UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2016

or

☐ **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 (State or other jurisdiction of incorporation or organization)	**20-8873453** (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 ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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 ☒ No ☐

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

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

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

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, 2016 as reported by the NASDAQ Global Market on such date, was approximately $73.6 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 13, 2017, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 23,913,359.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the information called for by Part III of this Form 10-K is hereby incorporated by reference to the definitive proxy statement for the registrant's 2017 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2016.

AVINGER, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016
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“Avinger,” “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.

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,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or 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 and expectations regarding our clinical studies, including our VISION trial and plans to conduct further clinical studies;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through our “at-the-market” program and future equity or debt financings;
- 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, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to continue as a going concern;
- 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 revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;
- 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.

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 international 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 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.

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 for PAD include stents, angioplasty, and atherectomy, which is the use of a catheter-based device 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 though the use of 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. 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 commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select international markets in March 2016 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. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, 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 $19.2 million in 2016, $10.7 million in 2015 and $11.2 million in 2014.

Our Products

Our current products include our Lightbox console and our various catheters used in PAD treatment. 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 international markets. 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 subtotal 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, plaques 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 subtotal 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 subtotal 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.

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 vessel 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 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 EEL 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 enables physicians to specifically target 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 within the device.

In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We made minor modifications to Pantheris after the completion of the VISION trial and commenced sales in the United States and select international markets following receipt of FDA approval for 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 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. 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 peripheral arteries above the knee. 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.

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%

Although the original VISION study protocol was not designed to follow patients beyond six months, we recently began working with 18 of the VISION sites to re-consent patients in order for them to be evaluated for patient outcomes through 12 and 24 months following initial treatment. These longer-term outcomes were presented for an interim subset of 55 patients at a major medical conference in January 2016. The key metrics reported for this group were freedom from target lesion revascularization, or TLR, and freedom from amputation at 12 months and 24 months, which were 86% and 82%, respectively, based on Kaplan-Meier curve assessments.

Data collection for the remaining patients from participating sites is ongoing, and we expect to receive 12 and 24-month results for a total of approximately 125 patients by May 2017 and to release this data at a major medical conference shortly thereafter.

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 currently consists of two area Vice Presidents, Regional and Territory Sales managers, Lumivascular Account specialists, and one Director of International Sales. Territory Sales managers are responsible for all product sales, which include disposable catheters and sale and service of our Lightbox console, while Lumivascular account specialists are primarily responsible for case coverage and account support. 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 training and education, marketing communications 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, 2016, we had 70 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 2016, 2015 and 2014 were $40.0 million, $29.2 million and $18.5 million, respectively. No single customer accounted for more than 10% of our revenues during 2016, 2015 or 2014.

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.

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, 2016, we held 11 issued U.S. patents and had 23 U.S. utility patent applications and 2 PCT applications pending. As of December 31, 2016, we also had 17 issued patents from outside of the United States. As of December 31, 2016, we had 41 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 products and technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our 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, 2016, we held four registered U.S. trademarks and one pending U.S. trademark application. In Europe, we hold three 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 have developed versions of Pantheris 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, 2016, we had 29 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, 2016, 2015 and 2014 were $15.5 million, $15.7 million and $11.2 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 assemble all of our products at our manufacturing facility but certain critical processes such as coating and sterilization are done by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2018.

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 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 single vendors for our laser and data acquisition card that are key components of our Lightbox. 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 products 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 products 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 CDHS. 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. Our Quality System has undergone 20 external audits by third-parties and regulatory authorities since 2009, the latest of which occurred in January 2017 and resulted in zero observations of 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. In the United States 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) premarket notification submission. A completely novel product must go through the more rigorous premarket approval, or PMA, 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. Class I and Class II devices are considered lower risk and often can gain approval for commercial distribution by submitting an application 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.

The 510(k) clearance path can be significantly less time-consuming and arduous than PMA approval, making this route generally preferable for a medical device company. A 510(k) application must include documentation that its device is substantially equivalent to a technology already cleared through a 510(k) or in distribution before May 28, 1976 for which the FDA has not required a PMA submission. The FDA has 90 days from the date of the premarket equivalence acceptance to authorize or decline commercial distribution of the device. However, similar to the PMA process, clearance 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, and a PMA must be approved before the device can be commercialized. 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.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a change in its intended use, will require a new 510(k) submission and clearance before the modified device can be commercialized. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with the 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 of the modified device and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, a manufacturer may be subject to significant regulatory fines, penalties, and enforcement actions.

A PMA application must include reasonable scientific and clinical data that demonstrates the device is safe and effective for the intended uses and indications being sought. The application must also include preclinical testing, technical, manufacturing and labeling information. If the FDA determines the application can undergo substantive review, 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 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 advisory panel. As part of this process, the FDA will usually inspect the manufacturing facilities and operations prior to approval to verify compliance with quality control regulations. Significant changes in the manufacturing of a device, or changes in the intended use, indications and 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.

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. 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. In the latest FDA audit in 2013, there were no observations that involved a material violation of regulatory requirements, and no non-conformances were noted. Our responses to the observations noted in 2009 and 2011 were accepted by the FDA, and we believe that we are in substantial compliance with the QSR. BSI, our European Notified Body, inspected our facility several times between 2010 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. The BSI audit performed in January 2017 resulted in zero non-conformances.

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

- warning letters, adverse publicity, 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 28 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.

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.

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. 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.

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. Furthermore, the current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the United States may have on our business.

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.

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 2017 went into effect as of October 1, 2016. National average Medicare payment rates for PAD procedures for fiscal year 2017 are $10,593 - $19,754 for inpatient procedures and, $4,800 - $14,511 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, 2016, we had 197 employees, including 54 in manufacturing and operations, 70 in sales and marketing, 21 in research and development, 25 in clinical affairs, regulatory affairs, and quality assurance and 27 in finance, general administrative and executive administration. All 197 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

Investing in our common stock involves a high degree of risk. 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. If any of the risks actually occur, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. 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."

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;
- market acceptance of our Lumivascular platform and products, including Pantheris;
- 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, political, industry and market conditions, including economic and political uncertainty caused by the recent U.S. presidential election;
- 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 $56.1 million in 2016, $47.3 million in 2015 and $32.0 million in 2014. As of December 31, 2016, we had an accumulated deficit of approximately $252.4 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 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 continue to incur significant legal, accounting and other expenses. 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.

Our limited commercialization experience and number of approved products makes it difficult to evaluate our current business, predict our future prospects, assess the long-term performance of our products, 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. In October 2015, we received 510(k) clearance from the 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 international markets promptly thereafter. 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, market acceptance of our products, and increasing and unforeseen expenses as we continue to attempt to grow our business.

In addition, we have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have addressed certain of these concerns and plan to make additional product changes and improvements as a result of this feedback. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our reputation could suffer, which could lead to decreased sales of our products. In 2016, our revenue was adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, including improvements to the Pantheris imaging fiber connection, and to replace products in accordance with our warranty policy. This additional expense, and any future expense that we may incur as a result of future product performance issues, will negatively impact our financial performance and results of operations. If we are unable to improve the performance of our products to meet the concerns of the physicians our revenue may decline further or fail to increase.

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 and use 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, and Pantheris became commercially available in the United States and select international markets promptly thereafter. 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. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. In some cases utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivascular platform products does not increase 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 the current model of 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, potentially making it less financially attractive for physicians and their hospitals and medical facilities. 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.

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 our "at-the-market" program, whereby we may issue and sell shares of common stock, together with our cash and cash equivalents at December 31, 2016 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations until at least September 30, 2017. We will need to raise additional funds through future equity or debt financings within the next nine months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next nine months could cause substantial dilution to our existing stockholders.

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, our "at-the-market" program, our initial public offering, or IPO, and our follow-on public offering in August 2016. 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 businesses technologies 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 degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris;
- 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 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, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations. 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 rely heavily on our sales professionals to market and sell our products. If we are unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on our ability to hire, train, manage and improve the productivity levels of our sales professionals. We have experienced direct sales employee and sales management turnover in the past. For example, in February 2017, John D. Simpson, our Senior Vice President, Sales and Marketing resigned. The loss of any of senior management in our sales team could weaken our sales expertise and harm our business, and we may not be able to find adequate replacements on a timely basis, or at all. The changes in senior management that have occurred over the past several years may continue to create instability in our sales force leading to attrition in sales representatives in the future.

Competition for sales professionals who are familiar with and trained to sell our products continues to be strong. We train our existing and recently recruited sales professionals to better understand our existing and new product technologies and how they can be positioned against our competitors' products. These initiatives are intended to improve the productivity of our sales professionals and our revenue and profitability. It takes time for the sales professionals to become productive following their hiring and training and there can be no assurance that sales representatives will reach adequate levels of productivity, or that we will not experience significant levels of attrition in the future. Measures we implement to improve the productivity may not be successful and may instead contribute to instability in our operations, additional departures from our sales organization, or further reduce our revenue, profitability, and harm our business and our stock price may be adversely impacted as a result.

If our revenue does not improve, or if our cost of revenue and/or operating expenses increase by a greater percentage than our revenue, our gross margins and operating margins may be adversely impacted, our loss from operations will increase, and our cash used in operating activities will increase, which could reduce our assets and have a material adverse effect on our stock price.

Our gross margin decreased to 25% for the year ended December 31, 2016 compared to 40% for the year ended December 31, 2015. This decrease was primarily attributable to costs associated with our expanded manufacturing infrastructure related to the introduction of Pantheris against lower than anticipated volumes, and lower manufacturing yields as we implemented our improvement to the Pantheris imaging fiber connection. Gross margin was also negatively impacted by an increase of $1.0 million related to warranty expense and a $0.8 million charge in the year ended December 31, 2016, predominantly related to excess and obsolete Pantheris inventories.

Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. To the extent that our revenue does not grow as quickly as expected or declines, it is difficult to improve our gross margins as our fixed costs must be spread over a lower revenue base. Our future revenue may be adversely affected by a number of factors including the competitive market environment in which we operate, which may result in a decrease in the number of products sold or a decrease in the average selling prices achieved for our product sales. If our revenue does not improve, or if our cost of revenue increases by a greater percentage than our revenue, or if we are not able to reduce expenses in the event of a decline in revenue, we may continue to generate losses from operations and use cash, which could reduce our cash faster than budgeted, cause us to need to obtain additional financing and have a material adverse effect on our operations and stock price.

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, 2016, we had $41.3 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. 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 had to achieve minimum revenue of $7.0 million in 2015 and $23.0 million in 2016, and will have to achieve minimum revenue of $40.0 million in 2017, $50.0 million in 2018, $60.0 million in 2019 and $70.0 million in 2020 and in each year thereafter, as applicable. On October 28, 2016, we amended the terms of the Loan Agreement, to reduce the minimum revenue that we must achieve in 2016 to $18.0 million. 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. 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 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.

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.

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 obtain 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.

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 limited 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 other applications for which we do not currently have clearance, such as the 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.

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 Office of Inspector General, or 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;
- 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;
- 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 single vendors for our laser and data acquisition card that are key components of our 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. For example, in February 2017, John D. Simpson, our Senior Vice President of Sales and Marketing, resigned. 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 B. 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 professionals. 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.

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 international 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, 2016, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $219.1 million and $161.8 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2017 for state purposes. Generally, NOLs can be used to offset 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. It is possible that prior transactions with respect to our stock may have caused, and that 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.

We may acquire other companies or technologies or be the target of strategic transactions, 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.

In addition, we sometimes receive inquiries relating to potential strategic transactions, including from third parties who may seek to acquire us. We will continue to consider and discuss such transactions as we deem appropriate. Such potential transactions may divert the attention of management, and cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

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. They may devote substantial resources towards obtaining claims that cover the design of our atherectomy products to prevent the marketing and selling of competitive products. 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.

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, 2016, we held 11 issued U.S. patents and had 23 U.S. utility patent applications and 2 PCT applications pending. As of December 31, 2016, we also had 17 issued patents outside of the United States. As of December 31, 2016, we had 41 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;
- 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. We plan to apply for 510(k) clearance for improvements to our Pantheris device mid-2017, and we intend to file for FDA clearance of a lower-profile device for below-the-knee peripheral vascular applications in the second half of 2017. 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

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 publicly 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 scientific 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, adverse publicity, 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 or approvals 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 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 products 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 2014 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. The BSI audit performed in January 2017 resulted in zero non-conformances. We can provide no assurance that we will continue to remain in substantial 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.

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.

The current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

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;
- HIPAA, as amended by the HITECH Act, which 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 party 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. We have incurred and expect to incur additional costs to comply with these disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in our products. Additional costs could include the cost of remediation and other changes to products, processes, or sources of supply as a consequence of such verification activities. In addition, our 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.

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 significantly 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:

- sales of stock by our existing stockholders, including our affiliates;
- market acceptance of our Lumivascular platform and products, including Pantheris;
- the results of our clinical trials;
- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' and our own estimates;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- actual or anticipated fluctuations in our financial condition and operating results;
- quarterly variations in our or our competitors' results of operations;

- 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.

From time to time, our affiliates may sell stock for reasons due to their personal financial circumstances. These sales may be interpreted by other stockholders as an indication of our performance and result in subsequent sales of our stock that have the effect of creating downward pressure on the market price of our common stock. 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.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which would cause our stock price to decline.

We have provided and may continue to provide guidance about our business and future operating results. In developing this guidance, our management must make certain assumptions and judgments about our future performance, including projected revenues and the timing of regulatory approvals. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock would decline.

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.

We will need to raise additional funds through future equity or debt financings within the next 12 months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next 12 months could cause substantial dilution to our existing stockholders.

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. The Registration Statement was declared effective by the SEC on March 8, 2016. In August 2016, we issued and sold 9,857,800 shares of our common stock in our follow-on public offering at a public offering price of $3.50 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. We have also established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Registration Statement. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under our "at-the-market" program with Cowen at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. 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, which 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 March 1, 2017, our directors, officers and their affiliates collectively control approximately 19.2% 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.

Our 2016 financial statements contain disclosure that there is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern within one year from the date the financial statements are issued. Our independent registered public accounting firm has expressed in its auditors' report on our financial statements, included in this Annual Report on Form 10-K, a "going concern" opinion, meaning that we have recurring losses from operations and negative cash flows from operations that raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our 2016 financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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 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;
- 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.

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. In February 2016, we entered into an additional non-cancelable operating lease for 6,600 square feet of warehouse and storage space in Redwood City, California, the lease agreement expires in November 2019. We believe that our current facilities are adequate for our current and anticipated future needs through at least 2018.

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.

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:

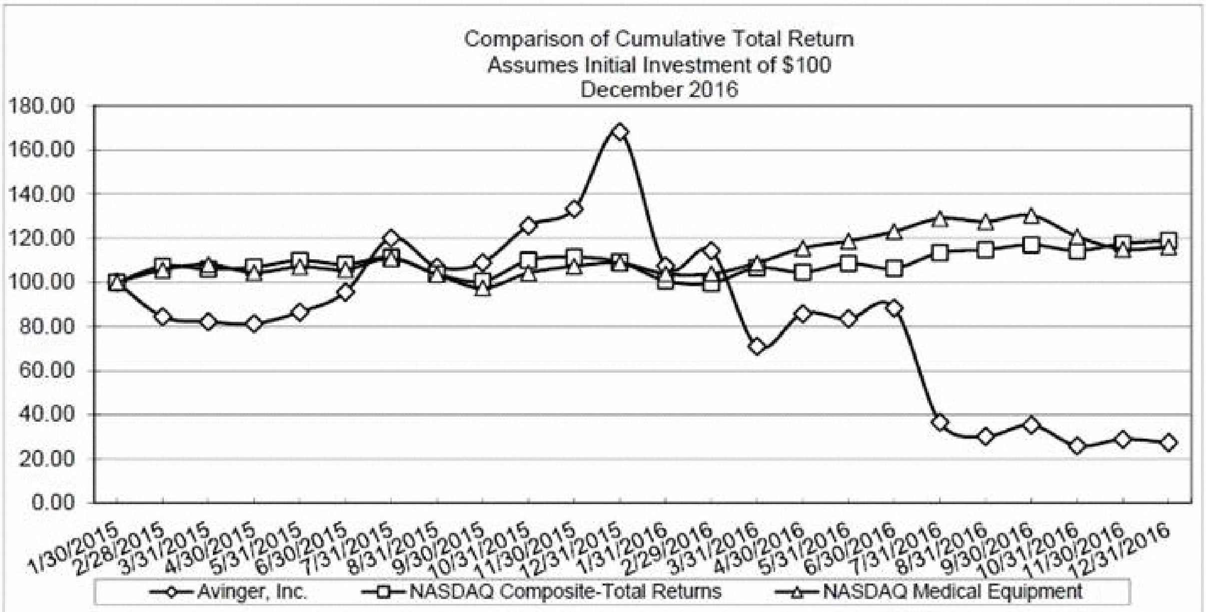
	Low	High
Fiscal Year ending December 31, 2015		
First Quarter (beginning January 30, 2015)	$ 10.00	$ 13.32
Second Quarter	$ 10.50	$ 13.15
Third Quarter	$ 12.52	$ 16.45
Fourth Quarter	$ 14.67	$ 24.75
Fiscal Year ending December 31, 2016		
First Quarter	$ 8.51	$ 20.46
Second Quarter	$ 9.92	$ 13.72
Third Quarter	$ 3.66	$ 11.99
Fourth Quarter	$ 3.50	$ 5.05

HOLDERS OF RECORD

As of March 13, 2016, there were 23,913,359 shares of our common stock held by 196 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, 2016. 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.



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. In addition, 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, 2016, 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)	6,074,304	$ 9.60	1,183,937

(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 Equity Incentive 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 2016 other than those transactions previously reported to the SEC on a Quarterly Report on Form 10-Q or Current Report on Form 8-K.

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, 2016, 2015 and 2014 and the balance sheet data as of December 31, 2016 and 2015 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,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Revenues	$ 19,214	$ 10,713	$ 11,213	$ 12,964	$ 8,560
Cost of revenues	14,445	6,478	6,513	8,205	4,151
Gross profit	4,769	4,235	4,700	4,759	4,409
Operating expenses:					
Research and development	15,536	15,694	11,224	15,973	15,416
Selling, general and administrative	39,950	29,231	18,503	25,758	22,848
Total operating expenses	55,486	44,925	29,727	41,731	38,264
Loss from operations	(50,717)	(40,690)	(25,027)	(36,972)	(33,855)
Interest income (expense), net	(5,399)	(5,127)	(6,014)	(2,923)	19
Other income (expense), net	(12)	(1,527)	(909)	5	(19)
Loss before provision for income taxes	(56,128)	(47,344)	(31,950)	(39,890)	(33,855)
Provision for income taxes	—	—	14	11	9
Net loss and comprehensive loss	(56,128)	(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	$ (56,128)	$ (49,728)	$ (31,964)	$ (39,901)	$ (33,864)
Net loss attributable to common stockholders per share, basic and diluted	$ (3.39)	$ (4.38)	$ (132.63)	$ (170.52)	$ (162.03)
Weighted average common shares used to compute net loss per share, basic and diluted	16,574	11,362	241	234	209

Balance Sheets Data:

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Cash and cash equivalents	$ 36,096	$ 43,059	$ 12,316	$ 12,221	$ 20,617
Working capital	20	43,576	9,917	15,734	22,462
Total assets	53,557	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	(252,389)	(196,261)	(146,533)	(114,569)	(74,668)
Total stockholders' equity (deficit)	4,241	15,589	(143,868)	(112,782)	(73,644)

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, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. 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 international markets. Our current products include our Lightbox imaging console, as well as our Wildcat, Kittycat 2, 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.

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 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. Although the original VISION study protocol was not designed to follow patients beyond six months, we recently began working with 18 of the VISION sites to re-consent patients in order for them to be evaluated for patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites is ongoing, and we expect to receive 12 and 24-month results for a total of approximately 125 patients by May 2017 and to release this data shortly thereafter. We commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select international markets in March 2016, 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.

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 assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2018.

In addition to commercialization of Pantheris in the United States and select international markets in March 2016, 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 $19.2 million in 2016, $10.7 million in 2015 and $11.2 million in 2014. During the years ended December 31, 2016, 2015 and 2014, our net loss was $56.1 million, $47.3 million and $32.0 million, respectively. We have not been profitable since inception, and as of December 31, 2016, our accumulated deficit was $252.4 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 and an additional $10.0 million on June 15, 2016 under the Loan Agreement. Contingent on achievement of certain revenue milestones, among other conditions, we would have been eligible to borrow an additional $10.0 million, on or prior to March 29, 2017; however, we did not achieve the level of revenues required to borrow the final $10.0 million. 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 filed 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 an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through 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 was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. In addition, in August 2016, we completed a follow-on public offering of 9,857,800 shares of our common stock for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 9,857,800 shares include the exercise in full by the underwriters of their option to purchase an additional 1,285,800 shares of our common stock.

Components of our Results of Operations

Revenues

All of our revenues are currently derived from sales of our Lightbox console and sales of our various PAD catheters, as well as related services in the United States and select international markets. We expect our revenues to increase as we introduce new Lumivascular platform products including new versions of Pantheris. No single customer accounted for more than 10% of our revenues during 2016, 2015 or 2014.

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.

Cost of Revenues and Gross Margin

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. 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 placed Lightboxes held by customers and certain direct costs such as those incurred for shipping our products.

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. 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 current sales efforts focus on establishing new Lumivascular platform sites by marketing our products to physicians and hospital administrators. Additionally, we seek to support and 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 believe that our U.S. sales infrastructure and establishing distributor relationships in select regions outside the United States will drive further adoption of our Lumivascular platform.

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.

Results of Operations:

	Year Ended December 31,		
	2016	2015	2014
		(in thousands)	
Revenues	$ 19,214	$ 10,713	$ 11,213
Cost of revenues	14,445	6,478	6,513
Gross profit	4,769	4,235	4,700
Gross margin	25%	40%	42%
Operating expenses:			
Research and development	15,536	15,694	11,224
Selling, general and administrative	39,950	29,231	18,503
Total operating expenses	55,486	44,925	29,727
Loss from operations	(50,717)	(40,690)	(25,027)
Interest income (expense), net	(5,399)	(5,127)	(6,014)
Other income (expense), net	(12)	(1,527)	(909)
Loss before provision for income taxes	(56,128)	(47,344)	(31,950)
Provision for income taxes	—	—	14
Net loss and comprehensive loss	$ (56,128)	$ (47,344)	$ (31,964)

Comparison of Years Ended December 31, 2016 and 2015

Revenues. Revenues increased $8.5 million, or 79%, to $19.2 million during the year ended December 31, 2016, compared to $10.7 million during the year ended December 31, 2015. For the year ended December 31, 2016, sales of our Lightbox imaging consoles increased by 15% to $4.7 million and sales of our disposable catheters increased by 119% to $14.5 million. The increased revenues in 2016 reflects the commercial launch of Pantheris in March 2016 and our continuing focus on Lumivascular programs to educate physicians on the benefits of OCT, training related to image interpretation and building the installed base of the Lightbox imaging consoles.

Cost of Revenues and Gross Margin. Cost of revenues increased $7.9 million, or 123%, to $14.4 million during the year ended December 31, 2016, compared to $6.5 million during the year ended December 31, 2015. This increase was attributable to the increase in revenues from sales and manufacturing overhead costs as we invested significantly in operational infrastructure to support anticipated growth and the commercial launch of Pantheris. Gross margin for the year ended December 31, 2016 decreased to 25%, compared to 40% in the year ended December 31, 2015. This decrease was primarily attributable to costs associated with our expanded manufacturing infrastructure related to the introduction of Pantheris against lower than anticipated volumes, and lower manufacturing yields as we implemented our improvement to the Pantheris imaging fiber connection and the proportion of revenues attributable to our products sold under agreements with international distributors. Gross margin was also negatively impacted by an increase of $1.0 million related to warranty expense and a $0.8 million charge in the year ended December 31, 2016 predominantly related to excess and obsolete Pantheris inventories.

Research and Development Expenses. R&D expenses decreased $0.2 million, or 1%, to $15.5 million during the year ended December 31, 2016, compared to $15.7 million during the year ended December 31, 2015. This decrease was primarily due to a $0.7 million decrease in outside services and depreciation. These decreases were partially offset by a $0.2 million increase in personnel-related expenses and an increase of $0.3 million in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $2.7 million compared to $2.5 million for the year ended December 31, 2016 and 2015, respectively.

Selling, General and Administrative Expenses. SG&A expenses increased $10.8 million, or 37%, to $40.0 million during the year ended December 31, 2016, compared to $29.2 million during the year ended December 31, 2015. This increase was primarily due to a $8.4 million increase in personnel-related expenses, an increase of $2.0 million in marketing costs and an increase of $0.4 million relating to the allocation of facilities expense. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of $4.1 million and $3.1 million for the years ended December 31, 2016 and 2015, respectively. Increases in our marketing costs were associated with pre-commercial preparation expenses primarily relating to $1.1 million of Pantheris devices being designated as training and demonstration units for use by our sales and marketing personnel.

Interest Income (Expense), Net. Interest income (expense), net increased $0.3 million, or 5%, to an expense of $5.4 million during the year ended December 31, 2016, compared to an expense of $5.1 million during the year ended December 31, 2015. This increased expense was attributable to the additional interest expense associated with the $10.0 million of borrowings on June 15, 2016 under our Loan Agreement with CRG, partially offset by the retirement of our outstanding principal and accrued interest with PDL, and extinguishment of the principal and accrued interest underlying our notes using the proceeds from the CRG borrowing and securities purchase in September 2015.

Other Income (Expense), Net. Other income (expense), net decreased to an expense of $12,000 during the year ended December 31, 2016, compared to expense of $1.5 million during the year ended September 30, 2015. 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.

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 was related to our commercial focus on our Lumivascular programs to broaden physician exposure to OCT, image interpretation and building the installed base of the Lightbox imaging console prior to the commercial launch of Pantheris, 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.

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.

Liquidity and Capital Resources

As of December 31, 2016, we had cash and cash equivalents of $36.1 million and an accumulated deficit of $252.4 million, compared to cash and cash equivalents of $43.1 million and an accumulated deficit of $196.3 million as of December 31, 2015. We currently believe our existing cash and cash equivalents, expected revenues and the net proceeds from our "at-the-market" program, will be sufficient to meet our capital requirements and fund our operations until at least September 30, 2017. We will need to raise additional funds through future equity or debt financings within the next nine months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next 12 months could cause substantial dilution to our existing stockholders. 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 significantly scale back our business and operations. To date, our primary sources of capital have been private placements of preferred stock, debt financing agreements, our "at-the-market" program, our IPO and our follow-on public offering in August 2016.

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 was drawn down on June 15, 2016 and the remaining $10.0 million was contingent on the achievement of certain net revenue milestones prior to December 31, 2016,which were not met as of this date. As of December 31, 2016, we had $41.3 million outstanding under the Loan Agreement. See section titled "Contractual Obligations."

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 had to achieve minimum revenue of $7.0 million in 2015 and $23.0 million in 2016, and must achieve minimum revenue of $40.0 million in 2017, $50.0 million in 2018, $60.0 million in 2019 and $70.0 million in 2020 and in each year thereafter, as applicable. On October 28, 2016, we amended the terms of the Loan Agreement, to reduce the minimum revenue that we must achieve in 2016 to $18.0 million. 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, 2016.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen, as sales agent, through which we may, from time to time, issue and sell common stock with an aggregate value of up to $50.0 million. The shelf registration statement was declared effective by the Securities and Exchange Commission, or SEC, on March 8, 2016. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. Common stock sold in the "at-the-market" program is sold at prevailing market prices at the time of the sale, and, as a result, prices vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. In addition, in August 2016, we issued and sold 9,857,800 shares of our common stock in a follow-on public offering at a public offering price of $3.50 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 9,857,800 shares include the exercise in full by the underwriters of their option to purchase an additional 1,285,800 shares of our common stock.

Cash Flows

	Year Ended December 31,		
	2016	2015	2014
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (53,069)	$ (40,883)	$ (21,801)
Investing activities	(971)	(322)	(117)
Financing activities	47,077	71,948	22,013
Net increase in cash and cash equivalents	$ (6,963)	$ 30,743	$ 95

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2016 was $53.1 million, consisting primarily of a net loss of $56.1 million and an increase in net operating assets of $8.7 million, offset by non-cash charges of $11.7 million. The increase in net operating assets was primarily due to the commercial launch of Pantheris in March 2016 resulting in an increase in accounts receivable and inventories. The increase in net operating assets was also attributable to an increase in prepaids and other current assets, and decreases in accrued expenses and other current liabilities, due to timing of payments, decreases in other liabilities related to the repayment of assigned interest to PDL and a decrease 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 CRG, and an increased reserve for excess and obsolescence in inventories.

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.

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 Investing Activities

Net cash used in investing activities in the year ended December 31, 2016 was $1.0 million consisting of purchases of property and equipment. 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 was $0.1 million consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the year ended December 31, 2016 of $47.1 million primarily relates to net proceeds of $36.6 million from the issuance of common stock pursuant to our follow-on public offering and under the Sales Agreement with Cowen, net proceeds of $9.7 million from the debt financing under the Loan Agreement with CRG, and $0.8 million proceeds from purchases under our employee stock purchase plan and from the exercise of stock options.

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.

Off-Balance Sheet Arrangements

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

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, 2016, 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	$ 1,974	$ 3,948	$ —	$ —	$ 5,922
Capital lease obligations	26	13	—	—	39
Ongoing royalty obligations with PDL	1,220	474	—	—	1,694
CRG Loan	—	14,329	41,761	—	56,090
Noncancellable purchase commitments	3,542	—	—	—	3,542
	$ 6,762	$ 18,764	$ 41,761	$ —	$ 67,287

Our contractual obligations have not otherwise significantly changed from December 31, 2016.

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 and an additional $10.0 million on June 15, 2016. We did not achieve the level of revenues required to be eligible to borrow the final $10.0 million. 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.

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.

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 were 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.

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 April 2018 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, 2016.

Lease Agreements

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. In February 2016, we entered into an additional non-cancelable operating lease for warehouse and storage space in Redwood City, California, that expires in November 2019.

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.

Revenue Recognition

All of our revenues are currently derived from sales of our Lumivascular platform products, sales of various non-imaging PAD catheters and related services in the United States and select international 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. In addition, we provide our Lightbox under a limited commercial evaluation program to allow certain strategic accounts to install and utilize the Lightbox for a limited trial period of three to six months. When a Lightbox is placed, we retain title to the equipment and it remains capitalized on our balance sheet under property and equipment. The costs to maintain these placed Lightboxes held by customers are charged to cost of revenues as incurred.

We evaluate our lease and commercial evaluation program 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: (i) vendor-specific objective evidence of fair value of the respective elements, (ii) third-party evidence of selling price, and (iii) 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 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 contingent disposable products are delivered.

For sales through distributors, we recognize revenue when title to the product and the risk of loss transfers from us to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in our distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay us upon invoice regardless of its ability to resell the product.

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.

Inventories

Inventories, which includes material, labor and overhead costs, are stated at standard cost, which approximates actual cost, determined on a first-in, first-out basis, and not in excess of net realizable value. The cost basis of our inventory is reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by management, additional inventory write-downs may be required, which could have a material impact on our gross profit and inventory balances.

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.

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

	Year Ended December 31,		
	2016	2015	2014
Expected term (years)	6.1	6.3	6.3
Expected volatility	49.7%	49.8%	59.1%
Risk-free interest rate	1.5%	1.8%	1.8%
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 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 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 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.

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 the 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, 2016, 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. None and one of our customers represented more than 10% of our accounts receivable as of December 31, 2016 and 2015, 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 57 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, 2016. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2016, our disclosure controls and procedures were effective.

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, 2016.

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 2016 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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with our 2017 annual meeting of stockholders, or the 2017 Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2016, and is incorporated by reference in this report.

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*. Changes to or waivers of the code will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the code in the future by disclosing such information on our website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in the 2017 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be set forth in the 2017 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be set forth in the 2017 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in the 2017 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following Financial Statements are filed as part of this Annual Report on Form 10-K:

(a)(2) Financial Statement Schedules

All other schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto. Financial statement schedules relating to the allowance for doubtful accounts receivable and for sales returns follows (in thousands):

Description	Balance at Beginning of Year	Charged to costs and expenses	Write offs	Balance at End of Year
Allowance for doubtful accounts receivable:				
Fiscal year ended 2014	$ 20	$ —	$ —	$ 20
Fiscal year ended 2015	$ 20	$ —	$ —	$ 20
Fiscal year ended 2016	$ 20	$ 3	$ 2	$ 21

	Balance at Beginning of Year	Charged to costs and expenses	Write offs	Balance at End of Year
Allowance for sales returns:				
Fiscal year ended 2014	$ 88	$ 135	$ 146	$ 77
Fiscal year ended 2015	$ 77	$ 37	$ 55	$ 59
Fiscal year ended 2016	$ 59	$ 114	$ 130	$ 43

(a)(3) Exhibits

The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

AVINGER, INC.
INDEX TO FINANCIAL STATEMENTS
As of December 31, 2016 and 2015, and the
Years Ended December 31, 2016, 2015 and 2014

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Avinger, Inc.

We have audited the accompanying balance sheets of Avinger, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule included in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Avinger, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations and its need for additional capital raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Redwood City, California
March 14, 2017

AVINGER, INC.
BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 36,096	$ 43,059
Accounts receivable, net of allowance for doubtful accounts of $21 at December 31, 2016 and $20 at December 31, 2015	3,570	2,060
Inventories	8,462	5,405
Prepaid expenses and other current assets	662	533
Total current assets	48,790	51,057
Property and equipment, net	4,555	2,822
Other assets	212	225
Total assets	$ 53,557	$ 54,104
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,607	$ 1,113
Accrued compensation	2,807	3,083
Accrued expenses and other current liabilities	3,067	3,285
Borrowings, current portion	41,289	—
Total current liabilities	48,770	7,481
Borrowings, net of current portion	—	29,565
Other long-term liablities	546	1,469
Total liabilities	49,316	38,515
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock issuable in series, par value of $0.001		
Shares authorized: 5,000,000 at December 31, 2016 and December 31, 2015		
Shares issued and outstanding: none at December 31, 2016 and December 31, 2015	—	—
Common stock, par value of $0.001		
Shares authorized: 100,000,000 at December 31, 2016 and December 31, 2015		
Shares issued and outstanding: 23,776,033 at December 31, 2016 and 12,643,538 at December 31, 2015	24	13
Additional paid-in capital	256,606	211,837
Accumulated deficit	(252,389)	(196,261)
Total stockholders' equity	4,241	15,589
Total liabilities and stockholders' equity	$ 53,557	$ 54,104

See accompanying notes.

AVINGER, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Year Ended December 31, 2014
Revenues	$ 19,214	$ 10,713	$ 11,213
Cost of revenues	14,445	6,478	6,513
Gross profit	4,769	4,235	4,700
Operating expenses:			
Research and development	15,536	15,694	11,224
Selling, general and administrative	39,950	29,231	18,503
Total operating expenses	55,486	44,925	29,727
Loss from operations	(50,717)	(40,690)	(25,027)
Interest income	125	40	2
Interest expense	(5,524)	(5,167)	(6,016)
Other income (expense), net	(12)	(1,527)	(909)
Loss before provision for income taxes	(56,128)	(47,344)	(31,950)
Provision for income taxes	—	—	14
Net loss and comprehensive loss	(56,128)	(47,344)	(31,964)
Adjustment to net loss resulting from convertible preferred stock modification	—	(2,384)	—
Net loss and comprehensive loss attributable to common stockholders	$ (56,128)	$ (49,728)	$ (31,964)
Net loss attributable to common stockholders per share, basic and diluted	$ (3.39)	$ (4.38)	$ (132.63)
Weighted average common shares used to compute net loss per share, basic and diluted	16,574	11,362	241

See accompanying notes.

Table of Contents

AVINGER, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2013	326,591	$ 6,183	225,235	$ 6,649	755,486	$ 27,272	561,423	$ 22,397	722,367	$ 37,153	—	$ —	240,692	$ —	$ 1,787	$ (114,569)	$ (112,782)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	2,568	—	28	—	28
Employee stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	641	—	641
Issuance of Series E Convertible Preferred stock, net of issuance costs	—	—	—	—	—	—	—	—	—	—	2,671,626	32,606	—	—	—	—	—
Issuance of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	—	—	175	—	175
Reclass of warrant liability to additional paid-in capital	—	—	—	—	—	—	—	—	—	—	—	—	—	—	34	—	34
Net and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(31,964)	(31,964)
Balance at December 31, 2014	326,591	6,183	225,235	6,649	755,486	27,272	561,423	22,397	722,367	37,153	2,671,626	32,606	243,260	—	2,665	(146,533)	(143,868)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	49,621	—	432	—	432
Employee stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5,899	—	5,899
Vesting of restricted stock subject to repurchase	—	—	—	—	—	—	—	—	—	—	—	—	—	—	18	—	18
Issuance of Series E Convertible Preferred stock, net of issuance costs	—	—	—	—	—	—	—	—	—	—	490,472	5,372	—	—	—	—	—
Issuance of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	—	—	804	—	804
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	34,470	—	323	—	323
Conversion of preferred stock to common stock in connection with the IPO	(326,591)	(6,183)	(225,235)	(6,649)	(755,486)	(27,272)	(561,423)	(22,397)	(722,367)	(37,153)	(3,162,098)	(37,978)	5,753,200	6	137,626	—	137,632
Additional shares of common stock issued upon the conversion of preferred stock into common stock due to anti-dilution provisions													1,214,725	1	(1)	—	—
Issuance of common stock in IPO, net of underwriting discount, commissions and issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	5,000,000	5	56,893	—	56,898
Issuance of common stock related to CRG Loan, net of issuance costs													348,262	1	4,794	—	4,795
Convertible preferred stock modification	—	—	—	—	—	—	—	—	—	—	—	—	—	—	2,384	(2,384)	—
Net and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(47,344)	(47,344)
Balance at December 31, 2015	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**—**	**12,643,538**	**13**	**211,837**	**(196,261)**	**15,589**
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	163,936	—	805	—	805

Employee stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	7,392	—	7,392
Exercise of common stock warrants	—	—	—	—	—	—	—	—	—	—	—	—	15,381	—	—	—	—
Issuance of common stock in Public Offerings, net of underwriting discount, commissions and issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	10,953,178	11	36,572		36,583
Net and comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(56,128)	(56,128)
Balance at December 31, 2016	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**23,776,033**	**$ 24**	**$ 256,606**	**$ (252,389)**	**$ 4,241**

See accompanying notes.

AVINGER, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2016	2015	2014
Cash flows from operating activities			
Net loss	$ (56,128)	$ (47,344)	$ (31,964)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,506	1,300	1,451
Amortization of debt issuance costs and debt discount	222	199	212
Stock-based compensation	7,392	5,899	641
Remeasurement of embedded derivatives	—	(835)	(378)
Write off of embedded derivatives	—	1,066	—
Noncash interest expense and other charges	1,812	2,074	3,485
Loss on extinguishment of convertible notes	—	86	1,234
Provision for doubtful accounts receivable	3	—	—
Provision for excess and obsolete inventories	797	(26)	(48)
Changes in operating assets and liabilities:			
Accounts receivable	(1,512)	7	(441)
Inventories	(6,099)	(2,307)	1,714
Prepaid expenses and other current assets	(130)	(363)	444
Other assets	13	(35)	2
Accounts payable	470	84	17
Accrued compensation	(275)	1,936	(128)
Accrued expenses and other current liabilities	(191)	(962)	2,080
Other long-term liabilities and accrued interest	(949)	(1,662)	(122)
Net cash used in operating activities	(53,069)	(40,883)	(21,801)
Cash flows from investing activities			
Purchase of property and equipment	(971)	(577)	(117)
Restricted cash	—	255	—
Net cash used in investing activities	(971)	(322)	(117)
Cash flows from financing activities			
Principal paydown of capital lease obligations	(27)	(22)	(17)
Payments on borrowing	—	(27,625)	—
Proceeds from convertible notes, net of issuance costs	—	—	4,700
Proceeds from borrowings, net of issuance costs	9,716	29,124	—
Proceeds from the issuance of convertible preferred stock, net of issuance costs	—	6,176	19,155
Proceeds from the issuance of common stock related to CRG loan, net of issuance costs	—	4,794	—
Proceeds from public offerings, net of issuance costs	36,583	58,746	—
Proceeds from the exercise of common stock warrants	—	323	—
Payments for deferred initial public offering costs	—	—	(1,848)
Proceeds from the issuance of common stock	805	432	23
Net cash provided by financing activities	47,077	71,948	22,013
Net change in cash and cash equivalents	(6,963)	30,743	95
Cash and cash equivalents, beginning of period	43,059	12,316	12,221
Cash and cash equivalents, end of period	$ 36,096	$ 43,059	$ 12,316
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 4,354	$ 5,934	$ 2,281
Noncash investing and financing activities:			
Conversion of convertible preferred stock to common stock upon initial public offering	$ —	$ 137,632	$ —
Accounts payable for purchases of property and equipment	24	16	—
Modification of convertible preferred stock	—	2,384	—
Reclass of warrant liability to additional paid-in capital	—	—	34
Vesting of common stock subject to repurchase	—	18	5
Issuance of common stock warrants	—	804	175
Transfer between inventory and property and equipment	2,245	921	(916)
Conversion of convertible notes and accrued interest into Series E convertible preferred stock	—	—	11,582

See accompanying notes.

AVINGER, INC.

Notes to Financial Statements

1. Organization

Organization, Nature of Business

Avinger, Inc. (the "Company"), a Delaware corporation, was founded in March 2007 by cardiologist and medical device entrepreneur Dr. John B. Simpson. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("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. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ("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. The Company's Lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company's current products include its non-imaging catheters, Wildcat and Kittycat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). In March 2016, the Company also received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for commercialization of Pantheris, the Company's image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company commenced sales of Pantheris in the U.S. and select international markets promptly thereafter. The Company is located in Redwood City, California.

Liquidity Matters

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company adopted FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) effective December 31, 2016, which requires the Company to make certain disclosures if it concludes that there is substantial doubt about the entity's ability to continue as a going concern within one year from the date of the issuance of these financial statements. In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2016, the Company had an accumulated deficit of $252,389,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $36,096,000 at December 31, 2016, expected revenues and the net proceeds from its "at-the-market" program will be sufficient to allow the Company to fund its current operations until approximately September 30, 2017. The Company will seek additional sources of funding in the form of debt financing or equity issuances. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these financial statements. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding. Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Term Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of borrowings at December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

Public Offerings

In January 2015, the Company issued and sold 5,000,000 shares of its common stock in its initial public offering ("IPO") at a public offering price of $13.00 per share, for net proceeds of approximately $56,897,000 after deducting underwriting discounts and commissions of approximately $4,550,000 and expenses of approximately $3,553,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock resulting in the reclassification of $137,626,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to $150,000,000 of its securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company ("Cowen"), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, the Company sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5,171,000, after payment of $160,000 in commissions and fees to Cowen. In August 2016, the Company issued and sold 9,857,800 shares of its common stock in its follow-on public offering, which includes the exercise in full by the underwriters of their option to purchase 1,285,800 shares of common stock, at a public offering price of $3.50 per share. Net proceeds from the follow-on public offering were approximately $31,549,000 after deducting underwriting discounts and commissions of approximately $2,415,000 and expenses of approximately $538,000.

2. Summary of Significant Accounting Policies

Basis of Presentation

On January 14, 2015, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-45 reverse stock split of the Company's common stock and convertible preferred stock. The par value of the common stock and convertible preferred stock was not adjusted as a result of the reverse stock split. All common stock, convertible preferred stock, stock options and warrants, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split. The reverse stock split was effected on January 28, 2015.

The financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuation of the common stock warrants, the valuation of compound embedded derivatives, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2016 and 2015. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the borrowings approximate their fair value. Fair value accounting was applied to the warrant liabilities and embedded derivatives. No warrant liabilities or embedded derivatives were outstanding as of December 31, 2016 and 2015.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of December 31, 2016 and 2015, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit). There were no unrealized gains and losses as of December 31, 2016 and 2015. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

Restricted Cash

At December 31, 2014, a deposit of $255,000 was restricted from withdrawal. The restricted cash secured obligations of the Company associated with its corporate credit card. The restricted deposit account was included in prepaid expenses and other current assets. During 2015, the Company was no longer required to secure its corporate card obligations. The release of the restriction against the Company's cash was included within investing activities on its statement of cash flows for the year ended December 31, 2015.

Concentration of Credit Risk, and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the balance sheets.

The Company's policy is to invest in cash and cash equivalents, consisting of money market funds. These financial instruments are held in Company accounts at one financial institution. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing.

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at December 31, 2016 and 2015.

The Company's accounts receivable are due from a variety of health care organizations in the United States and select international markets. At December 31, 2016 and 2015, there were none and one, respectively, of the Company's customers that represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2016, 2015 and 2014, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

The Company manufactures its commercial products in-house, including Pantheris and the Ocelot family of catheters. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payors to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this may have a material adverse impact on the Company.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing accounts receivable. The Company determines the allowance for doubtful accounts based upon an aging of accounts receivable, historical experience, and management judgment. Accounts receivable balances are reviewed individually for collectability. To date, the Company has not experienced significant credit-related losses.

Inventories

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has expired or become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of revenues. Inventory used in clinical trials is expensed at the time of production and recorded as research and development expense.

Property and equipment

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets of three to five years. Depreciation expense includes the amortization of assets acquired under capital leases and equipment located at customer sites. Equipment held by customers is comprised of the Lightboxes located at customer sites under a lease or placement agreement and are recorded at cost. Upon execution of a lease or placement agreement, the related equipment is reclassified from inventory to the property and equipment account. Depreciation expense for equipment held by customers is recorded as a component of cost of revenues. Leasehold improvements and assets recorded under capital leases are amortized using the straight-line method over the shorter of the lease term or estimated useful economic life of the asset.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to an offering of equity securities, were capitalized. As of December 31, 2016, there we no deferred offering costs capitalized in other assets on the balance sheet. Deferred offering costs of $29,000 were capitalized as of December 31, 2015.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived asset exceeds its fair value. The Company has not recorded any impairment of long-lived assets since inception through December 31, 2016.

Convertible Preferred Stock

Prior to its IPO the Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs and classified the convertible preferred stock outside of stockholders' equity (deficit) on the balance sheets as events triggering the liquidation preferences were not solely within the Company's control. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock resulting in the reclassification of $137,626,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

Warrant Liability and Embedded Derivative Instruments

The Company accounts for its warrants for shares of common stock in accordance with the accounting guidance for derivatives. The accounting guidance provides a two-step model to be applied in determining whether a financial instrument is indexed to an entity's own stock and, therefore, qualifies for a scope exception. The two-step model requires a contract for a financial instrument to be both (1) indexed to the entity's own stock and (2) classified in the stockholders' equity (deficit) section of the balance sheet. If a financial instrument qualifies for a scope exception, it would not be considered a derivative financial instrument.

As the price per share of the common stock warrants issued with the convertible notes was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, these warrants were initially classified as a derivative liability. As a derivative liability, the warrants were initially recorded at fair value and were subject to remeasurement at each balance sheet date until September 2014. Any change in fair value as a result of a remeasurement was recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. The Company re-evaluated the terms of the common stock warrants issued with the convertible notes after the issuance of the Series E Convertible Preferred Stock in September 2014 and determined that they then met the first criterion of the two-step model. Accordingly, the associated current fair value of the warrant liability was reclassified to additional paid-in capital in the stockholders' equity (deficit) section of the balance sheet at that time, thus satisfying the second criterion of the two-step model.

The Company issued convertible notes in 2013 and 2014 that included features which were determined to be embedded derivatives requiring bifurcation and separate accounting. Prior to their extinguishment in September 2015, the Company recorded a compound derivative asset or liability related to redemption features embedded within its outstanding convertible notes. The embedded derivatives were initially recorded at fair value and are subject to remeasurement as of each balance sheet date. Any change in fair value is recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. In September 2015, the Company repaid the outstanding convertible notes and accrued interest obligations in their entirety. Accordingly, 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

Revenue Recognition

The Company's revenues are derived from (1) sale of its Lightbox (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 605-10, Revenue Recognition, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement.

The Company's revenue recognition policies generally result in revenue recognition at the following points:

1. Lightbox sales: The Company sells its products directly to hospitals and medical centers. Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form by the customer acknowledging that the training and installation process is complete.

2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.

3. Service revenue: Service revenue is recognized ratably over the term of the service period. To date service revenue has been insignificant.

The Company offers its customers the ability to purchase or lease its Lightbox. In addition, the Company provides a Lightbox under a limited commercial evaluation program to allow certain strategic accounts to install and utilize the Lightbox for a limited trial period of three to six months. When a Lightbox is placed under a lease agreement or under a commercial evaluation program, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these placed Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these placed Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in ASC 840, *Leases* and ASC 605-25, *Revenue Recognition—Multiple Element Arrangements*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price 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 ("BESP"). The Company allocates arrangement consideration using BESP.

The Company assessed whether the embedded lease is an operating lease or sales-type lease. Based on the Company's assessment of the guidance and given that any payments under the lease agreements are dependent upon contingent future sales, it was determined that collectability of the minimum lease payments is not reasonably predictable. Accordingly, the Company concluded the embedded lease did not meet the criteria of a sales-type lease and accounts for it as an operating lease. The Company recognizes revenue allocated to the lease as the contingent disposable product purchases are delivered and are included in revenues within the statement of operations and comprehensive loss.

For sales through distributors, the Company recognizes revenue when title to the product and the risk of loss transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

The Company estimates reductions in revenue for potential returns of products by customers. In making such estimates, management analyzes historical returns, current economic trends and changes in customer demand and acceptance of its products. The Company expenses shipping and handling costs as incurred and includes them in the cost of revenues. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

Cost of Revenues

Cost of revenues consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of the Company's 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. Cost of revenues also includes depreciation expense for the Lightboxes under lease agreements and certain direct costs such as shipping costs.

Product Warranty Costs

The Company typically offers a one-year warranty for parts and labor on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. Warranty costs are reflected in the statement of operations and comprehensive loss as a cost of revenues. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Warranty provisions and claims are summarized as follows (in thousands):

	Year Ended December 31, 2016	2015	2014
Balance beginning of year	$ 70	$ 167	$ 105
Warranty provision	1,048	70	140
Usage/Release	(609)	(167)	(78)
Balance end of year	$ 509	$ 70	$ 167

Research and Development

The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with pre-clinical and clinical development activities, and costs for prototype products that are manufactured prior to market approval for that prototype product; internal and external costs associated with the Company’s regulatory compliance and quality assurance functions, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings; and overhead costs, including allocated facility and related expenses.

Clinical Trials

The Company accrues and expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs include design and production costs, including website development, physician and patient testimonial videos, written media campaigns, and other items. Advertising costs of approximately $526,000, $515,000 and $720,000 were expensed during the years ended December 31, 2016, 2015 and 2014, respectively.

Common Stock Valuation and Stock-Based Compensation

Stock-based compensation for the Company includes amortization related to all stock options, restricted stock units (“RSUs”) and shares issued under the employee stock purchase plan, based on the grant-date estimated fair value. The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model and recognized as expense on a straight-line basis over the vesting period of the award. The Company measures the fair value of RSUs using the closing stock price of a share of the Company’s common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. Because noncash stock-based compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. The Company estimates a forfeiture rate for its stock options and RSUs based on an analysis of its actual forfeiture experience and other factors. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

Prior to the Company's IPO in January 2015, the fair value of the Company's common stock was determined by its Board of Directors with assistance from management and third-party valuation specialists. Management's approach to estimate the fair value of the Company's common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. Management considered several factors to estimate enterprise value, including significant milestones that would generally contribute to increases in the value of the Company's common stock. Following the closing of the Company's IPO, the fair value of its common stock is determined based on the closing price of its common stock on The NASDAQ Global Market.

Foreign Currency

The Company records net gains and losses resulting from foreign exchange transactions as a component of foreign currency exchange losses in other income (expense), net. During the years ended December 31, 2016, 2015 and 2014, the Company recorded $12,000, $18,000 and $21,000 of foreign currency exchange net losses, respectively.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense when they occur. During the years ended December 31, 2016, 2015 and 2014, the Company did not recognize accrued interest or penalties related to unrecognized tax benefits.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. For the computation of net loss per share attributable to common stockholders, common stock shares subject to repurchase of none, none and 583 were excluded from the calculations as of December 31, 2016, 2015 and 2014, respectively. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

Prior to its IPO in January 2015, the Company calculated its basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. The shares of the Company's convertible preferred stock participated in any dividends declared by the Company and were therefore considered to be participating securities. The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company.

Net loss per share attributable to common stockholders was determined as follows (in thousands, except per share data):

	Year Ended December 31,		
	2016	2015	2014
Net loss	$ (56,128)	$ (47,344)	$ (31,964)
Adjustment to net loss resulting from convertible preferred stock modification	—	(2,384)	—
Net loss attributable to common stockholders	$ (56,128)	$ (49,728)	$ (31,964)
Weighted average common stock outstanding	16,574	11,362	241
Net loss attributable to common stockholders per share, basic and diluted	$ (3.39)	$ (4.38)	$ (132.63)

In addition to the outstanding convertible notes as of December 31, 2014 (Note 8), the following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an antidilutive impact due to losses reported:

	December 31, 2016	December 31, 2015	December 31, 2014
Convertible preferred stock outstanding	—	—	5,262,728
Common stock options	3,708,011	3,356,981	3,010,373
Unvested restricted stock units	214,176	92,946	—
Common stock warrants	2,152,117	2,193,507	1,552,327
	6,074,304	5,643,434	9,825,428

Comprehensive Loss

For the years ended December 31, 2016, 2015 and 2014, there was no difference between comprehensive loss and the Company's net loss.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the years ended December 31, 2016, 2015 and 2014, 96%, 98% and 99%, respectively, of the Company's revenues, were in the United States, based on the shipping location of the external customer.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB"), jointly with the International Accounting Standards Board, issued a comprehensive new standard on recognition from contracts with customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company currently plans to adopt this accounting standard in the first quarter of fiscal year 2018 using the modified retrospective approach, with the cumulative effect being recorded within retained earnings on January 1, 2018. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company has not completed its assessment of the adoption on its financial statements.

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in the standard should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02), which increases transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, using a modified retrospective approach, and early adoption is permitted. The Company is evaluating the impact of the adoption of this standard on its financial statements. The Company does expect that the adoption will increase its lease assets and correspondingly increase its lease liabilities.

In March 2016, the FASB issued ASU No. 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee share-based payments, including income tax consequences, application of award forfeitures to expense, classification on the statement of cash flows, and classification of awards as either equity or liabilities. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company plans to adopt this new standard on January 1, 2017 and do not expect a material impact on its financial statements given the full valuation allowance position on its deferred tax assets.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2016 and 2015, cash equivalents were all categorized as Level 1 and consisted of money market funds. In connection with the convertible notes issuances in 2013 and 2014 (Note 8), the Company issued warrants to purchase shares of its common stock. As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date until September 2014. The convertible notes also contained redemption features which were determined to be a compound embedded derivative which, prior to their extinguishment in September 2015, required fair value accounting. The common stock warrant liability and embedded derivatives in the convertible notes were categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Any change in fair value is recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss.

There were no transfers between fair value hierarchy levels during the years ended December 31, 2016, 2015 and 2014.

Common Stock Warrant Liability

As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date. Contemporaneous with the Series E Convertible Preferred Stock issuance, the Company determined that these common stock warrants met the requirements for equity classification and the current fair value of the common stock warrant liability was reclassified to additional paid-in capital. Subsequent to September 2014, there were no changes in fair value. The following table sets forth a summary of the changes in the estimated fair value of the Company's common stock warrant liability, which represents a financial instrument classified as Level 3. Accordingly, the expense in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Fair value - beginning of year	$ —	$ —	$ (6)
Issuance of warrants	—	—	—
Change in fair value recorded in other income (expense), net	—	—	(28)
Reclass of warrant liability to additional paid-in capital	—	—	34
Fair value - end of year	$ —	$ —	$ —

The fair value of the common stock warrants liability was determined by using an option pricing model to allocate the total enterprise value to the various securities within the Company's capital structure. The model's inputs reflect assumptions that market participants would use in pricing the instrument in a current period transaction. The following table summarizes these various assumptions as of September 2, 2014, the date the price per share of the common stock warrants was fixed:

	September 2, 2014
Time to liquidity (years)	0.7
Expected volatility	45%
Discounted cash flow rate	23%
Risk-free interest rate	0.07%
Marketability discount rate	17%

The time to liquidity input was based on the Company's estimate of when potential liquidity could be provided to stockholders. The volatility factor was based on the average historic price volatility for publicly-traded industry peers. The discounted cash flow rate takes into consideration a company specific risk premium, market risk premium and an assumed risk free rate of return. The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities similar to the time to liquidity. The marketability discount is used to reflect that private company securities are generally less liquid than the securities of a public company. These assumptions are inherently subjective and involve significant management judgment. Generally, increases (decreases) in the fair value of the underlying common stock would result in a directionally similar impact to the fair value measurement. Subsequent to September 2014, there were no changes in fair value.

Embedded Derivatives in Convertible Notes

The following table sets forth a summary of the changes in the estimated fair value of the Company's compound embedded derivative associated with its convertible notes, which represent a financial instrument classified as Level 3. Upon the extinguishment of the convertible notes in September 2015, the fair value of the compound embedded derivatives at the date of extinguishment was expensed to other income (expense), net. The income (expense) in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Fair value of asset (liability) - beginning of year	$ —	$ 231	$ (175)
Issuance of convertible notes	—	—	—
Change in fair value recorded in other income (expense), net	—	835	406
Reversal of fair value recorded in other income (expense), net	—	(1,066)	—
Fair value of asset (liability) - end of year	$ —	$ —	$ 231

Through December 31, 2014, the Company determined the value of the compound derivative utilizing a Monte Carlo Simulation model. The inputs used to determine the estimated fair value of the derivative instrument include the probability of an underlying event triggering the embedded derivative occurring and its timing. The fair value measurement is based upon significant inputs not observable in the market. The inputs included the probability that the Company would need to raise additional equity in 2014, as well as various financing and exit events in 2015. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions as of December 31, 2014:

	Year Ended December 31, 2014
Equity financing in 2014	100.0%
Equity financing in 2015	14.3%
Liquidation	0.1%
Initial public offering	79.5%
Change of control	6.2%

Subsequent to the Company's IPO and through the extinguishment of the convertible notes on September 22, 2015, the value of the compound derivative was determined utilizing a Black-Derman-Toy model. The inputs used to determine the estimated fair value of the derivative instrument include the term structure of yields which are observed in the market, the credit spread, which was estimated by the Company, and the volatility, which was estimated using an analysis of comparable bonds in the market. The fair value measurement is based upon significant inputs not observable in the market. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions as of September 22, 2015, the date of extinguishment:

	September 22, 2015
Time to first call option (years)	—
Credit spread	17.6%
Expected volatility	40.0%

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company measures certain non-financial assets (including property, plant and equipment) at fair value on a non-recurring basis in periods after initial measurement in circumstances when the fair value of such asset is impaired below its recorded cost.

4. Inventories

Inventories consisted of the following (in thousands):

	December 31, 2016	December 31, 2015
Raw materials	$ 5,706	$ 2,662
Work-in-process	—	372
Finished products	2,756	2,371
Total inventories	$ 8,462	$ 5,405

5. Property and Equipment, Net

Property and equipment, net, consisted of the following (in thousands):

	December 31, 2016	December 31, 2015
Computer software	$ 456	$ 436
Computer equipment	1,268	1,096
Machinery and equipment	4,313	3,372
Furniture and fixtures	636	578
Leasehold improvements	679	655
Equipment held by customers	3,475	1,718
	10,827	7,855
Less: Accumulated depreciation and amortization	(6,389)	(5,044)
Add: Construction-in-progress	117	11
	$ 4,555	$ 2,822

Depreciation expense for the years ended December 31, 2016, 2015 and 2014, was $1,506,000, $1,300,000 and $1,451,000, respectively. Amortization of capital leased assets included in depreciation for the years ended December 31, 2016, 2015 and 2014, was $11,000, $17,000 and $17,000, respectively. Property and equipment includes certain equipment that is leased to customers and located at customer premises. The Company retains the ownership of the leased equipment and has the right to remove the equipment if it is not being utilized according to expectations. Depreciation expense relating to the leased equipment held by customers of $539,000, $260,000 and $378,000, was recorded in cost of revenues during the years ended December 31, 2016, 2015 and 2014, respectively. The net book value of this equipment was $2,587,000 and $1,236,000 at December 31, 2016 and 2015, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2016	December 31, 2015
Accrued interest payable	$ 1,220	$ 1,220
Accrued professional services	43	563
Accrued travel expenses	429	550
Accrued sales, use and other taxes	40	82
Accrued warranty	509	70
Sales return allowance	43	59
Accrued clinical trial costs	134	55
Other accrued liabilities	649	686
	$ 3,067	$ 3,285

7. Borrowings

CRG

On September 22, 2015, the Company entered into a Term Loan Agreement (the "Loan Agreement") with CRG under which, subject to certain conditions, the Company may borrow up to $50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed $30,000,000 on September 22, 2015. The Company borrowed an additional $10,000,000 on June 15, 2016 under the Loan Agreement. The Company would have been eligible to borrow an additional $10,000,000, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions, but those milestones were not achieved. 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. The Company makes quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, the Company 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 ("PIK") for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the borrowings. To date, the Company has elected the PIK interest option to the extent available and has 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.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% 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 borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amounts borrowed plus any PIK is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company's assets. The Loan Agreement requires that the Company adheres 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 the Company maintain a minimum of $5,000,000 of cash and certain cash equivalents, and the Company had to achieve minimum revenue of $7,000,000 in 2015, and must achieve minimum revenue of $23,000,000 in 2016, $40,000,000 in 2017, $50,000,000 in 2018, $60,000,000 in 2019 and $70,000,000 in 2020 and in each year thereafter, as applicable. On October 28, 2016, the Company amended the terms of the Loan Agreement, to reduce the minimum revenue that the Company must achieve in 2016 to $18,000,000. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays 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 the Company's 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 the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of December 31, 2016, the Company was in compliance with all applicable covenants.

As of December 31, 2016, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,	Principal and PIK Loan Repayments
2017	$ —
2018	—
2019	10,000
2020	20,000
2021	10,000
	40,000
Add: Accretion of closing fees	399
Add: PIK	1,809
	42,208
Less: Amount representing debt financing costs	(919)
Borrowings	$ 41,289

Contemporaneous with the execution of the Loan Agreement, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with CRG which allowed it to purchase up to $5,000,000 of the Company's common stock. CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of $14.357 per share, which is the 10-day average of closing prices of the Company's common stock ending on September 21, 2015. The closing price on September 22, 2015 was $13.97 yielding a $0.387 per share premium. Both the premium and the issuance costs were allocated to the borrowings under Loan Agreement and the common stock purchase under the Securities Purchase Agreement based on the relative fair values of each security. The portion of the premium allocated to the borrowings is being amortized over the term of the Loan Agreement. Pursuant to the Securities Purchase Agreement, the Company filed a shelf registration statement covering, among other things, 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.

In connection with the initial drawdown under the Loan Agreement, the Company recorded a debt discount of $876,000. The debt discount comprised financing fees of $450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and Securities Purchase Agreement with CRG of $541,000 net of the common stock premium of $115,000 based on the relative fair values of each security. In connection with the June 2016 drawdown under the Loan Agreement, the Company recorded a debt discount of $275,000 which comprised financing fees of $150,000, paid directly to CRG, and other costs directly attributable to the Loan Agreement with CRG of $125,000. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of December 31, 2016 and 2015, the balance of the aggregate debt discount was $919,000 and $834,000, respectively.

As noted in Note 1 to these financial statements, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the CRG Loan Agreement, the entire amount of borrowings at December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

PDL BioPharma

On April 18, 2013, the Company entered into a Credit Agreement ("Agreement") with PDL BioPharma, Inc. ("PDL") whereby PDL agreed to loan up to $40,000,000. Contemporaneous with the execution of the Agreement the Company borrowed an initial $20,000,000 ("Term Note").

The Term Note was scheduled to mature April 18, 2018, had a stated interest rate of 12.0% per annum and could be prepaid by the Company at any time. The Company paid interest-only through the first ten quarters and, thereafter, repayment of principal in equal installments including accrued and unpaid interest, payable each quarter. As provided under the terms of the Agreement, for the first eight quarterly interest payments, or through 2015, on the Term Note the Company elected to convert an amount of interest, up to 1.5% per annum, into additional loans, referred to as PIK loans. The PIK loans accrued interest and were added to the aggregate principal balance of the Term Note.

In September 2015, in connection with the consummation of the Loan Agreement with CRG, the Company repaid all amounts outstanding under the Agreement. The payoff amount of $21,363,000 included accrued interest through the repayment date of $563,000 and $200,000 as an end-of-term final payment fee recorded in other income (expense), net on the statement of loss and comprehensive loss. For the years ended December 31, 2016, 2015 and 2014, the Company incurred interest expense of $380,000, $2,785,000 and $3,380,000, respectively.

In addition to the interest and principal payments, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company's quarterly net revenues. Upon the prepayment of the Term Note, the Company's obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable monthly. The ongoing obligation was determined to be an embedded element of the Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interests obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2016, was used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. At the time of the repayment the resulting increase in the carrying value of the Assigned Interests, of $942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interests obligations of $1,463,000 and $2,303,000, representing the net present value of the future minimum royalty obligation as of December 31, 2016 and 2015, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities and within other long-term liabilities as of December 31, 2016 and 2015, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion on the balance sheet.

Additionally, until April 2018, the Company must periodically pay PDL a percentage of its net revenue and comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company was in compliance with the covenants under the Agreement as of December 31, 2016.

8. Convertible Notes

On October 29, 2013, the Company entered into a Note and Warrant Purchase Agreement (the "Convertible Note Agreement"), as amended in May 2014, with certain existing convertible preferred stockholders, third-parties and employees for the issuance of convertible notes for up to an aggregate principal amount of $25,000,000. Under the terms of the Convertible Note Agreement, the Company issued convertible notes in October and November 2013 for total proceeds of $13,472,000, and in May and July 2014 for additional total proceeds of $4,720,000. The Company was required to pay interest on these convertible notes at a rate of 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20%. The notes will mature and the accrued interest thereon would have become payable upon the earlier of: (i) October 29, 2018, (ii) an event of default, or (iii) a change of control event.

The principal and accrued interest on the notes were convertible, at the option of the holder, upon a future issuance of the Company's convertible preferred stock or common stock (the "Equity Financing") into that same stock at a conversion price equal to 85% of the price paid by other investors in the financing event. For holders who elected not to convert their notes upon the closing of the Company's Series E Preferred Stock financing or upon its IPO, the Company may repay the holder, at its sole election, a payment equal to the greater of (i) 125% of the outstanding principal and accrued and unpaid interest, or (ii) the amount providing the investor with a 20% minimum internal rate of return, at any time prior to their maturity date.

In conjunction with the issuance of the convertible notes, the Company issued warrants to purchase up to the number of shares of common stock equal to 15% of the principal amount of the convertible notes divided by an exercise price per share equal to the lesser of $39.15 per share, or the price per share paid by the investors in the first bona fide preferred stock financing subsequent to the date of the convertible notes. Upon the Series E Convertible Preferred Stock issuance in September 2014, the exercise price per share was fixed at $12.60 per share and the Company issued warrants to purchase a total of 216,547 shares of common stock. The warrants, which were immediately exercisable, expired upon the closing of the Company's IPO. The estimated fair value of the warrants upon issuance, of $1,000, was based on an option pricing model. The Company recorded the fair value of the warrants at issuance as a debt discount and as a warrant liability. The debt discount was accreted using the effective interest method as additional interest expense over the term of the convertible notes. Immediately prior to the closing of the Company's IPO, 149,288 of the warrants to purchase common stock were net exercised, 24,403 of the warrants to purchase common stock were exercised and the remaining balance of 42,856 warrants to purchase common stock expired.

The convertible notes have redemption features that were determined to be compound embedded derivatives requiring bifurcation and separate accounting. The fair value of the compound embedded derivative upon issuance was determined to be a liability of $179,000. The fair value of these derivative instruments was recognized as an additional discount and as a derivative liability on the balance sheets upon issuance of the convertible notes. The compound embedded derivative associated with the convertible notes required periodic re-measurements to fair value while the instruments are still outstanding. In September and

November 2014, in connection with the issuance of the Series E Convertible Preferred Stock, $11,582,000 of the outstanding convertible notes and accrued interest thereon was converted into shares of Series E Convertible Preferred Stock (Note 11). Upon the conversion of the convertible notes, the Company recorded a net loss from the extinguishment of the debt in the amount of $1,234,000 which is reflected in other income (expense), net in the statement of operations and comprehensive loss.

In September 2015, in connection with the consummation of the Loan Agreement, the Company repaid all amounts outstanding under the convertible notes. The carrying value of the convertible notes and accrued interest was $9,867,000 prior to payoff. The Company recorded a loss on extinguishment of the convertible notes of $86,000 as a component of other income (expense), net, on the statements of operations and comprehensive loss.

The Company's interest expense associated with the convertible notes amounted to none, $1,230,000 and $2,633,000 during the years ended December 31, 2016, 2015 and 2014, respectively, based on the minimum internal rate of return of 20%.

9. Capital Leases

Capital lease obligations consist of leased office equipment. As of December 31, 2016 and 2015, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $39,000 and $39,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of December 31, 2016, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2017	$ 26
2018	13
2019	1
Total minimum payments	40
Less: Amount representing future interest	1
Present value of minimum lease payments	$ 39

10. Commitments and Contingencies

Lease Commitments

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In connection with the facility lease, the landlord also provided incentives of $369,000 to the Company in the form of leasehold improvements. These amounts were reflected as deferred rent and were amortized as a reduction to rent expense over the original term of the Company's operating lease. In February 2016, the Company entered into an additional non-cancelable operating lease for warehouse and storage space that expires in November 2019. Rent expense was $1,098,000, $938,000 and $922,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

The future aggregate minimum lease payments as of December 31, 2016, are as follows (in thousands):

Year ending December 31,	Future Minimum Lease Payments
2017	$ 1,974
2018	2,033
2019	1,915
Total minimum lease payments	$ 5,922

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had noncancellable commitments to suppliers for purchases totaling $3,542,000 and $4,347,000 as of December 31, 2016 and 2015, respectively

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future, but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

Legal Proceedings

The Company was not party to any legal proceedings at December 31, 2016 and 2015. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable.

On February 15, 2014, the Company entered into an engagement letter with a financial advisor which provided for such firm to serve as its placement agent and for the Company to make certain payments to them in connection with its Series E Convertible Preferred Stock financing. After the entry into such engagement letter, the financial advisor did not provide the level of service the Company was expecting and was not responsible for introducing the Company to any of the Series E Convertible Preferred Stock investors. In December 2014, the Company and its former financial advisor agreed to amend and to terminate their engagement letter, effective immediately. Pursuant to the terms of the amended engagement letter, the Company agreed to pay the former financial advisor a transaction fee of $650,000, to be paid in four equal quarterly installments starting on December 31, 2014, and ending on September 30, 2015 and $35,000 for reimbursement of the former financial advisor's out-of-pocket expenses, which were due upon execution of the amendment. The transaction fee and out-of-pocket expenses were reflected as additional Series E Convertible Preferred Stock issuance costs during the year ended December 31, 2014.

11. Convertible Preferred Stock

Upon the closing of the Company's IPO in February 2015, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock. As of December 31, 2016 and 2015, the Company does not have any convertible preferred stock issued or outstanding.

12. Stockholders' Equity (Deficit)

Preferred Stock

At December 31, 2016, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At December 31, 2016, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 23,776,033 shares were issued and outstanding.

Common Stock Warrants

In connection with the issuance of the Company's Series E Convertible Preferred Stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible Preferred Stock, warrants to purchase up to the number of shares of common stock equal to 50% of the number of shares of the Company's Series E Convertible Preferred Stock purchased.

The warrants are immediately exercisable, at an exercise price per share of $12.60, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company. The Company determined that these common stock warrants meet the requirements for equity classification. In connection with the issuance of its Series E Convertible Preferred Stock in September through December 2014, the Company issued warrants to purchase an aggregate of 1,335,779 shares of common stock. The common stock warrants were recorded at their allocated fair value of $175,000 within stockholders' equity (deficit).

In connection with the issuance of the Company's Series E Convertible Preferred Stock in January 2015, the Company issued warrants to purchase an aggregate of 245,235 shares of common stock. The common stock warrants were recorded at their allocated fair value of $804,000 within stockholders' equity (deficit).

On January 14, 2015, the Company amended its Series E Convertible Preferred Stock Purchase Agreement to provide for the issuance of common stock warrants to each investor who purchased shares of Series E Convertible Preferred Stock equal to 70% of the number of shares of the Company's Series E Convertible Preferred Stock purchased by such investor. As with the common stock warrants previously issued, any new common stock warrants were immediately exercisable, at an exercise price of $12.60 per share, and expire upon the earlier of September 2, 2019 or upon consummation of a change in control of the Company. As a result of this amendment to the Series E Convertible Preferred Stock Purchase Agreement, the Company issued additional warrants to purchase 632,381 shares of common stock to investors who previously acquired shares of Series E Convertible Preferred Stock from September 2014 through January 2015.

As of December 31, 2016 and 2015, warrants to purchase an aggregate of 2,152,117 and 2,193,507 shares of common stock were outstanding, respectively.

The Company determined that the amendment to the Series E Convertible Preferred Stock Purchase Agreement should be accounted for as a modification. Accordingly, the incremental fair value from the modification, the additional warrants to purchase 632,381 shares of common stock warrants, of $2,384,000, was recorded as an increase to stockholders' equity (deficit) and as an adjustment to net loss attributable to common stockholders in the Company's statement of operations and comprehensive loss for the year ended December 31, 2015. This amount represents a return to the preferred stockholders and is treated in a manner similar to the treatment of dividends paid to holders of preferred stock in the computation of earnings per share. As a result, the "deemed dividend" is subtracted from net loss available to common stockholders in reconciling net loss to net loss available for common stockholders.

Stock Plans

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). The 2015 Plan replaced the 2009 Stock Plan (the "2009 Plan") which was terminated immediately prior to consummation of the Company's IPO, collectively the "Plans." The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of nonstatutory stock options ("NSOs"), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 1,320,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan, plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 1,690,000 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the 2015 Plan was increased by 632,176 shares of common stock. As of December 31, 2016, 1,183,937 shares were available for grant under the 2015 Plan.

Pursuant to the Plans, ISOs and NSOs may be granted with exercise prices at not less than 100% of the fair value of the common stock on the date of grant and the exercise price of ISOs granted to a stockholder, who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of the stock of the Company, shall be not less than 110% of the fair market value per share of common stock on the date of grant. The Company's Board of Directors determines the vesting schedule of the options. Options granted generally vest over four years and expire ten years from the date of grant.

Stock option activity under the Plans is set forth below:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2013	398,740	$ 16.15	$ —
Options granted	2,720,174	$ 4.68	
Options exercised	(2,568)	$ 8.85	
Options cancelled	(105,973)	$ 16.62	
Balance at December 31, 2014	3,010,373	$ 5.78	$ 13,188
Options granted	614,363	$ 16.73	
Options exercised	(17,642)	$ 4.50	
Options cancelled	(250,113)	$ 9.33	
Balance at December 31, 2015	3,356,981	$ 7.53	$ 50,970
Options granted	701,612	$ 11.69	
Options exercised	(23,230)	$ 4.50	
Options cancelled	(327,352)	$ 12.89	
Balance at December 31, 2016	3,708,011	$ 7.86	$ 5

Additional information related to the status of options as of December 31, 2016 is summarized as follows:

Options Outstanding and Vested as of December 31, 2016					
Options Outstanding				Options Vested	
Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 3.55	27,559	9.84	$ 3.55	—	$ 3.55
$ 3.68	37,056	9.83	$ 3.68	—	$ 3.68
$ 4.05	4,350	2.44	$ 4.05	4,350	$ 4.05
$ 4.50	1,659,913	8.01	$ 4.50	831,258	$ 4.50
$ 4.95	862,777	7.87	$ 4.95	443,651	$ 4.95
$ 5.12	29,600	9.57	$ 5.12	—	$ 5.12
$ 6.26	1,511	5.06	$ 6.26	1,511	$ 6.26
$ 10.91	25,222	8.18	$ 10.91	11,786	$ 10.91
$ 10.98	4,000	8.33	$ 10.98	1,666	$ 10.98
$ 11.01	9,385	9.44	$ 11.01	—	$ 11.01
$ 12.38	64,200	9.33	$ 12.38	—	$ 12.38
$ 12.60	66,484	4.54	$ 12.60	66,484	$ 12.60
$ 12.96	120,000	9.19	$ 12.96	—	$ 12.96
$ 12.99	297,820	9.18	$ 12.99	7,228	$ 12.99
$ 14.85	40,586	5.05	$ 14.85	40,586	$ 14.85
$ 15.21	53,044	8.58	$ 15.21	19,949	$ 15.21
$ 17.72	2,000	8.83	$ 17.72	583	$ 17.72
$ 19.61	272,348	8.97	$ 19.61	81,736	$ 19.61
$ 20.25	93,949	6.53	$ 20.25	84,524	$ 20.25
$ 22.05	7,319	5.75	$ 22.05	7,319	$ 22.05
$ 22.50	28,888	5.56	$ 22.50	28,286	$ 22.50
	3,708,011	8.10	$ 7.86	1,630,917	$ 7.40

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2016, 2015 and 2014 was $5.51, $8.24 and $6.60 per share, respectively. As of December 31, 2016, the weighted average remaining contractual life of options outstanding and vested was 7.63 years. As of December 31, 2016, the aggregate intrinsic value of options outstanding and vested was $0. The aggregate intrinsic value of options exercised was $135,000, $236,000 and none during the years ended December 31, 2016, 2015 and 2014, respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the years ended December 31, 2016, 2015 and 2014.

The Company's RSUs vest annually over four years in equal increments. A summary of all RSU activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Awards outstanding at December 31, 2014	—	$ —	—	$ —
Awarded	92,946	$ 19.61		
Awards outstanding at December 31, 2015	92,946	$ 19.61	3.88	$ 2,111
Awarded	185,500	$ 12.98		
Released	(26,911)	$ 18.04		
Forfeited	(37,359)	$ 14.96		
Awards outstanding at December 31, 2016	214,176	$ 14.88	3.09	$ 792

As of December 31, 2016, $2,780,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.05 years. The Company used the closing market price of $3.70 per share at December 31, 2016, to determine the aggregate intrinsic value.

2015 Employee Stock Purchase Plan

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ("ESPP") under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. Initially 500,000 shares of common stock were reserved for issuance, which is subject to an automatic increase on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 493,000 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the ESPP was increased by 189,653 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of December 31, 2016, approximately 543,879 shares of common stock remained reserved for issuance under the ESPP. The Company incurred $372,000 and $217,000 in stock-based compensation expense related to the ESPP for the year ended December 31, 2016 and 2015, respectively.

13. Stock-Based Compensation

Stock-based compensation for the Company includes amortization related to all stock options, RSUs and shares issued under the ESPP, based on the grant-date estimated fair value. The Company estimates the fair value of stock options and shares issued under the ESPP on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company's common stock, and the volatility over the expected term of the awards. The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Prior to the Company's IPO in January 2015, due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, stage of development, risk profile, and position within the industry as well as selecting companies with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based payments. Following the closing of the Company's IPO, the Company supplements its own available company specific historical volatility with the volatility of the previously selected peer group of publicly traded companies. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

As noncash stock-based compensation expense recognized in the financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The Company estimates a forfeiture rate for its stock options and RSUs based on an analysis of its actual forfeitures based on actual forfeiture experience and other factors. Forfeitures are estimated at the time of grant and revised, if necessary, over the service period to the extent that actual forfeitures differ, or are expected to differ, from prior estimates. Forfeitures are estimated based on estimated future employee turnover and historical experience. The fair value for the Company's employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following average assumptions:

	Year Ended December 31,		
	2016	2015	2014
Expected term (years)	6.1	6.3	6.3
Expected volatility	49.7%	49.8%	59.1%
Risk-free interest rate	1.5%	1.8%	1.8%
Dividend rate	—	—	—

As of December 31, 2016 and 2015, the total unamortized compensation expense related to stock options granted to employees and directors was $12,312,000 and $16,871,000, which is expected to be amortized over the next 2.33 and 3.15 years, respectively.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following assumptions:

	Year Ended December 31,	
	2016	2015
Expected term (years)	0.5	0.5
Expected volatility	72.1%	46.2%
Risk-free interest rate	0.41%	0.17%
Dividend rate	—	—

The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. The total fair value of shares vested pursuant to RSUs in the year ended December 31, 2016 and 2015 was $486,000 and zero, respectively. As of December 31, 2016, total unamortized stock-based compensation expense related to unvested RSUs was $2,780,000, with a weighted-average remaining recognition period of 3.05 years.

Total noncash stock-based compensation expense relating to the Company's stock options, ESPP and RSUs recognized, before taxes, during the years ended December 31, 2016, 2015 and 2014, is as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Cost of revenues	$ 608	$ 346	$ 55
Research and development expenses	2,732	2,489	155
Selling, general and administrative expenses	4,052	3,064	431
	$ 7,392	$ 5,899	$ 641

14. Income Taxes

For the years ended December 31, 2016, 2015 and 2014, the Company's provision for income taxes consisted of state income tax expense of none, none and $14,000, respectively. A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows (in thousands):

	Year Ended December 31, 2016	2015	2014
Tax at federal statutory rate	$ (19,077)	$ (16,905)	$ (10,863)
State taxes, net of federal benefit	—	—	14
Permanent differences	1,023	1,722	730
Change in valuation allowance	18,321	15,250	10,316
Research credits	(245)	(218)	(219)
Other	(22)	151	36
Provision for taxes	$ —	$ —	$ 14

Significant components of the Company's net deferred tax assets as of December 31, 2016 and 2015 consist of the following (in thousands):

	As of December 31, 2016	2015
Deferred tax assets:		
Federal, state, and foreign net operating losses	$ 82,353	$ 64,739
Research and other credits	2,953	2,521
Fixed assets	623	215
Interest	581	899
Accruals and other	4,906	2,810
Total deferred tax assets	91,416	71,184
Less: Valuation allowance	(91,416)	(71,184)
Net deferred tax assets	$ —	$ —

The valuation allowance increased by $20,232,000, 15,076,000 and $12,193,000 during the years ended December 31, 2016, 2015 and 2014, respectively.

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $219,087,000, which begin to expire in 2027, and state net operating loss carryforwards of approximately $161,812,000, which begin to expire in 2017.

As of December 31, 2016, the Company had federal research and development credit carryforwards of approximately $2,469,000, which expire in the years 2027 through 2035, and state research and development credit carryforwards of approximately $2,651,000. The state research and development credit can be carried forward indefinitely.

Federal and state tax laws impose substantial restrictions on the utilization of the net operating loss, and credit carryforwards in the event of an ownership change as defined in Section 382 of the Internal Revenue Code. Accordingly, the Company's ability to utilize these carryforwards may be limited as a result of such ownership change. Such a limitation could result in the expiration of carryforwards before they are utilized.

The Company had unrecognized tax benefits of approximately $1,536,000 and $3,902,000, as of December 31, 2016 and 2015, of which $1,266,000 and $2,792,000, respectively, would affect the effective tax rate if recognized, before consideration of the valuation allowance.

A reconciliation of the unrecognized tax benefits from January 1, 2014 through December 31, 2016 is as follows (in thousands):

	As of December 31, 2016	2015	2014
Balance at beginning of year	$ 3,902	$ 1,121	$ 919
Increase/decrease based on the tax positions in the current year	(2,593)	2,593	202
Additions for tax positions of prior years	227	188	—
Balance at end of year	$ 1,536	$ 3,902	$ 1,121

The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next twelve months for items that arise in the ordinary course of business. The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the nation. The Company is not currently under audit by the Internal Revenue Service or other similar state and local authorities. All tax years remain open to examination by major taxing jurisdictions to which the Company is subject.

15. Related-Party Transactions

During the years ended December 31, 2016, 2015 and 2014, the Company purchased marketing services from Recreation, Inc., a brand strategy and design agency headquartered in San Francisco, California for $697,000, $1,016,000 and $984,000, respectively. John D. Simpson, the Company’s Senior Vice President of Sales, was the Chief Executive Officer of Recreation, Inc. until March 2015 and is the son of Dr. John B. Simpson, the Company’s founder and the Executive Chairman of the Board of Directors. As of December 31, 2016 and 2015, amounts due to Recreation, Inc., included in accounts payable and accrued liabilities, were $6,000 and $76,000, respectively.

From October 2013 through July 2014, the Company entered into convertible notes with certain investors, including existing stockholders, some members of the Board of Directors and their affiliated companies and some members of management for a total aggregate principal amount of $18,192,000 (Note 8) and issued warrants to purchase shares of the Company’s common stock at an exercise price of $12.60 per share. The issuance of $5,122,000 of the total aggregate principal amount of the convertible notes was considered a related-party transaction. In September 2015, the Company repaid all amounts outstanding under the convertible notes. As of December 31, 2016 and 2015, the carrying value of the related-party convertible notes was none. For the years ended December 31, 2016, 2015 and 2014, the Company recognized none, $388,000 and $1,021,000, respectively, of interest expense related to the related-party convertible notes within interest expense in the Company’s statements of operations and comprehensive loss.

In April 2015, the Company entered into an agreement with Chansu Consulting, LLC (“Chansu”) to provide consulting services related to regulatory affairs. The General Partner of Chansu is the son-in-law of Dr. John B. Simpson, the Company’s founder and the Executive Chairman of the Board of Directors. For the year ended December 31, 2016 and 2015, Chansu provided regulatory consulting services of $3,000 and $17,000, respectively. As of December 31, 2016 and 2015, there were no amounts due to Chansu included in accounts payable and accrued liabilities.

In October 2015, the Company entered into an agreement with Consensys Imaging Service (“Consensys”) to provide field engineers to assist the Company with the installation, service and maintenance of its Lightbox consoles. Jeffrey M. Soinski, the Company’s President, Chief Executive Officer and a member of its Board of Directors is also a member of the Board of Directors of Consensys. For the year ended December 31, 2016 and 2015, Consensys provided services of $123,000 and none, respectively. As of December 31, 2016 and 2015, amounts due to Consensys included in accounts payable and accrued liabilities, were $20,000 and none, respectively.

16. 401(k) Plan

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code (“IRC”) under which participants may contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. Eligible employees vest in the Company’s contributions over a graded four year schedule. To date, the Company has made no contributions to the 401(k) plan.

17. Subsequent Events

2015 Equity Incentive Plan

In January 2017, the number of shares of common stock authorized for issuance under the 2015 Plan was automatically increased by 1,188,801shares, which was ratified by the Company’s Board of Directors.

2015 Employee Stock Purchase Plan

In January 2017, the number of shares of common stock authorized for issuance under the 2015 ESPP was automatically increased by 356,640 shares, which was ratified by the Company’s Board of Directors.

18. Selected Quarterly Financial Information (Unaudited)

The following table represents certain unaudited quarterly information for the eight quarters ended December 31, 2016. This data has been derived from unaudited financial statements that, in the opinion of the Company's management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such information when read in conjunction with the Company's annual audited financial statements and notes thereto appearing elsewhere in this report. These operating results are not necessarily indicative of results for any future period (in thousands, except per share data):

	Three Months Ended				Three Months Ended			
	Mar 31, 2016	Jun 30, 2016	Sep 30, 2016	Dec 31, 2016	Mar 31, 2015	Jun 30, 2015	Sep 30, 2015	Dec 31, 2015
Revenues	$ 4,539	$ 4,680	$ 5,316	$ 4,679	$ 2,088	$ 3,047	$ 2,721	$ 2,857
Gross profit	1,179	1,035	1,574	981	800	1,413	971	1,051
Operating expenses	16,208	13,328	13,005	12,945	10,225	10,496	10,847	13,357
Net loss	(16,167)	(13,496)	(12,969)	(13,497)	(12,801)	(10,220)	(13,250)	(13,456)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.28)	$ (1.06)	$ (0.73)	$ (0.58)	$ (1.53)	$ (0.83)	$ (1.08)	$ (1.07)

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

Avinger, Inc.
(Registrant)

Date: March 14, 2017	/s/ JEFFERY M. SOINSKI Jeffrey M. Soinski *Chief Executive Officer* *(Principal Executive Officer)*
Date: March 14, 2017	/s/ MATTHEW B. FERGUSON Matthew B. Ferguson *Chief Financial Officer* *(Principal Financial and Accounting Officer)*

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Soinski and Matthew Ferguson, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JEFFREY M. SOINSKI Jeffrey M. Soinski	Chief Executive Officer (Principal Executive Officer); Director	March 14, 2017
/s/ MATTHEW B. FERGUSON Matthew B. Ferguson	Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	March 14, 2017
/s/ DONALD A. LUCAS Donald A. Lucas	Director	March 14, 2017
/s/ JOHN B. SIMPSON John B. Simpson, Ph.D., M.D.	Executive Chairman of the Board of Directors; Director	March 14, 2017
/s/ JAMES B. MCELWEE James B. McElwee	Director	March 14, 2017
/s/ JAMES G. CULLEN James G. Cullen	Director	March 14, 2017
/s/ THOMAS J. FOGARTY Thomas J. Fogarty	Director	March 14, 2017

EXHIBIT INDEX

Exhibit Number	Exhibit Title
3.1 [1]	Amended and Restated Certificate of Incorporation of the registrant.
3.2 [1]	Bylaws of the registrant.
4.1 [2]	Specimen Common Stock certificate of the registrant.
10.1 [3]	Form of Indemnification Agreement for directors and executive officers.
10.2 [4]	2009 Stock Plan and Form of Option Agreement thereunder.
10.3 [4]	2014 Preferred Stock Plan.
10.4 [3]	2015 Equity Incentive Plan.
10.5 [3]	Form of Restricted Stock Unit Award Agreement.
10.6 [3]	Form of Stock Option Agreement.
10.7 [3]	2015 Employee Stock Purchase Plan.
10.8 [3]	Executive Incentive Compensation Plan.
10.9 [4]	Amended and Restated Investors' Rights Agreement dated September 2, 2014 by and among the registrant and certain stockholders.
10.10 [4]	Lease Agreement, dated July 30, 2010, by and between the registrant and HCP LS Redwood City, LLC for office space located at 400 and 600 Chesapeake Drive, Redwood City, California.
10.11 [4]	First Amendment to Lease Agreement dated September 30, 2011 by and between registrant and HCP LS Redwood City, LLC.
10.12 [5]	Second Amendment to Lease Agreement dated March 4, 2016 by and between registrant and HCP LS Redwood City, LLC.
10.13 [4]	Credit Agreement dated April 18, 2013 by and between registrant and PDL Biopharma.
10.14 [4]	Security Agreement dated April 18, 2013 by and between registrant and PDL BioPharma.
10.15 [4]	Employment Letter dated November 5, 2014 by and between registrant and John B. Simpson.
10.16 [4]	Employment Letter dated April 2, 2014 by and between registrant and John D. Simpson.
10.17 [4]	Employment Letter dated December 29, 2010 by and between registrant and Matthew B. Ferguson.
10.18 [4]	Employment Letter dated November 28, 2011 by and between registrant and Sougata Banerjee.
10.19 [4]	Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and John B. Simpson.
10.20 [4]	Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and Matthew B. Ferguson.
10.21 [4]	Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and Sougata Banerjee.
10.22 [4]	Employment Letter dated December 17, 2014 by and between registrant and Jeffrey M. Soinski.
10.23 [3]	Note and Warrant Purchase Agreement dated October 29, 2013 by and between registrant and holders of convertible promissory notes.
10.24 [3]	Amendment No. 1 to the Note and Warrant Purchase Agreement dated May 6, 2014 by and between registrant and holders of convertible promissory notes.
10.25 [6]	Term Loan Agreement, dated as of September 22, 2015, by and among Avinger, Inc., certain of its subsidiaries from time to time party thereto as guarantors and CRG Partners III L.P. and certain of its affiliated funds, as lenders.
10.26 [6]	Securities Purchase Agreement, dated as of September 22, 2015, by and among Avinger, Inc., and CRG Partners III L.P. and certain of its affiliated funds, as purchasers.
10.27[7]	Sales Agreement dated as of February 3, 2016, between the Registrant and Cowen and Company, LLC
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on signature page).
31.1	Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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Exhibit Number	Exhibit Title
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Previously filed an Exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2015, and incorporated by reference herein.

(2) Previously filed as an Exhibit to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 28, 2015, and incorporated by reference herein.

(3) Previously filed as an Exhibit to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 20, 2015, and incorporated by reference herein.

(4) Previously filed as an Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-201322), filed with the Securities and Exchange Commission on December 30, 2014, and incorporated by reference herein.

(5) Previoulsy filed as an Exibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2016, and incorporated by reference herein.

(6) Previously filed as an Exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2015, and incorporated by reference herein.

(7) Previously filed as an Exhibit to the Registrant's Registration Statement on Form S-3 (File No. 333-209368), filed with the Securities and Exchange Commission on February 3, 2016, and incorporated by reference herein.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-209368) of Avinger, Inc. and

(2) Registration Statement (Form S-8 No. 333-201928) pertaining to the 2009 Stock Plan, the 2015 Equity Incentive Plan, the 2015 Employee Stock Purchase Plan, Stand-Alone Option Agreement of Avinger, Inc., and

(3) Registration Statement (Form S-8 No. 333-209364) pertaining to the 2015 Equity Incentive Plan and the 2015 Employee Stock Purchase Plan of Avinger, Inc.

of our report dated March 14, 2017 with respect to the financial statements and schedule of Avinger, Inc., and to the reference to our firm under the caption "Risk Factors" included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Redwood City, California
March 14, 2017

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey Soinski, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report on Form 10-K, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report on Form 10-K based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 14, 2017

/s/ JEFFREY M. SOINSKI
Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Matthew Ferguson, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 14, 2017

/s/ MATTHEW B. FERGUSON
Matthew B. Ferguson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

**CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Avinger, Inc. (the “Company”) on Form 10-K for the period ended December 31, 2016, as filed with the Securities and Exchange Commission (the “Report”), Jeffrey Soinski, as Chief Executive Officer of the Company, and Matthew Ferguson, Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 14 day of March, 2017.

/s/ JEFFREY M. SOINSKI	/s/ MATTHEW B. FERGUSON
Jeffrey M. Soinski	Matthew B. Ferguson
Chief Executive Officer	*Chief Financial Officer*
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.