Avinger Inc
Form 10-K
March 27, 2015
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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, 2014

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 o 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. x

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

Indicate by check mark whether the registrant is a shell company (as defined 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 January 30, 2015 as reported by the NASDAQ Global Market on such date was approximately $13.50. The registrant has elected to use January 30, 2015, which was the initial trading date on the NASDAQ Global Market, as the calculation date because on June 30, 2014 (the last business day of the registrant s mostly recently completed second fiscal quarter), the registrant was a privately-held company. Shares of the registrant s common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 26, 2015, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 12,228,260.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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AVINGER, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014

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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, including VISION, 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 submission of a 510(k) to FDA for 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 a 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 or a smaller reporting company under the Securities Act;

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

- our financial performance; 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 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. 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 arterial disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to the arms 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. We are also developing Pantheris, our image-guided atherectomy device, designed to allow physicians to precisely remove arterial plaque in PAD patients. Pantheris is currently undergoing a U.S. clinical trial intended to support a 510(k) submission in the second half of 2015 to the U.S. Food and Drug Administration, or FDA. We believe that Pantheris, if cleared by FDA, 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 $1.2 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 we refer to as the black line.

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 133-patient clinical trial designed to support a filing with FDA for our Pantheris atherectomy device. VISION is designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging. We believe the data from VISION will also allow us to demonstrate that avoiding the black line reduces the likelihood of restenosis in these patients. If Pantheris is cleared by FDA, we plan to commercialize it as part of our lumivascular platform in the United States and in select European countries after obtaining any 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 $11.2 million in 2014, $13.0 million in 2013 and $8.6 million in 2012.

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

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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

PAD is atherosclerosis in the arteries that supply blood to the arms 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.

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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.

Importance of the Black Line. 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 we call the black line. A study by the Sanford Burnham Institute concluded that disruption of the area around the black line creates an inflammatory response significantly greater than when the black line 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. Black line disruption can be caused by wire-based CTO crossing, dissection from balloon angioplasty, stent placement, or an atherectomy device cutting through this area.

Lumivascular View

Cross-Sectional View

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

A study from New York s Mount Sinai Hospital, published in the Journal of the American College of Cardiology, or JACC, 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 102 patients and assessed restenosis rates after one year. The study found that in 54% of the patients, the extracted portion contained healthy tissue, indicating disruption of the black line. In this group of patients the restenosis rate, one-year after treatment, was 96%, while in the group of patients without evidence of black line disruption, the restenosis rate was only 15%.

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The data from the Mount Sinai Hospital 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.

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 black line. 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 disrupt the black line 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 JACC, stents placed in the legs fracture in approximately 25% of cases and 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. Currently available atherectomy devices rely on fluoroscopy rather than on- board imaging to provide visual guidance throughout the entire procedure. 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, current atherectomy technologies can damage the black line, 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 currently provides physicians with real-time OCT images from the inside of an artery during CTO crossing, and we believe Pantheris will be the first product to offer intravascular visualization during atherectomy.

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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:

- ***Improved efficacy through reduced risk of restenosis.*** Clinical evidence supports the proposition that more desirable outcomes in treating PAD are achieved by minimizing black line disruption, thereby reducing the risk of restenosis. Our lumivascular platform is designed to provide physicians with a clear picture from inside the artery during treatment. This visualization helps physicians to avoid disrupting the black line during an intervention, which we believe reduces the risk of restenosis. 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 human feasibility trials have demonstrated that Pantheris avoided cutting the black line in 99% of the 86 tissue samples collected. Additionally, a study conducted at Mount Sinai Hospital, New York involving 102 patients found one-year restenosis rates of 96% and 15% in patients with and without black line disruption, respectively. The Mount Sinai Hospital 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 black line 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 97% efficacy and 98% safety rates in CTO cases using Ocelot.

- ***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, if cleared by FDA, 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

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limit future treatment options. 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 expect that Pantheris will qualify 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 the current model of Pantheris may require two physicians to operate the catheter and that training for technicians and physicians will be required to enable them to effectively operate our lumivascular platform products. Our Pantheris product is not cleared or approved by FDA for commercial sale. Pantheris may not be sold in the United States without clearance from FDA. 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:

- ***Successfully complete the Pantheris VISION clinical trial.*** In March 2015, we completed enrollment of patients in the VISION clinical trial, which is a pivotal, non-randomized, prospective, single-arm trial to evaluate the safety and effectiveness of Pantheris in performing atherectomy procedures. The trial includes 134 patients at 20 sites within the United States and Europe. Data collection from the VISION trial is ongoing, and data monitoring and auditing of the acute procedural data and 30-day and six-month follow-up data is currently underway. We intend to use the data from our VISION trial to support an FDA 510(k) submission in the second half of 2015 for Pantheris. If Pantheris is cleared by FDA and other regulatory authorities, we plan to commercialize it as part of our lumivascular platform in the United States and in select European countries after obtaining any required marketing authorizations.

- ***Increase the installed base and penetration of our lumivascular platform.*** We have a direct sales organization that is divided into two distinct roles, sales of capital equipment and sales of disposable products. 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. We expect to grow our sales force in preparation for the commercial launch of Pantheris in order to increase the base of customers using 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 compared to other endovascular treatments for PAD, and demonstrate the benefits of our lumivascular platform. We plan to conduct studies comparing the safety, efficacy and cost of our lumivascular platform products to competitive products and may also conduct studies to gain 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 black line 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

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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 if it is cleared for commercialization. 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. In the future, we may seek to manufacture certain of our products outside the United States to further reduce costs.

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		