts under the guidance pertaining to accounting for leases and for revenue arrangements with multiple deliverables. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling prices of the deliverables, using a specific hierarchy. The hierarchy is as follows: vendor-specific objective evidence of fair value of the respective elements, third-party evidence of selling price, or best estimate of

selling price, or BESP. We allocate arrangement consideration using BESP.

We assessed whether the embedded lease is an operating lease or sales-type lease and determined that collectability of the minimum lease payments is not reasonably predictable given that any payments under the lease agreements are dependent upon contingent future Ocelot catheter sales. We concluded, therefore, that the embedded lease did not meet the criteria of a sales-type lease and we account for it as an operating lease. We recognize revenue allocated to the lease as the Ocelot catheters are delivered.

We must make significant assumptions regarding the future collectability of accounts receivable from customers to determine whether revenue recognition criteria have been met. If collectability is not assured at the time of shipment, we defer revenues until such criterion has been met. We estimate reductions in revenue for potential returns of products by customers. In making such estimates, we analyze historical returns, current economic trends and changes in customer demand and acceptance of our products.

Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentive for employees, consultants and members of our board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards, including employee stock options. We recognize this expense over the requisite service period. In addition, we recognize stock-based compensation expense in the statements of operations and comprehensive loss based on awards expected to vest and, therefore, the amount of expense has been reduced for estimated forfeitures. We use the straight-line method for expense attribution.

The valuation model we used for calculating the fair value of awards for stock-based compensation expense is the Black-Scholes option-pricing model, or the Black-Scholes model. The Black-Scholes model requires us to make assumptions and judgments about the variables used in the calculation, including the weighted average period of time that the options granted are expected to be outstanding, the volatility of common stock, an assumed risk-free interest rate and an estimated forfeiture rate.

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The following table summarizes the weighted average assumptions we used to determine the fair value of stock options:

	Year Ended December 31,		
	2015	2014	2013
Expected term (years)	6.3	6.3	6.9
Expected volatility	49.8%	59.1%	52.1%
Risk-free interest rate	1.8%	1.8%	1.4%
Dividend rate			

Fair Value of Common Stock. Prior to completion of our IPO in January 2015, the fair value of the shares of our common stock underlying the stock options has historically been determined by our board of directors after considering independent third-party valuation reports. Because there had previously been no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of our preferred stock, our operating and financial performance and the general and industry-specific economic outlook. Following the closing of our IPO in January 2015, the fair value of our common stock is determined based on the closing price of our common stock on The NASDAQ Global Market.

Expected Term. We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the simplified method for estimating the expected term of options, which is the average of the weighted average vesting period and contractual term of the option.

Expected Volatility. Since there had previously been no public market for our common stock and lack of company specific historical volatility, we had determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we considered factors such as stage of development, risk profile, enterprise value and position within the industry. Following the closing of our IPO in January 2015, we supplement our available company historical volatility with the volatility of a peer group of publicly traded companies.

Risk-free Interest Rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

Dividend Rate. We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

Expected Forfeiture Rate. We are required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, we record the difference as a cumulative adjustment in the period that the estimates are revised.

Service period. We amortize all stock-based compensation over the requisite service period of the awards, which is generally the same as the vesting period of the awards. We amortize the stock-based compensation cost on a straight-line basis over the expected service periods.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that our assumptions are incorrect, the amount of stock-based compensation recorded will change.

Compound Embedded Derivative

We have derivative instruments related to redemption features embedded within the notes. The compound embedded derivatives were accounted for as a liability at the inception of the obligation and are remeasured to fair value as of each balance sheet date, with the related remeasurement adjustment recognized as other income (expense), net in the statement of operations and comprehensive loss. The fair value of the compound embedded derivative is determined based on an income approach that identified the cash flows using a with-and-without valuation methodology. The inputs used to determine estimated fair value of the derivative instruments include the probabilities of the underlying events triggering the embedded derivative and their timing. We continued to record adjustments to the estimated fair value of the compound embedded derivative associated with the notes until the notes were repaid in September 2015. The associated current fair value of the embedded derivative asset was expensed as a component of other income (expense), net in the statements of operations and comprehensive loss at that time.

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JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

Credit Risk

As of December 31, 2015, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our Lumivascular platform products to hospitals and medical centers in the United States. One and none of our customers represented more than 10% of our accounts receivable as of December 31, 2015 and 2014, respectively.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item appears in a separate section of this Annual Report on Form 10-K beginning on page 86 and is incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2015. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2015, our disclosure controls and procedures were effective.

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Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for emerging growth companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management s evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fourth quarter of 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our chief executive officer and chief financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting 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. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered 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, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is 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, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

Lease Amendment

On March 4, 2016, we entered into the Second Amendment to Lease with HCP LS Redwood City, or the Second Amendment, which amended our facility lease agreement for our headquarters and manufacturing facility. The Second Amendment extends the lease term for a period of three years and has a rental commencement date of December 1, 2011, a term of eight years and expires in November 2019. Under the terms of the Second Amendment, we are obligated to pay approximately $5.7 million in base rent payments through November 2019.

Modification of Compensation Arrangements

The Compensation Committee of our Board of Directors, approved the modification of cash compensation arrangements, each effective January 1, 2016, for Matthew B. Ferguson, our Chief Business Officer and Chief Financial Officer, on March 3, 2016, and for John B. Simpson, our Executive Chairman, and Jeffrey M. Soinski, our Chief Executive Officer, on March 7, 2016. The cash compensation arrangement for each individual was modified as follows:

- Mr. Ferguson s base salary was increased from $275,000 to $300,000 and his target bonus percentage was increased from 30% to 40%;

- Dr. Simpson s base salary was increased from $335,000 to $390,000 and his target bonus percentage was increased from 40% to 50%; and

- Mr. Soinski s base salary was increased from $375,000 to $390,000 and his target bonus percentage was increased from 40% to 50%.

The annual cash compensation of Mr. Ferguson, Dr. Simpson and Mr. Soinski, each as modified, will now be as follows:

Name	Position	Salary	Cash Bonus Target	Target Cash Compensation
Matthew B. Ferguson	Chief Business Officer and Chief Financial Officer	$ 300,000	$ 120,000	$ 420,000
John B. Simpson	Executive Chairman	$ 390,000	$ 195,000	$ 585,000
Jeffrey M. Soinski	Chief Executive Officer	$ 390,000	$ 195,000	$ 585,000

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Directors and Key Employees

The following table sets forth information, as of February 29, 2016, regarding our executive officers, directors and key employees.

Name	Age	Title
Jeffrey M. Soinski	54	President, Chief Executive Officer and Director
John B. Simpson, Ph.D., M.D.	72	Director and Executive Chairman of the Board of Directors
Matthew B. Ferguson	48	Chief Business Officer and Chief Financial Officer
Sougata Banerjee	49	Senior Vice President, Operations and Quality
Bart C. Beasley	47	Vice President, Marketing
Arjun M. Desai, M.D.	34	Chief Medical Officer
Daniel V. George	46	Vice President, Finance
Patricia A. Hevey	50	Vice President, Clinical, Quality & Regulatory Affairs
Himanshu N. Patel	56	Chief Technology Officer
Philip R. Preuss	38	Vice President, Strategy and Business Operations
Joseph Rafferty	58	Vice President, Sales
John D. Simpson	37	Vice President, Business Development
James G. Cullen(1)(2)(3)	73	Director
Thomas J. Fogarty(3)	82	Director
Donald A. Lucas(1)(2)(3)	53	Director
James B. McElwee(1)(2)(3)	63	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and governance committee.

Jeffrey M. Soinski has served as our President, Chief Executive Officer and a member of our Board of Directors since December 2014. From its formation in September 2009 until the acquisition of its Unisyn business by GE Healthcare in May 2013, Mr. Soinski served as Chief Executive Officer of Medical Imaging Holdings and its primary operating company Unisyn Medical Technologies, a national provider of technology-enabled products and services to the medical imaging industry. Mr. Soinski remains a Director of Medical Imaging Holdings and its remaining operating company Consensys Imaging Service. Mr. Soinski is also a director of Merriman Holdings, a capital market advisory and research, corporate and investment banking services company, since 2008. From July 2008 to June 2013, Mr. Soinski served periodically as a Special Venture Partner for Galen Partners, a leading healthcare-focused private

equity firm, which has Medical Imaging Holdings as one of its portfolio companies. From 2001 until its acquisition by C.R. Bard in 2008, Mr. Soinski was President and CEO of Specialized Health Products International, a publicly-traded manufacturer and marketer of proprietary safety medical products. Mr. Soinski served as a consultant to BLOXR Corporation, a venture-backed medical device company, from October 2013 until September 2014. He has served on the board of directors of Merriman Holdings, parent of Merriman Capital, a San Francisco-based investment banking and brokerage firm, since 2008. Mr. Soinski holds a B.A. degree from Dartmouth College.

We believe Mr. Soinski is qualified to serve as a member of our board of directors because of his extensive corporate finance and business strategy experience as well as his experience with public companies.

John B. Simpson, Ph.D., M.D. founded our company in March 2007 and has served as a member of our board of directors since March 2007. From March 2007 to December 2014, Dr. Simpson served as our Chief Executive Officer. Since March 2000 Dr. Simpson has served in various positions at De Novo Ventures, a venture capital fund, including managing director and clinical director. Since 1983, Dr. Simpson has been a partner at Cardiovascular Medicine and Coronary Interventions, a cardiology physician group. Prior to founding our company,

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Dr. Simpson founded several other interventional cardiology companies, including Perclose, a manufacturer of femoral artery access site closure devices, Devices for Vascular Intervention, a manufacturer of atherectomy devices, Advanced Cardiovascular Systems, a manufacturer of balloon angioplasty devices and FoxHollow Technologies, a manufacturer of atherectomy devices. Dr. Simpson holds a B.S. in Agriculture from Ohio State University, an M.D. from the Duke University School of Medicine and an M.S. and a Ph.D. in Biomedical Science from the University of Texas.

We believe Dr. Simpson is qualified to serve as a member of our board of directors because of his medical background, extensive knowledge of medical device company operations, and his experience working with companies, regulators and other stakeholders in the medical device industry.

Matthew B. Ferguson has served as our Chief Business Officer and Chief Financial Officer since January 2011, and also as our Co-President from August 2012 to October 2013. From December 2009 to December 2010, Mr. Ferguson served as the Chief Financial Officer at Tethys Bioscience, a provider of molecular diagnostic tests for cardiometabolic conditions. From January 2008 to April 2009 he served as the Chief Financial Officer at Proteolix, a developer of novel drugs for the treatment of cancer and autoimmune diseases. Mr. Ferguson also served as the Chief Financial Officer and as Vice President of Finance and Business Development at FoxHollow Technologies. Mr. Ferguson holds a B.S. in Civil Engineering from Stanford University, an M.S. in Mechanical Engineering from the University of Pennsylvania and an M.B.A. from the University of California at Berkeley.

Sougata (Bunty) Banerjee joined out company in January 2012 and has served as our Senior Vice President of Operations and Quality since February 2015 and served as our Senior Vice President of Operations from January 2012 to January 2015. From November 2009 to January 2012, Mr. Banerjee was Vice President of Operations and Quality at Evalve where he oversaw the acquisition of Evalve by Abbott Laboratories in 2009 and led the post-acquisition integration and business expansion as Head of Operations at Abbott Vascular, Structural Heart. Prior to Evalve, Mr. Banerjee served as Plant Manager at Epicor, holding general management responsibilities including operations, quality, product development, finance, human resources, and providing leadership in product commercialization and new product introductions. Prior to Epicor, Mr. Banerjee held several operations leadership positions at several business units of Boston Scientific. Earlier in his career, Mr. Banerjee held various engineering positions at Crompton-Greaves, Caterpillar, and Larsen-Toubro. Mr. Banerjee received a B.S. in Electrical Engineering from Jadavpur University, India and an M.S. in Industrial Management from Clemson University.

Bart C. Beasley has been our Vice President of Marketing since January 2013. From January 2009 to January 2013, he served as the Senior Director of Marketing at Transcend Medical. From January 2007 to January 2009, Mr. Beasley worked as an independent consultant providing consulting on sales and marketing strategy matters within the medical device industry. Mr. Beasley holds a B.S. in Economics from Santa Clara University and an M.B.A. from IESE, University of Navarra in Spain.

Arjun M. Desai, M.D. joined our company in January 2012 and has served as our Chief Medical Officer since

November 2013. From July 2010 to December 2011, Dr. Desai served as a consultant and advisor for Incline Therapeutics, developing the IONSYS transdermal fentanyl delivery system and for other companies. From 2008 to December 2011, Dr. Desai was a Staff Physician at Stanford University in the Department of Anesthesia where he completed his advanced anesthesia residency training. Dr. Desai continues to be affiliated with Stanford University. Dr. Desai has also served as a fellow in the United States House Policy Committee, advising members of Congress on healthcare legislation. Additionally, Dr. Desai represented the United States State Department and Rotary International as an Ambassador of Goodwill to Singapore where he led vaccine prophylaxis campaigns and lectured in the department of health economics at the National University of Singapore. Dr. Desai holds an M.D. from the University of Miami Miller School of Medicine and a B.A. in Economics from the University of Oklahoma.

Daniel V. George has served as our Vice President, Finance since August 2014. From June 2012 to August 2014, Mr. George served as a consultant and Vice President of Finance for ApniCure, a medical device company specializing in the treatment of sleep apnea. From March 2009 to June 2012, Mr. George worked for Avantis Medical Systems, a manufacturer of colonoscopy visualization technology, where he was both a consultant and Chief Financial Officer. Mr. George was also the Sr. Director of Finance at FoxHollow Technologies and

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worked for PricewaterhouseCoopers in the assurance and business advisory practice. Mr. George holds B.S. degrees in both Accounting and Finance from California State University, Long Beach.

Patricia A. Hevey has served as our Vice President of Clinical, Regulatory and Quality Affairs since September 2014. From April 2014 to September 2014, Ms. Hevey was our Vice President of Clinical and Regulatory Affairs and from February 2011 to February 2014, she served as our Director of Clinical and Regulatory Affairs. From July 2010 until February 2011, Ms. Hevey was the President of Hevey Clinical Consulting and from October 2008 to July 2010, she was the Director of Clinical and Regulatory Affairs at Baxano. Ms. Hevey holds a B.S. in Clinical Research Administration from George Washington University Medical School and an associate of science in Radiology Science from Canada College.

Himanshu N. Patel served as our Chief Technology Officer from January 2011 to November 2011 and since October 2013. From September 1999 to February 2007, Mr. Patel led research and development activities as the Director of Advanced Technologies at FoxHollow Technologies. Mr. Patel holds a B.S. in Mechanical Engineering from M.S. University of Baroda, India, and an M.S. in Mechanical Engineering from the University of Florida.

Philip R. Preuss joined our company in August 2009 and has served as our Vice President, Strategy and Business Operations since April 2015. From September 2014 to March 2015 Mr. Preuss was our Vice President, Corporate Development and from September 2012 to August 2014, Mr. Preuss served as our Vice President, Finance and Corporate Development. Prior to joining our company, Mr. Preuss was a Manager of Business Development at another medical device company founded by Dr. Simpson. Mr. Preuss was also a Senior Associate of Corporate Development at FoxHollow Technologies, where he worked on internal strategic priorities and the exploration of external business opportunities. Before entering the medical device industry, Mr. Preuss held various roles in the financial services sector, and specifically within the field of equity research. Mr. Preuss holds an M.B.A. from the Kellogg School of Management and a B.A. in both Economics and History from Stanford University.

Joseph Rafferty has served as our Vice President, Sales since January 2016. Mr. Rafferty has more than 30 years of medical technology sales and marketing experience, primarily with peripheral vascular and coronary products and procedures. From June 2009 to December 2015, Mr. Rafferty served as President and Chief Executive Officer of National Medical Sales, an organization providing third-party commercialization services to emerging medical technology companies, primarily in the fields of peripheral and coronary interventional devices. From July 2007 to May 2009, Mr. Rafferty held the position of Vice President of Sales and later Vice President of Global Sales at Pathway Medical Technologies, Inc., a manufacturer of atherectomy systems to treat arterial disease. Mr. Rafferty holds a B.S. in Journalism from Temple University.

John D. Simpson joined our company in August 2009 and has served as our Vice President, Business Development since April 2015. Prior to that, Mr. Simpson served as our Vice President, Sales from March 2014 to March 2015. He was

also our Co-President from August 2012 to October 2013, our Chief Marketing Officer from August 2011 to July 2012 and our Vice President, Commercial Operations from August 2009 to July 2011. He also served as a member of our board of directors from December 2009 to January 2015. From 2001 to 2005, Mr. Simpson worked at FoxHollow Technologies in a Clinical Affairs, Sales and Marketing role. From 2005 to 2006, Mr. Simpson worked at Palo Alto Investors, an independent, privately held investment advisor. Mr. Simpson rejoined FoxHollow Technologies in 2006 where he worked in Corporate Development. Mr. Simpson is a Founder and the former Chief Executive Officer of Recreation, which is a full service creative, digital and media agency focused on brand strategy and implementation for life changing innovations. Mr. Simpson holds a B.A. in Sociology from Duke University.

James G. Cullen has served as a member of our board of directors since December 2014. During the last five years, Mr. Cullen has held board and committee positions with various companies. Mr. Cullen is currently the non-executive Chairman of the board of Neustar, Inc., a neutral provider of real-time information services and analytics, a director and member of the investment and finance committees of Prudential Financial, non-executive Chairman of the Board of Agilent Technologies, and a director of Keysight Technologies. Mr. Cullen previously served as a director and chairman of the audit committee of Johnson & Johnson. From 1993 to 2000, Mr. Cullen was President, Vice Chairman and Chief Operating Officer of Bell Atlantic Corporation (now Verizon). From 1989 to 1993, he was President and Chief Executive Officer of Bell Atlantic-New Jersey. Mr. Cullen holds a B.A. in

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Economics from Rutgers University and an M.S. in Management Science from the Massachusetts Institute of Technology.

We believe Mr. Cullen is qualified to serve as a member of our board of directors because of his extensive experience serving on the boards of public companies as well as his financial and business expertise.

Thomas J. Fogarty, M.D. has served as a member of our board of directors since December 2014. Dr. Fogarty is a managing director of Emergent Medical Partners, an investment firm focused on private medical device companies, which he founded in 2007. Prior to Emergent Medical Partners, Dr. Fogarty held various positions at Stanford University where he performed both cardiac and peripheral vascular surgery. His positions at Stanford University included Professor of Cardiovascular Surgery and President of the Medical Staff. Dr. Fogarty holds a B.S. degree in Biology from Xavier University and an M.D. from Cincinnati College of Medicine.

We believe Dr. Fogarty is qualified to serve as a member of our board of directors because of his medical background and extensive knowledge of medical device company operations.

Donald A. Lucas has served as a member of our board of directors since 2013 and has been an investor in our company since 2011. Mr. Lucas has been a venture capitalist since 1985, having invested in companies such as Oracle, Macromedia and Cadence Design alongside his father Donald L. Lucas. Mr. Lucas has sourced or led investments in companies such as Intuitive Surgical, Coulter Pharmaceutical, Dexcom, Infinera, Signifyd, Obalon Therapeutics, MD Insider, Palantir and Theranos. Mr. Lucas has served on the boards of Dexcom and the Silicon Valley Chapter of the JDRF and is a member of the UCSF Diabetes Center Leadership Council. Mr. Lucas holds a B.A. from Santa Clara University.

We believe Mr. Lucas is qualified to serve as a member of our board of directors because of his substantial corporate finance, business strategy and corporate development expertise gained from his significant experience in the venture capital industry, analyzing, investing in, serving on the boards of, and providing guidance to various technology companies.

James B. McElwee has served as a member of our board of directors since March 2011. Mr. McElwee serves as an independent venture capital investor since 2010. Mr. McElwee served as general partner of Weston Presidio, a private equity and venture capital firm, from 1992 to 2010. During his tenure as a general partner and member of the investment committee, Weston Presidio led the start up financing of JetBlue Airways and made investments in Fender Musical Instruments, The Coffee Connection, Guitar Center, Mapquest, Party City, Petzazz, RE/MAX, and others. Prior to Weston Presidio, Mr. McElwee was Senior Vice President of the Security Pacific Venture Capital Group and the founding Managing Director of its Menlo Park office where he was responsible for early private investments in Costco, Universal Health Services, Cypress Semiconductor, Aspect Telecommunications, Xilinx, MIPS Computer Systems, Harmonic, Microchip, Vitesse and others. Prior to entering the venture capital industry in 1979, Mr. McElwee was a Senior Consultant with Accenture working on a variety of clients in the retailing, healthcare and

technology industries. Mr. McElwee holds a B.A. in Economics from Claremont McKenna College and an M.B.A. from the Wharton Graduate School of Business.

We believe Mr. McElwee is qualified to serve as a member of our board of directors because of his substantial corporate development and business strategy expertise gained in the venture capital industry.

Executive Officers

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. John B. Simpson, the Executive Chairman of our board of directors, is the father of John D. Simpson, our Vice President, Business Development.

Board of Directors

Our business is managed under the direction of our board of directors, which consists of six directors. Our directors hold office until the earlier of their death, resignation, removal or disqualification, or until their successors

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have been elected and qualified. We are actively searching for qualified candidates to add to our board of directors or to replace current members. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our board of directors should be separate. Prior to our initial public offering, the members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation and a voting agreement among certain of our stockholders. The voting agreement terminated upon the closing of our initial public offering, on February 5, 2015, and none of our stockholders have any special rights regarding the election or designation of members of our board of directors.

Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors. Our board of directors is divided into three classes with staggered three-year terms. Our first annual meeting of stockholders will be in 2016. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Our directors have been divided among the three classes as follows:

- The Class I directors are Jeffrey M. Soinski and John B. Simpson, and their terms will expire at our annual meeting of stockholders to be held in 2016
- The Class II directors are Donald A. Lucas and James B. McElwee, and their terms will expire at our annual meeting of stockholders to be held in 2017; and
- The Class III directors are James G. Cullen and Thomas J. Fogarty and their terms will expire at our annual meeting of stockholders to be held in 2018.

This classification of the board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management.

Director Independence

Under the rules of The NASDAQ Stock Market, independent directors must comprise a majority of a listed company s board of directors within a specified period of time after listing on The NASDAQ Stock Market. In addition, the rules of The NASDAQ Stock Market require that, subject to specified exceptions, each member of a listed company s audit, compensation, and nominating and governance committees be independent. Our board of directors has reviewed the independence of each director and determined that Messrs. Cullen, Fogarty, Lucas and McElwee are independent under the rules of The NASDAQ Stock Market. Our board of directors will review the independence of each director at least annually. During these reviews, the board of directors will consider current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our common stock by each non-employee director and the transactions involving them described in the section titled Certain Relationships and Related Transactions.

We believe that the composition of our board of directors meets the requirements for independence under the current requirements of The NASDAQ Stock Market. As required by The NASDAQ Stock Market, our independent directors meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

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Corporate Governance

We believe that good corporate governance is important to ensure that, as a public company, we will be managed for the long-term benefit of our stockholders. We and our board of directors have been reviewing the corporate governance policies and practices of other public companies, as well as those suggested by various authorities in corporate governance. We have also considered the provisions of the Sarbanes-Oxley Act and the rules of the SEC and The NASDAQ Stock Market.

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, we have established charters for the audit committee, compensation committee and nominating and governance committee, as well as a code of business conduct and ethics applicable to all of our directors, officers and employees.

Board Committees

Our board of directors has established a standing audit committee, a compensation committee, and a nominating and governance committee. Our board of directors has assessed the independence of the members of each of these standing committees as defined under the rules of The NASDAQ Stock Market and, in the case of the audit committee, the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended.

Audit Committee. Messrs. Lucas, McElwee and Cullen serve on our audit committee. Mr. Lucas serves as the chair of the audit committee. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of The NASDAQ Stock Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Messrs. Lucas, McElwee and Cullen have met the financial literacy and financial sophistication requirements and that Messrs. Lucas, McElwee and Cullen are independent under SEC and The NASDAQ Stock Market rules. Our board of directors expects to make a determination of whether at least one of the members of the audit committee meets the requirements of an audit committee financial expert prior to the filing of a proxy statement relating to our 2016 annual meeting of stockholders. The audit committee s primary responsibilities include:

- appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is Ernst & Young LLP;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- monitoring our internal control over financial reporting, disclosure controls and procedures;

- reviewing our risk management status;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management; and
- monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our board of directors has adopted a written charter for the audit committee which will be available on our website at *www.avinger.com*.

Compensation Committee. Messrs. Lucas, Cullen and McElwee serve on our compensation committee. Mr. McElwee serves as the chair of the compensation committee. The compensation committee s responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- determining the compensation of our chief executive officer and our other executive officers;
- reviewing and making recommendations to our board of directors with respect to director compensation; and
- overseeing and administering our equity incentive plans.

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Our chief executive officer and chief financial officer make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Bonus Plan to the compensation committee. From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, we have periodically engaged Radford Consulting to help develop our compensation philosophy, select a group of peer companies to use for compensation benchmarking purposes and cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our board of directors has adopted a written charter for the compensation committee which is available on our website at *www.avinger.com*.

Nominating and Governance Committee. Messrs. Lucas, Cullen, McElwee and Dr. Fogarty serve on our nominating and governance committee. Mr. Cullen serves as the chair of the nominating and governance committee. The nominating and governance committee s responsibilities include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board s committees;
- reviewing and making recommendations to our board of directors with respect to management succession planning;
- developing, updating and recommending to our board of directors corporate governance principles and policies; and
- overseeing the evaluation of our board of directors and committees.

Our board of directors has adopted a written charter for the nominating and governance committee which is available on our website at *www.avinger.com*.

Lead Independent Director

Our board of directors has appointed James G. Cullen to serve as our lead independent director. As lead independent director, Mr. Cullen is expected to preside over periodic meetings of our independent directors, to serve as a liaison between our Executive Chairman and the independent directors, and to perform such additional duties as our Board may otherwise determine and delegate. At the end of each board meeting, the independent directors are expected to meet without Mr. Soinski and Dr. Simpson present. Following each meeting, Mr. Cullen is expected to provide feedback to Mr. Soinski and Dr. Simpson on their performance and the performance of our employees during the meeting and to recommend new agenda items for the next meeting.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at *www.avinger.com*. We will post amendments to our code of business conduct and ethics or waivers of our code of business conduct and ethics for directors and executive officers on the same website.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; and
- any transaction from which the director derived an improper personal benefit.

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Our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors and officers liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder s investment may be adversely affected to the extent that we pay the costs of settlement and damages.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the year ended December 31, 2015, all of our officers, directors and greater than 10% beneficial owners have complied with Section 16(a) filing requirements.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an emerging growth company as defined in the JOBS Act we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by each individual who served as our principal executive officer at any time in 2015, and our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2015. These individuals were our named executive officers for 2015.

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Name and Principal Position	Year	Salary ($) (1)	Bonus ($) (2)	Stock Awards ($) (3)	Option Awards ($) (3)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($) (5)	Total ($)
John B. Simpson, Ph.D., M.D. (4)	2015	335,000				141,841			476,841
Executive Chairman	2014	362,917			1,994,872				2,357,789
	2013	340,584	63,410		301,061				705,055
Jeffrey M. Soinski (4)	2015	375,000				114,000		46,663	535,663
President and Chief Executive Officer	2014	4,327			1,474,016				1,478,343
Matthew B. Ferguson	2015	275,000				62,699		3,000	340,699
Chief Financial Officer and Chief Business Officer	2014	300,917			227,229				528,146
	2013	282,584	44,618		72,543				399,745

(1) The amounts reported include salary paid and 200% of salary deferred in each of the fiscal years. No more than 10% of a named executive officer s salary was deferred in each fiscal year.

(2) The 2013 bonus amounts were paid pursuant to an executive bonus plan based on quarterly performance in five areas: Pantheris development, sales, cash burn, Lightbox placements and Ocelot development.

(3) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officer in 2014, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in the section titled Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-Based Compensation.

(4) Mr. Soinski was appointed our President and Chief Executive Officer on December 29, 2014, succeeding our founder and then-Chief Executive Officer, Dr. John B. Simpson. Dr. Simpson became our Executive Chairman upon Mr. Soinski s appointment.

(5) The amounts reported for Mr. Soinski represent reimbursed relocation expenses, of $43,663, pursuant to his employment offer letter and funds contributed to his health savings account of $3,000. The amount reported for Mr. Ferguson represents funds contributed to his health savings account.

Executive Officer Employment Letters

John B. Simpson

We entered into an employment offer letter in November 2014 with John B. Simpson. The letter has no specific term and provides for at-will employment. The letter does not provide for any bonus. Effective November 1, 2014, Dr. Simpson s annual base salary is $335,000.

Jeffrey M. Soinski

We entered into an employment offer letter in December 2014 with Jeffrey M. Soinski, our President and Chief Executive Officer. The letter has no specific term and provides for at-will employment. The letter also provides that, in 2015, Mr. Soinski is eligible to receive an annual performance bonus of up to 40% of his annual salary based on the achievement of certain goals mutually agreed upon by him and our board of directors. Effective December 29, 2014, Mr. Soinski s annual base salary is $375,000.

Pursuant to Mr. Soinski s employment offer letter, if, within the 12 month period following a change in control, we terminate Mr. Soinski s employment without cause, or Mr. Soinski resigns for good reason (as such terms are defined in Mr. Soinski s employment offer letter), Mr. Soinski will receive accelerated vesting as to

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100% of his outstanding unvested stock options. If we experience a change in control, and Mr. Soinski remains our employee through such date, Mr. Soinski will receive accelerated vesting as to 50% of his outstanding unvested stock options and/or restricted stock.

If we terminate Mr. Soinski without cause at any time, he will be entitled to receive 12 months of base salary and COBRA medical and dental insurance coverage, in each case payable in substantially equal installments in accordance with our payroll practices, as severance, in exchange for signing and not revoking a severance agreement and general release against us and our affiliates within 60 days following his termination of employment.

The letter provides that Mr. Soinski may receive payments or reimbursements from us for up to $30,000 of reasonable and documented expenses related to temporary lodging, travel, and commuting costs incurred by Mr. Soinski prior to August 2015 in connection with his transition from Utah to Redwood City, California, and reimbursements of up to $100,000 related to the sale of Mr. Soinski s home in Utah and relocation to California.

Matthew B. Ferguson

We entered into an employment offer letter in December 2010 with Matt Ferguson, our Chief Financial Officer and Chief Business Officer. The letter has no specific term and provides for at-will employment. The letter did not provide for any bonus. Effective November 1, 2014, Mr. Ferguson s annual base salary is $275,000.

Pension Benefits and Nonqualified Deferred Compensation

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2015.

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Outstanding Equity Awards at 2015 Year-End

The following table sets forth information regarding outstanding stock options and stock awards held by our named executive officers as of December 31, 2015:

		Option Awards				Stock Awards	
Name	**Grant Date(1)**	**Number of Securities Underlying Unexercised Options (#) Exercisable(2)**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)(3)**	**Option Expiration Date**	**Number of Shares or Units of Stock That Have Not Vested (#)**	**Market Value of Shares or Units of Stock That Have Not Vested ($)**
John B. Simpson	5/1/2013(4)	28,888		22.50	5/1/2018		
	12/31/2014(5)	838,250		4.95	12/31/2024		
Jeffrey M. Soinski	12/31/2014(5)	619,385		4.50	12/31/2024		
Matthew B. Ferguson	7/29/2011(6)	33,965		12.60	7/29/2021		