Avinger Inc
Form 424B3
November 20, 2017
Table of Contents

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-221368

**up to 9,950,000 Shares**

**of Common Stock**

---

This prospectus covers the offer and sale of up to 9,950,000 shares (the **Shares**) of common stock, $0.001 par value per share (the **Common Stock**), of Avinger, Inc. (**Avinger**, **we**, **our** or the **Company**), a Delaware corporation, by Lincoln Park Capital Fund, LLC (**Lincoln Park** or the **Selling Stockholder**).

The Shares that may be offered and sold by the Selling Stockholder through this prospectus have been or may be issued pursuant to the purchase agreement dated November 3, 2017 that we entered into with Lincoln Park (the **Purchase Agreement**). See The Lincoln Park Transaction for a description of the Purchase Agreement and Selling Stockholder for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the Shares will be determined by the prevailing market price for the Shares or in negotiated transactions.

We are not offering or selling any securities covered by this prospectus and will not receive any of the proceeds from the sale of the Shares by the Selling Stockholder.

The Selling Stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See Plan of Distribution for more information about how the Selling Stockholder may sell the shares of common stock being registered pursuant to this prospectus. The Selling Stockholder is an underwriter within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended (the **Securities Act**).

We will pay the expenses incurred in registering the offer and sale of the Shares by Lincoln Park under the Securities Act, including legal and accounting fees. See Plan of Distribution .

Our common stock is listed on The NASDAQ Global Market under the symbol AVGR. On November 16, 2017, the last reported sales price of our common stock was $0.234 per share.

---

**We are an emerging growth company as defined under the federal securities laws. Investing in our Shares involves a high degree of risk. Please see the section entitled Risk Factors starting on page 6 to read about risks you should consider carefully before buying the Shares.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

---

**The date of this prospectus is November 17, 2017**

Table of Contents

**TABLE OF CONTENTS**



**You should rely only on the information contained in this prospectus or contained in any free writing prospectus prepared by or on behalf of us. Neither we nor Lincoln Park have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the Shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of the Shares.**

You should also read and consider the information in the documents to which we have referred you under the captions Where You Can Find More Information and Incorporation of Documents by Reference in this prospectus.

For investors outside the United States, neither we nor Lincoln Park have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required.

Table of Contents

## PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our Shares, you should carefully read the entire prospectus, including Risk Factors beginning on page 6 and the financial statements and related notes. As used in this prospectus, references to we, our, us and Avinger refer to Avinger, Inc. unless the context requires otherwise.*

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 significantly 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, 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 United States and select European countries promptly thereafter. We also offer the Wildcat and Kittycat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

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 stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all 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 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 damage to healthy portions of the artery.

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 allows 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 have worked with 18 of the VISION sites to re-solicit consent from previous clinical trial patients in order for them to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites was completed in May 2017, and we released the final 12 and 24-month results for a total of 89 patients in July 2017. 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. During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a filing with the FDA to expand the indication for our Pantheris atherectomy device to include instent restenosis.

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-

Table of Contents

Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $11.2 million in 2014, $10.7 million in 2015, and $9.2 million and $6.0 million for the six months ended June 30, 2016 and 2017, respectively.

**Risks Associated with Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. These risks include, among others:

- 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 or cause us to become insolvent.

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

- 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.

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

- 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.

- 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.

- 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. Reductions in the size of our sales force may adversely

impact our business.

- 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.

- 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 sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

**Company Information**

We were incorporated in Delaware on March 8, 2007. Our principal executive offices are located at 400 Chesapeake Drive, Redwood City, CA 94063, and our telephone number is (650) 241-7900. Our website address is www.avinger.com. The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

Avinger, Pantheris and Lumivascular are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this prospectus supplement and accompanying prospectus are our property. Other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus and accompanying prospectus 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 tradenames.

Table of Contents

**Implications of Being an Emerging Growth Company**

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. As an emerging growth company:

- we have availed ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;

- we will provide less extensive disclosure about our executive compensation arrangements; and

- we will not require shareholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of our initial public offering, or December 31, 2020. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenues exceed $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We may choose to take advantage of some but not all of these reduced burdens. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

Table of Contents

**THE OFFERING**

| | |
|---|---|
| Shares offered by the Selling Stockholder | 9,950,000 shares consisting of:<br>• 943,396 Commitment Shares issued to Lincoln Park upon the execution of the Purchase Agreement; and<br>• 9,006,604 shares we may sell to Lincoln Park under the Purchase Agreement from time to time after the date of this prospectus. |
| Common stock outstanding prior to the offering | 31,539,117 shares, as of November 3, 2017. |
| Common stock outstanding after this offering (assuming all Shares are sold under the Purchase Agreement) | 41,489,117 shares |
| Use of proceeds | We will receive no proceeds from the sale of Shares by Lincoln Park in this offering. We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used for working capital and general corporate purposes, including the repayment of debt. See Use of Proceeds. |
| Risk Factors | Investing in our common stock involves significant risks. You should read the Risk Factors section beginning on page 6 of this prospectus and in the documents incorporated by reference in this prospectus, including the risk factors described under the section entitled Risk Factors contained in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, for a discussion of factors to consider before deciding to purchase the Shares. |
| NASDAQ Global Market symbol | AVGR . |

**Purchase Agreement with Lincoln Park**

On November 3, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $15,000,000 of our Common Stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Also on November 3, 2017, we entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park pursuant to which we have filed with the Securities and Exchange Commission ( SEC ) the registration statement that includes this prospectus to register for resale under the Securities Act, the shares of Common Stock that have been or may be issued from time to time to Lincoln Park under the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 943,396 shares of our Common Stock, or the Commitment Shares, to Lincoln Park as consideration for its commitment to purchase shares of our Common Stock under the Purchase Agreement.

We do not have the right to commence any sales of our Common Stock to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park s control, have been satisfied, including that the SEC has declared

effective the registration statement that includes this prospectus. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 250,000 shares on any single business day, and such amounts may be increased to up to 350,000 shares on a single business day if the market price of our common stock meets certain price thresholds set forth in the Purchase Agreement, subject to a maximum of $500,000 per purchase. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement in these regular purchases will be equal to the lesser of (1) the lowest closing sale price of the Common Stock on the purchase date or (2) the average of the three (3) lowest closing sale prices of the Common Stock during the ten (10) business days prior to the purchase date. In addition, upon notice to Lincoln Park, we may, from time to time and at our sole discretion, direct Lincoln Park to make additional purchases of shares of our common stock under certain circumstances. The purchase price of the shares purchased in these accelerated purchases or additional accelerated purchases will be equal to

Table of Contents

the lesser of (1) the closing market price of our stock on the date of such purchase or (2) 97% of the volume-weighted average price, provided that no such purchase shall take place if the price of the Company s common stock on the date of such purchase notice is below $0.25 per share. We will control the timing and amount of any sales of our common stock to Lincoln Park, subject to certain trading volume, share price and beneficial ownership limitations set forth in the Purchase Agreement. In each case, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than a prohibition on entering into a Variable Rate Transaction, as defined in the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement. Please see the Purchase Agreement, which is incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part, and the section of this prospectus entitled Lincoln Park Transaction for more information.

As of November 3, 2017, there were 31,539,117 shares of our Common Stock outstanding, of which 29,872,521 shares were held by non-affiliates, excluding the 943,396 Commitment Shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to $15,000,000 of our Common Stock to Lincoln Park, only 9,950,000 shares of our Common Stock are being offered under this prospectus, which represents: (i) 943,396 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 9,006,604 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement. Depending on the market prices of our Common Stock at the time we elect to issue and sell shares to Lincoln Park under the Purchase Agreement, we may need to register for resale under the Securities Act additional shares of our Common Stock in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If all of the 9,950,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 24% of the total number of shares of our Common Stock outstanding and 25% of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 9,950,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Under applicable rules of The NASDAQ Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our Common Stock outstanding immediately prior to the execution of the Purchase Agreement (which is 6,304,669 shares based on 31,539,117 shares outstanding immediately prior to the execution of the Purchase Agreement), or the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our Common Stock to Lincoln Park under the Purchase Agreement equals or exceeds $0.374 per share (which represents the closing consolidated bid price of our Common Stock on November 2, 2017, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our Common Stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The NASDAQ Global Market.

The Purchase Agreement also prohibits Lincoln Park from purchasing any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of our common stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder, which limitation we refer to as the Beneficial Ownership Cap.

Issuances of our Common Stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of Common Stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of

our total outstanding shares after any such issuance to Lincoln Park.

Table of Contents

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including the financial statements and the related notes incorporated by reference in this prospectus, before deciding whether to invest in shares of our common stock. If any of the following risks or other risks actually occur, our business, financial condition, results of operations and future prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. 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, and the timing of such clearances and approvals, particularly with respect to current and future generations of 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 increase the amount of business we generate from 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 sales team;

• the ability of our remaining sales and marketing personnel to maintain and increase our revenues after the April organizational realignment and September 2017 cost reduction plan;

• the cost and potential outcomes of existing and future litigation, including, without limitation, the purported stockholder class action described below under *Risks Related to Ownership of our Common Stock Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.* ;

Table of Contents

• 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 $32.0 million in 2014, $47.3 million in 2015, $56.1 million in 2016, and $28.1 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of approximately $280.7 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.

***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 or cause us to become insolvent.***

We believe that the net proceeds from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement, together with our cash and cash equivalents at June 30, 2017, net proceeds of $3.2 million from an at-the-market program pursuant to a Sales Agreement with Cowen and Company, or Cowen, in September 2017 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations for at least the next nine months. Even after the issuance and sale of up to $15 million in our common stock under the Purchase Agreement, 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 and may subsequently require additional fundraising. 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. On November 3, 2017, the Company entered into the Purchase Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park up to $15,000,000 in shares of the Company s common stock, subject to certain limitations and conditions set forth therein, over the 30-month term of the Purchase Agreement. 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 will 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, and any next-generation versions of such products;

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

• the costs and expenses of maintaining or 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;

Table of Contents

• 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 defending ourselves against existing and future litigation, including pending stockholder class action claims;

• 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 intend to raise additional 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. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and/or if we convert all or a portion of our existing debt to equity, 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, or we may become insolvent. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

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

As of June 30, 2017, we had $42.5 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, or CRG. Our significant amount of debt may:

• make it more difficult for us to satisfy our obligations with respect to the Loan Agreement;

• increase our vulnerability to adverse changes in general economic, industry and competitive conditions;

• require us to dedicate a substantial portion of our cash flow from operations to make payments on our debt, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;

• limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;

• restrict us from exploiting business opportunities;

• make it more difficult to satisfy our financial obligations, including payments on the Loan Agreement

• place us at a competitive disadvantage compared to our competitors that have less debt obligations; and

• limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes on satisfactory terms or at all.

The existence of a substantial amount of debt may make it difficult for us to run our business effectively or raise the capital we need to continue our operations.

Table of Contents

***Covenants under the Loan Agreement will restrict our business in many ways.***

The Loan Agreement contains various covenants that limit, subject to certain exceptions, our ability to, among other things:

- incur or assume liens;

- incur additional debt or provide guarantees in respect of obligations of other persons;

- issue redeemable stock and preferred stock;

- pay dividends or make distributions on capital stock, repurchase, redeem or make payments on capital stock or repay, repurchase, redeem, retire, defease, acquire or cancel debt prior to the stated maturity thereof;

- make loans, investment or acquisitions;

- create or permit restrictions on the ability of our subsidiaries to pay dividends or make other distributions to us or to guarantee our debt, limit our or any of our subsidiaries ability to create liens, or make or pay intercompany loans or advances;

- enter into certain transactions with affiliates;

- sell, transfer, license, lease or dispose of our or our subsidiaries assets, including the capital stock of our subsidiaries; and

- dissolve, liquidate, consolidate or merge with or into, or sell substantially all the assets of us and our subsidiaries, taken as a whole, to, another person.

In particular, the covenants of the Loan Agreement, as amended, 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 $18.0 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. 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. As of the date of this prospectus, we believe we will fail to meet the applicable minimum revenue threshold for 2017 and plan to renegotiate this covenant before the end of the year but can provide no assurance that we will be successful in renegotiating this covenant or any other covenants.

The covenants contained in the Loan Agreement could adversely affect our ability to:

- finance our operations;

- make needed capital expenditures;

- make strategic acquisitions or investments or enter into alliances;

- withstand a future downturn in our business or the economy in general;

- refinance our outstanding indebtedness prior to maturity;

- engage in business activities, including future opportunities, that may be in our interest; and

- plan for or react to market conditions or otherwise execute our business strategies.

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,

Table of Contents

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. If we default under any of these debt covenants, we would need relief from default, which may involve waivers or amendments to the applicable debt agreement, if we were unable to cure the default within the relevant cure period. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

***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.***

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. We received 510(k) clearance from the FDA, for commercialization of Pantheris in October 2015, an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States 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. Our revenue has been and continues to be adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, 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 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 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

Table of Contents

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 acceptance among physicians of these products may not increase or may decline. 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. Sales of Pantheris and our other Lumivascular platform products may decline as a result of the reduced sales and marketing personnel headcount after our organizational realignment in April and the implementation of our cost reduction plan in September 2017. 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. 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 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. Reductions in the size of our sales force may adversely impact our business.***

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. The loss of any member of our sales team s senior management 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 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.

Table of Contents

In addition, in April 2017, we undertook an organizational realignment, which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016, and reducing our field sales personnel by nearly 50%. As of June 30, 2017, we had 28 sales professionals. In September 2017, we effected a cost reduction plan, which also included a company-wide reduction in force, lowering our total headcount by 24 employees. Our field sales personnel headcount was reduced to 20. Other employees may leave voluntarily as a result of the reduction in force that we implemented. Given the significant reduction in our sales force, there can be no assurance that our remaining field sales personnel will be adequate to successfully commercialize our products. Further reductions in sales staff may have additional adverse impacts on our business.

***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 -59% and -34% for the three and six months ended June 30, 2017, respectively, compared to 22% and 24% for the three and six months ended June 30, 2016, respectively. Gross margin for the three and six months ended June 30, 2017 was negatively impacted by an increase of $2.1 million and $3.1 million in charges related to excess and obsolete Lightbox and Pantheris inventories, respectively.

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 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.

***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 competitors products, or do not believe that such benefits improve clinical outcomes, our Lumivascular platform products may not be widely adopted.

Table of Contents

***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.

In order to remain competitive, we must continue to develop new product offerings and enhancements to our existing Lumivascular platform products. In particular, we are currently developing two next-generation versions of our Pantheris atherectomy device, Pantheris 3.0 and a lower profile Pantheris. We believe these versions will represent significant improvements in reliability and usability compared to our existing products. We anticipate that Pantheris 3.0 and the lower profile Pantheris will translate into revenue growth and achieve increased physician acceptance. Because we believe they are important to our future revenues, we are devoting a significant portion of our resources to their development. However, we do not yet know whether these or any other new offerings will be well received and broadly accepted by physicians, and if so, whether sales will be sufficient for us to offset costs of development, implementation, support, operation, sales and marketing. Additionally, new products may subject us to additional risks of product performance, customer complaints and litigation. If sales of our new product offerings, including Pantheris 3.0 and the lower profile Pantheris, are lower than we expect, fails to gain anticipated market acceptance or causes us to expend additional resources to fix unforeseen problems and develop modifications, our revenues and results of operations may not improve and our business will be adversely affected.

Table of Contents

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, and Philips. 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

Table of Contents

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.

Table of Contents

***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

Table of Contents

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.

***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:

• any expansion in our manufacturing capacity, could require changes to our production processes;

• 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; and

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

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:

Table of Contents

• 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 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.

Table of Contents

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. In particular, our founder and Executive Chairman, Dr. John 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.

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 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. The sale of our common stock to Lincoln Park pursuant to the Purchase Agreement may affect our ability to use NOLs. 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.

Table of Contents

***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, our technology and product development efforts have 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.

Table of Contents

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 June 30, 2017, we held 15 issued U.S. patents and had 22 U.S. utility patent applications and 7 PCT applications pending. As of June 30, 2017, we also had 24 issued patents outside of the United States. As of June 30, 2017, we had 48 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.

Table of Contents

**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 in the fourth quarter of 2017, and we intend to file for FDA clearance of a lower-profile device for below-the-knee peripheral vascular applications in the first quarter of 2018. 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.

Table of Contents

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

Table of Contents

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 CDPH. 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 CDPH 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, CDPH 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

Table of Contents

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 may continue 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. 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

Table of Contents

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 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;

Table of Contents

- 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.

Our stock price has decreased significantly over the course of the past year and we are currently defending against a securities class action lawsuit. Securities litigation, regardless of the outcome, can ultimately result in substantial costs and divert our management s attention and resources from our business. This litigation could have a material adverse effect on our business, results of operations, financial condition, reputation and cash flows as well as on the market price of our common stock. In addition, as a result of the decrease in our stock price, the options held by our employees are less valuable which make it more likely that certain of our employees may leave our company. The loss of key employees could have an adverse effect on our business.

***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 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

Table of Contents

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. Two analysts who previously published research reports on our stock have discontinued coverage. If one or more of the remaining 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 six 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 six months could cause substantial dilution to our existing stockholders.

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 issued and sold approximately 8.7 million shares of common stock having an aggregate offering value of approximately $8.7 million between the registration statement s effectiveness on March 8, 2016 and September 2017. In addition, 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 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 $0.2 million in commissions and fees to Cowen. During the six months ended June 30, 2017, we sold no shares of common stock under our at-the-market program with Cowen. During the three months ended September 30, 2017, we sold 7,587,593 shares of common stock under the at-the-market program at an average price of $0.44 and raised net proceeds of $3.2 million, after payment of $0.1 million in commissions and fees to Cowen. Due to the SEC s baby

shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, we are unable to issue more shares in our at-the-market program at this time. 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.

Our directors and employees may sell our stock through 10b5-1 trading plans or in the market during open windows under our insider trading policy without such plans in place. Sales of our common stock by our directors and employees could be perceived negatively by investors or cause downward pressure on our common stock and cause a reduction in the price of our common stock as a result. 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.

Table of Contents

***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 October 15, 2017, our directors, officers and their affiliates collectively beneficially own approximately 12.3% 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 contained 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. Our independent registered public accounting firm has expressed in its auditors report on our 2016 financial statements, included in our Annual Report on Form 10-K, as filed with the SEC on March 14, 2017, 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 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 Nasdaq 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

Table of Contents

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 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.

***Nasdaq may delist our securities from its exchange, which could harm our business and limit our stockholders liquidity.***

Our common stock is currently listed on Nasdaq, which has qualitative and quantitative listing criteria. On April 20, 2017 we received a letter from the Listing Qualifications Department of Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) as the market value of the Company s listed securities, or MVLS, was below the minimum $50 million for the previous 30 consecutive business days. This letter also informed us that we were not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), as we did not have total assets and total revenue of at least $50 million each for the most recently completed fiscal year. We did not regain compliance with these rules in the 180-day period ended October 17, 2017, and, on October 24, 2017, we received another letter from Nasdaq indicating that, based upon non-compliance with the MVLS requirement, ours securities would be subject to delisting from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel, or the Panel. We requested a hearing before the Panel and were granted a hearing date in January 2018. At the hearing we will present its plan to evidence compliance with all applicable requirements for continued listing on Nasdaq. We are considering a number of options in its efforts to regain compliance with the Nasdaq listing criteria, including raising additional equity capital and the implementation of a reverse stock split. Our request for a hearing will stay any delisting action by Nasdaq at least pending the ultimate outcome

of the hearing and any extension granted by the Panel. In the interim, our securities will continue to trade on The NASDAQ Global Market. To regain compliance, the MVLS of our common stock must reach at least $50 million for a minimum of 10 consecutive business days.

In addition, on May 24, 2017, we received a second letter from the Listing Qualifications Department of Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the minimum bid price for our listed securities was less than $1 for the previous 30 consecutive business days. This letter also informed us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(C), as the market value of our publicly held shares, or MVPHS, was less than $15 million for the previous 30 consecutive business days. We have a period of 180 calendar days, or until November 20, 2017, to regain compliance with these rules. To regain compliance, during the 180 day period, the bid price of our common stock must close at $1 or more and/or our MVPHS must close at $15 million or more, in each case for a minimum of ten consecutive business days.

The Company is diligently working to evidence compliance with all applicable Nasdaq listing criteria; however, there can be no assurance that the Panel will grant the Company s request for continued listing on Nasdaq or that the

Table of Contents

Company will be able to satisfy the applicable requirements within the timeframe that may be provided by the Panel. If we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the applicable compliance periods, we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. Such a delisting could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum market value of listed securities and minimum closing bid price requirements or prevent future non-compliance with Nasdaq s listing requirements.

***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

Table of Contents

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.

**Risks Related to This Offering**

***The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to decrease.***

On November 3, 2017, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15,000,000 of our common stock. Upon the execution of the Purchase Agreement, we issued 943,396 Commitment Shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to decrease.

Subject to certain restrictions as detailed in the Purchase Agreement, we have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some, or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. As a result, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire to effect sales.

***We may require additional financing to sustain our operations and without it we may not be able to continue operations.***

At June 30, 2017, we had cash of $14.0 million and a working capital surplus of $17.8 million. We had an operating cash flow deficit of $22.3 million for the six months ended June 30, 2017 and $53.1 million for the year ended December 31, 2016. We believe that our existing cash, net proceeds of $3.2 million from our at-the-market program with Cowen in September 2017, expected revenues from operations and the potential proceeds available under the Purchase Agreement with Lincoln Park, should be sufficient to fund our operations for at least the next nine months. We have generated significant losses to date and expect to continue to incur significant operating losses as we continue to commercialize and improve our products. In the future, we will be dependent on obtaining funding from third parties, such as proceeds from the issuance of

Table of Contents

debt, sale of equity, funded research and development programs and payments under partnership and collaborative agreements, in order to maintain our operations and meet our obligations to licensors. There is no guarantee that debt, additional equity or other funding will be available to us on acceptable terms, or at all.

We may direct Lincoln Park to purchase up to $15,000,000 worth of shares of our common stock under the Purchase Agreement over a 30-month period generally in amounts up to 250,000 shares of our common stock, which may be increased to up to 350,000 shares of our common stock depending on the market price of our common stock at the time of sale and subject to a maximum limit of $500,000 per purchase, on any such business day. Assuming a purchase price of $0.234 per share (the closing sale price of the common stock on November 16, 2017) and the purchase by Lincoln Park of the 9,006,604 purchase shares, proceeds to us would be $2,107,545. Under applicable rules of The NASDAQ Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our Common Stock outstanding immediately prior to the execution of the Purchase Agreement (which is 6,304,669 shares based on 31,539,117 shares outstanding immediately prior to the execution of the Purchase Agreement), or the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our Common Stock to Lincoln Park under the Purchase Agreement equals or exceeds $0.374 per share (which represents the closing consolidated bid price of our Common Stock on November 2, 2017, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules. This may mean that we need to obtain the vote of our stockholders in order to raise the full $15,000,000 under the Purchase Agreement.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $15,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. In addition, the Purchase Agreement contains provisions that limit the types of transactions we can engage in during the 30-month term of the Purchase Agreement or for a lesser period of time after termination of the Purchase Agreement or after all of the available shares under the Purchase Agreement are issued and sold. During the period in which these limitations apply, we will be prohibited from pursuing certain types of financings which limitations could cause a material adverse effect on our business, operating results, or financial condition.

Table of Contents

## CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any free writing prospectus that we have authorized for use in connection with this offering, including the documents that we incorporate by reference, contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipate, assume, believe, contemplate, continue, could, due, estimate, expec may, objective, plan, predict, potential, positioned, seek, should, target, will, would and other similar expressions that are p indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the outcome of and expectations regarding our current clinical studies and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through 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 our sales and marketing infrastructure;

- our ability to obtain and maintain customers with a reduced salesforce headcount after our April 2017 realignment and the implementation of our September 2017 cost reduction plan;

- 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;

- our intention to vigorously defend against pending securities lawsuits; 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

Table of Contents

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 prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors and elsewhere in this prospectus. 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 prospectus. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

You should read this prospectus, any free writing prospectus that we have authorized for use in connection with this offering and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Table of Contents

## MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates and information concerning our industry, including market size and growth rates of the markets in which we participate, that are based on industry publications and reports. We relied on industry, market and similar data from Millennium Research Group, the Sage Group, peer reviewed journals, formal presentations at medical society meetings and other sources. We also rely on our own research and estimates in this prospectus. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and reports. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled Risk Factors. These and other factors could cause results to differ materially from those expressed in these publications and reports.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

## USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. We estimate that the net proceeds to us from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will be up to $14,820,500 over an approximately 30-month period, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under the Purchase Agreement, and after other estimated fees and expenses. See Plan of Distribution elsewhere in this prospectus for more information.

We intend to use any proceeds that we receive under the Purchase Agreement for working capital, payment of interest on our debt and general corporate purposes. This anticipated use of net proceeds from the sale of our common stock to Lincoln Park under the Purchase Agreement represents our intentions based upon our current plans and business conditions. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend upon a number of factors, including future sales growth, success of research and product development efforts, cash generated from future operations and actual expenses to operate our business. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses or to repay principal on our debt; however, we currently have no agreements or commitments to complete any such transactions or to make any such principal repayments and are not involved in negotiations to do so.

Table of Contents

## LINCOLN PARK TRANSACTION

### General

On November 3, 2017, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to $15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 943,396 Commitment Shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

We do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park s control, have been satisfied, including the registration statement that includes this prospectus being declared effective by the SEC. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to 250,000 shares on any single business day, which amounts may be increased to up to 350,000 shares of our common stock depending on the market price of our common stock at the time of sale but in no event greater than $500,000 per such purchase. In addition, upon notice to Lincoln Park, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase additional shares of our common stock in accelerated purchases and additional accelerated purchases as set forth in the Purchase Agreement, provided that no such purchase shall take place if the price of the Company s common stock on the date of such purchase notice is below $0.25 per share. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of The NASDAQ Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of the Exchange Cap (which is 6,304,669 shares, or 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement), unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $0.374 per share (which represents the closing consolidated bid price of our common stock on November 2, 2017, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The NASDAQ Global Market.

The Purchase Agreement also prohibits Lincoln Park from purchasing any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of our common stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder, which limitation we refer to as the Beneficial Ownership Cap.

**Purchase of Shares Under the Purchase Agreement**

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 250,000 shares of our common stock on any such business day, which we refer to as a Regular Purchase, provided, however, that (i) the Regular Purchase may be increased to up to 300,000 shares, provided that the closing sale price is not below $0.50 on the purchase date, and (ii) the Regular Purchase may be increased to up to 350,000 shares, provided that the closing sale price is not below $0.75 on the purchase date. In each case, the maximum amount of any single Regular Purchase may not exceed $500,000 per purchase, and such Regular Purchases cannot occur more often than every other business day.

The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or

Table of Contents

- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and the closing sale price of our common stock is not below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, of up to the lesser of (i) 1,500,000 shares and (ii) 30% of the aggregate shares of our common stock traded during all or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed on the applicable accelerated purchase date, the portion of the normal trading hours on the applicable accelerated purchase date prior to such time that any one of such thresholds is crossed, which period of time on the applicable accelerated purchase date we refer to as the Accelerated Purchase Measurement Period .

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price of our common stock during the applicable Accelerated Purchase Measurement Period on the applicable accelerated purchase date; or

- the closing sale price of our common stock on the applicable accelerated purchase date.

In addition to the Regular Purchases and Accelerated Purchases described above, we may also direct Lincoln Park, not later than 1:00 p.m., Eastern time, on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Purchase Agreement, provided that the closing price of our common stock on the business day immediately preceding such business day is not below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), to purchase an additional amount of our common stock, which we refer to as an Additional Accelerated Purchase, of up to the lesser of (i) 1,500,000 shares and (ii) 30% of the aggregate shares of our common stock traded during a certain portion of the normal trading hours on the applicable additional accelerated purchase date as determined in accordance with the Purchase Agreement, which period of time on the applicable additional accelerated purchase date we refer to as the Additional Accelerated Purchase Measurement Period . We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park prior to 1:00 p.m., Eastern time, on a single accelerated purchase date, provided that all prior Accelerated Purchases and Additional Accelerated Purchases (including those that have occurred earlier on the same day) have been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Purchase Agreement.

The purchase price per share for each such Additional Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price of our common stock during the applicable Additional Accelerated Purchase Measurement Period on the applicable additional accelerated purchase date; or

- the closing sale price of our common stock on the applicable additional accelerated purchase date.

In each case, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

**Events of Default**

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of one business day;

Table of Contents

- the delisting of our common stock from The NASDAQ Global Market, our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NASDAQ Capital Market, the NASDAQ Global Select Market, the NYSE Market, the OTC Bulletin Board or OTC Markets (or nationally recognized successor thereto);

- the failure of our transfer agent to issue purchased shares to Lincoln Park within three business days after the applicable purchase date on which Lincoln Park is entitled to receive such shares;

- any breach of the representations or warranties or covenants contained in the Purchase Agreement or Registration Rights Agreement that has or could have a material adverse effect on us and, in the case of a breach of a covenant that is reasonably curable, that is not cured within five business days;

- if at any time the Exchange Cap is reached, to the extent applicable;

- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or

- if at any time we are not eligible to transfer our common stock electronically.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park s control, we may not direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

**Our Termination Rights**

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

**No Short-Selling or Hedging by Lincoln Park**

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

**Prohibitions on Variable Rate Transactions**

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than a prohibition on entering into a Variable Rate Transaction, as defined in the Purchase Agreement.

**Effect of Performance of the Purchase Agreement on Our Stockholders**

All 9,950,000 shares registered in this offering which have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 30 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to $15,000,000 of our common stock, exclusive of the 943,396 shares issued to Lincoln Park on the effective

Table of Contents

date of the Purchase Agreement as a commitment fee. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares of our common stock, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement shares of our common stock in excess of the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equal or exceed $0.374 per share, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

| Assumed Average Purchase Price Per Share | Number of Registered Shares to be Issued if Full Purchase (1) | Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (2) | Proceeds from the Sale of Shares to Lincoln Park Under the $15M Purchase Agreement |
|---|---|---|---|
| $ 0.20 | 9,006,604 | 22% | $ 1,801,320 |
| $ 0.234(3) | 9,006,604 | 22% | $ 2,107,545 |
| $ 0.50 | 9,006,604 | 22% | $ 4,503,302 |
| $ 1.00 | 9,006,604 | 22% | $ 9,006,604 |
| $ 1.50 | 9,006,604 | 22% | $ 13,509,906 |

(1) Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, we are only registering 9,950,000 shares under this prospectus which represents: (i) 943,396 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 9,006,604 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement, and which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering. If we seek to issue shares of our common stock, including shares from other transactions that may be aggregated with the transactions contemplated by the Purchase Agreement under the applicable rules of The NASDAQ Global Market, in excess of 6,304,669 shares, or 19.99% of the total common stock outstanding immediately prior to the execution of the Purchase Agreement, we may be required to seek stockholder approval in order to be in compliance with the rules of The NASDAQ Global Market.

(2) The denominator is based on 31,539,117 shares outstanding as of November 3, 2017, adjusted to include the issuance of (i) 943,396 commitment shares issued to Lincoln Park upon the execution of the Purchase Agreement, and (ii) the number of shares set forth in the adjacent column which we would have sold to Lincoln Park, assuming the purchase price in the adjacent column. The numerator is based on the number of shares issuable under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

(3) The closing sale price of our common stock on November 16, 2017 was $0.234 per share.

Table of Contents

## PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY

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 |
| **Fiscal Year ending December 31, 2017** | | |
| First Quarter | $ 1.60 | $ 3.66 |
| Second Quarter | $ 0.36 | $ 1.68 |
| Third Quarter | $ 0.22 | $ 0.96 |
| Fourth Quarter (through November 16, 2017) | $ 0.21 | $ 0.41 |

As of November 16, 2017, the last reported sale price of our common stock on the NASDAQ Global Market was $0.234.

As of November 3, 2017, there were 31,539,117 shares of our common stock held by 188 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.

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.

Table of Contents

## DETERMINATION OF OFFERING PRICE

The prices at which the Shares covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of our common stock, by negotiations between the Selling Stockholder and buyers of our common stock in private transactions or as otherwise described in Plan of Distribution.

## SELLING STOCKHOLDER

This prospectus relates to the possible resale by the Selling Stockholder, Lincoln Park, of shares of our common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on November 3, 2017 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the Selling Stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have issued or may issue to Lincoln Park under the Purchase Agreement. The Selling Stockholder may sell some, all or none of its shares. We do not know how long the Selling Stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the Selling Stockholder regarding the sale of any of the shares.

The following table presents information regarding the Selling Stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the Selling Stockholder, and reflects its holdings as of November 3, 2017. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Section 13(d) of the Exchange Act and Rule 13d-3 thereunder. The percentage of shares beneficially owned prior to the offering is based on 31,539,117 shares of our common stock actually outstanding as of November 3, 2017.

| Selling Stockholder | Shares Beneficially Owned Before this Offering | Percentage of Outstanding Shares Beneficially Owned Before this Offering | Shares to be Sold in this Offering | Percentage of Outstanding Shares Beneficially Owned After this Offering |
|---|---|---|---|---|
| Lincoln Park Capital Fund, LLC (1) | 943,396 (2) | 2.9%(3) | 9,950,000(4) | 0%(5) |

(1) As of the date of the Purchase Agreement, Lincoln Park Capital Fund, LLC beneficially owned 943,396 shares of our common stock. Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, the manager of Lincoln Park Capital Fund, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope and Scheinfeld have shared voting and

investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Neither Lincoln Park Capital, LLC nor Lincoln Park Capital Fund, LLC is a licensed broker dealer or an affiliate of a licensed broker dealer.

(2) Represents 943,396 Commitment Shares of our common stock issued to Lincoln Park upon our execution of the Purchase Agreement as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement, all of which shares are covered by the registration statement that includes this prospectus. We have excluded from the number of shares beneficially owned by Lincoln Park prior to the offering all of the shares of common stock that Lincoln Park may be required to purchase pursuant to the Purchase Agreement, because the issuance of such shares is solely at our discretion and is subject to certain conditions, the satisfaction of all of which are outside of Lincoln Park s control, including the registration statement of which this prospectus is a part becoming and remaining effective. Furthermore, under the terms of the Purchase Agreement, issuances and sales of shares of our common stock to Lincoln Park are subject to certain limitations on the amounts we may sell to Lincoln Park at any time, including the Exchange Cap. See the description under the heading The Lincoln Park Transaction for more information about the Purchase Agreement.

Table of Contents

(3) Based on 32,482,513 outstanding shares of our common stock as of November 3, 2017, which includes the 943,396 Commitment Shares we issued to Lincoln Park on November 3, 2017.

(4) Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, only 9,950,000 shares of our common stock are being offered under this prospectus, which represents: (i) 943,396 Commitment Shares issued to Lincoln Park upon our execution of the Purchase Agreement as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement; and (ii) an aggregate of 9,006,604 shares of our common stock that may be sold by us to Lincoln Park at our discretion from time to time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

(5) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the Selling Stockholder is under no obligation to sell any shares of common stock at this time.

Table of Contents

## 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 unaudited financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus 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 prospectus 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 areas away from the heart, particularly the pelvis and legs. Our mission is to significantly 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, 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. We received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris in October 2015, we received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. We also offer the Wildcat and Kittycat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

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 allows 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 have worked with 18 of the VISION sites to re-solicit consent from previous clinical trial patients in order for them to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the remaining patients from participating sites was completed in May 2017, and we released the final 12 and 24-month results for a total of 89 patients in July 2017. 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. During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a filing with the FDA to expand the indication for our Pantheris atherectomy device to include instent restenosis.

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. Pantheris qualifies 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 through at least 2019.

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

Table of Contents

platform products in the United States in late 2012. We generated revenues of $6.0 million in the six months ended June 30, 2017 and $9.2 million in the six months ended June 30, 2016. During the six months ended June 30, 2017 and 2016, our net loss was $28.1 million and $29.7 million, respectively. We have not been profitable since inception, and as of June 30, 2017, our accumulated deficit was $280.7 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. Contemporaneously 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 issued and sold approximately 8.7 million shares of common stock having an aggregate offering value of approximately $8.7 million between its effectiveness on March 8, 2016 and September 2017. 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 $0.2 million in commissions and fees to Cowen. During the six months ended June 30, 2017, we sold no shares of common stock under the at-the-market program. During the three months ended September 30, 2017, we sold 7,587,593 shares of common stock under the at-the-market program at an average price of $0.44 and raised net proceeds of $3.2 million, after payment of $0.1 million in commissions and fees to Cowen. Due to the SEC s baby shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, we are unable to issue more shares in our at-the-market program at this time. 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.

In April 2017, we undertook an organizational realignment which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016. The organizational realignment is designed to focus our commercial efforts on driving catheter utilization in our strongest markets, around our most productive sales professionals. Our field sales personnel headcount was reduced to 32, down from 60 people as of December 31, 2016. This workforce reduction is designed to reduce operating expenses while continuing to support major product development and clinical initiatives. The strategic reduction in the field sales force is designed to maintain robust engagement with higher volume users of our Lumivascular technology and position us to increase utilization of our catheters within our installed base of accounts in 2018 following the launch of our next generation products. In September 2017, we effected a cost reduction plan, which also included a company-wide reduction in force, lowering our total headcount by 24 employees. Our field sales personnel headcount was reduced to 20 people, down from 28 as of June 30, 2017.

We are developing two next-generation versions of our Pantheris atherectomy device, Pantheris 3.0 and a lower profile Pantheris, that we believe represent significant improvements over our existing product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe will improve usability and reliability, while the lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels and below-the-knee applications. We plan to make 510(k) submissions for Pantheris 3.0 in the fourth quarter of 2017 and Pantheris BTK in the first quarter of 2018.

Table of Contents

**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 the continued product performance issues with the current version of Pantheris as well as our strategic decision to reduce the size of our sales force in April 2017 and September 2017 to continue to adversely impact our revenues in the near term. However, we expect our revenues to increase in 2018 as we introduce new Lumivascular platform products including new versions of Pantheris. No single customer accounted for more than 10% of our revenues during the three and six months ended June 30, 2017 and 2016.

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 following the commercial launch of our next-generation Pantheris catheters in 2018. 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, charges for excess and obsolete inventories 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***

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, general corporate expenses and

Table of Contents

allocated facilities-related expenses. We expect SG&A expenses to remain decreased in the near term compared to recent prior quarters due to organizational reductions in force which took place in April and September 2017.

***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 foreign exchange transactions.

**Results of Operations:**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| | (in thousands, except percentages) | | | |
| Revenues | $ 2,459 | $ 4,680 | $ 5,950 | $ 9,219 |
| Cost of revenues | 3,919 | 3,645 | 7,994 | 7,005 |
| Gross profit (loss) | (1,460) | 1,035 | (2,044) | 2,214 |
| Gross margin | -59% | 22% | -34% | 24% |
| | | | | |
| Operating expenses: | | | | |
| Research and development | 3,097 | 3,867 | 7,020 | 7,914 |
| Selling, general and administrative | 6,189 | 9,461 | 15,507 | 21,622 |
| Restructuring charges | 519 | | 519 | |
| Total operating expenses | 9,805 | 13,328 | 23,046 | 29,536 |
| Loss from operations | (11,265) | (12,293) | (25,090) | (27,322) |
| | | | | |
| Interest income (expense), net | (1,540) | (1,207) | (3,058) | (2,345) |
| Other income (expense), net | 6 | 4 | 9 | 5 |
| Net loss and comprehensive loss | $ (12,799) | $ (13,496) | $ (28,139) | $ (29,662) |

***Comparison of Three Months Ended June 30, 2017 and 2016***

*Revenues.* Revenues decreased $2.2 million, or 47%, to $2.5 million during the three months ended June 30, 2017, compared to $4.7 million during the three months ended June 30, 2016. For the three months ended June 30, 2017, revenues related to sales of our disposable catheters decreased by 46% to $2.0 million while revenues related to our

Lightbox imaging consoles decreased by 50% to $0.5 million. The decreased revenues in the three months ended June 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris and the reduced size of our field sales force, as well as a strategic decision we made at the beginning of the year to align the focus of our sales force on driving the utilization at our current installed base versus a focus on building the installed base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

*Cost of Revenues and Gross Margin.* Cost of revenues increased $0.3 million, or 8%, to $3.9 million during the three months ended June 30, 2017, compared to $3.6 million during the three months ended June 30, 2016. This increase was primarily attributable to a $2.3 million charge in the three months ended June 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories and a $0.3 million charge related to scrapped inventories, partially offset by our decreased sales. Gross margin for the three months ended June 30, 2017 decreased to -59%, compared to 22% in the three months ended June 30, 2016. Gross margin was negatively impacted by an increase of $2.1 million in the charge for inventory excess and obsolescence in the three months ended June 30, 2017 compared to the prior year period.

*Research and Development Expenses.* R&D expenses decreased $0.8 million, or 20%, to $3.1 million during the three months ended June 30, 2017, compared to $3.9 million during the three months ended June 30, 2016. This decrease was primarily due to a $0.4 million decrease in personnel-related expenses, a decrease of $0.3 million in product development materials and related costs and a decrease of $0.1 million in outside services. Personnel-related expenses included stock-

Table of Contents

based compensation expense of $0.5 million compared to $0.7 million for the three months ended June 30, 2017 and 2016, respectively.

*Selling, General and Administrative Expenses.* SG&A expenses decreased $3.3 million, or 35%, to $6.2 million during the three months ended June 30, 2017, compared to $9.5 million during the three months ended June 30, 2016. This decrease was primarily due to a $2.8 million decrease in personnel-related expenses and a decrease of $0.5 million in marketing costs. Personnel-related expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. For the three months ended June 30, 2017, our marketing costs decreased as a result of our workforce reduction and efforts to reduce operating expenses. Personnel-related expenses included stock-based compensation expense of $0.7 million compared to $0.8 million for the three months ended June 30, 2017 and 2016, respectively.

*Restructuring.* In April 2017, we undertook an organizational realignment to conserve resources which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016. We recorded a restructuring charge of approximately $0.5 million, which consisted of severance related costs specific to the termination of 44 employees, at that time. As of June 30, 2017, all except $26,000 of costs associated with the restructuring were paid.

*Interest Income (Expense), Net.* Interest expense, net increased $0.3 million, or 28%, to an expense of $1.5 million during the three months ended June 30, 2017, compared to an expense of $1.2 million during the three months ended June 30, 2016. This increased expense was attributable to the additional $10.0 million borrowing on June 15, 2016 under our Loan Agreement with CRG.

*Other Income (Expense), Net.* Other income, net increased $2,000 to an income of $6,000, during the three months ended June 30, 2017, compared to an income of $4,000 during the three months ended June 30, 2016. Other income for the three months ended June 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

***Comparison of Six Months Ended June 30, 2017 and 2016***

*Revenues.* Revenues decreased $3.2 million, or 35%, to $6.0 million during the six months ended June 30, 2017, compared to $9.2 million during the six months ended June 30, 2016. For the six months ended June 30, 2017, revenues related to sales of our disposable catheters decreased by 29% to $5.0 million while revenues related to our Lightbox imaging consoles decreased by 55% to $1.0 million. The decreased revenues in the six months ended June 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris and the reduced size of our field sales force, as well as a strategic decision we made at the beginning of the year to align the focus of our sales force on driving the utilization at our current installed base versus a focus on building the installed

base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

*Cost of Revenues and Gross Margin.* Cost of revenues increased $1.0 million, or 14%, to $8.0 million during the six months ended June 30, 2017, compared to $7.0 million during the six months ended June 30, 2016. This increase was primarily attributable to a $3.6 million charge in the six months ended June 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories and a $1.2 million charge related to scrapped inventories, partially offset by our decreased sales. Gross margin for the six months ended June 30, 2017 decreased to -34%, compared to 24% in the six months ended June 30, 2016. Gross margin was negatively impacted by an increase of $3.1 million in the charges for inventory excess and obsolescence and an increase of $0.7 million of scrapped inventories during the six months ended June 30, 2017 compared to the prior year period, partially offset by a decrease of $0.3 million in warranty expenses.

*Research and Development Expenses.* R&D expenses decreased $0.9 million, or 11%, to $7.0 million during the six months ended June 30, 2017, compared to $7.9 million during the six months ended June 30, 2016. This decrease was primarily due to a $0.5 million decrease in personnel-related expenses and a decrease of $0.4 million in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $1.0 million compared to $1.3 million for the six months ended June 30, 2017 and 2016, respectively.

*Selling, General and Administrative Expenses.* SG&A expenses decreased $6.1 million, or 28%, to $15.5 million during the six months ended June 30, 2017, compared to $21.6 million during the six months ended June 30, 2016. This decrease was primarily due to a $5.1 million decrease in personnel-related expenses, a decrease of $1.7 million in marketing costs and a decrease of $0.1 million relating to depreciation, partially offset by an increase of $0.6 million in consulting, legal and professional fees and an increase of $0.3 million relating to the allocation of facilities expense. Personnel-related

Table of Contents

expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. Personnel-related expenses included stock-based compensation expense of $1.6 million compared to $2.0 million for the six months ended June 30, 2017 and 2016, respectively. Higher marketing costs for the six months ended June 30, 2016 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.

*Restructuring.* In April 2017, we undertook an organizational realignment to conserve resources which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016. We recorded a restructuring charge of approximately $0.5 million, which consisted of severance related costs specific to the termination of 44 employees, at that time. As of June 30, 2017, all except $26,000 of costs associated with the restructuring were paid.

*Interest Income (Expense), Net.* Interest income (expense), net increased $0.8 million, or 30%, to an expense of $3.1 million during the six months ended June 30, 2017, compared to an expense of $2.3 million during the six months ended June 30, 2016. This increased expense was attributable to the additional $10.0 million borrowing on June 15, 2016 under our Loan Agreement with CRG. *Other Income (Expense), Net.* Other income (expense), net increased to an income of $9,000 during the six months ended June 30, 2017, compared to income of $5,000 during the six months ended June 30, 2016. Other income for the six months ended June 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

**Liquidity and Capital Resources**

As of June 30, 2017, we had cash and cash equivalents of $14.0 million and an accumulated deficit of $280.7 million, compared to cash and cash equivalents of $36.1 million and an accumulated deficit of $252.4 million as of December 31, 2016. We currently believe our existing cash and cash equivalents, net proceeds of $3.2 million under the at-the-market program with Cowen in September 2017, expected revenues and the potential net proceeds from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement, will be sufficient to meet our capital requirements and fund our operations for at least the next nine months. 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. 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 or become insolvent.

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. As previously disclosed, on April 20 and May 24, 2017 we received letters from the Listing Qualifications Department of The NASDAQ Stock Market, LLC ( Nasdaq ) notifying us that the Company was not in compliance with applicable listing rules. In the event that we do not regain compliance with those rules and our stock is delisted by Nasdaq, our access to public capital markets would be impaired. For more information on this risk, see Part II, Item 1A *Risk Factors*.

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 borrowed by us. Of the remaining $20.0 million, we borrowed $10.0 million on June 15, 2016 and the availability of the remaining $10.0 million was contingent on the achievement of certain net revenue milestones prior to December 31, 2016, which were not achieved. As of June 30, 2017, we had $42.5 million outstanding under the Loan Agreement. For more information, see Part I, Item 2 *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, as amended, 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 $18.0 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. If we fail to meet the

Table of Contents

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 are currently in compliance with the covenants under the Loan Agreement, but if we default on any such covenants we will need, and may not be able to obtain, relief in the form of waivers or amendments to the applicable debt agreement. As of the date of this prospectus, we believe we will fail to meet the applicable minimum revenue threshold for 2017 and plan to renegotiate this covenant before the end of the year but cannot provide any assurance that we will be successful in this renegotiation.

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 issued and sold common stock with an aggregate value of approximately $8.7 million between the registration statement s effectiveness on March 8, 2016 and September 2017. 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 $0.2 million in commissions and fees to Cowen. During the six months ended June 30, 2017, we did not sell any shares of common stock under the at-the-market program. During the three months ended September 30, 2017 we sold 7,587,593 shares of common stock under the at-the-market program at an average price of $0.44 and raised net proceeds of $3.2 million, after payment of $0.1 million in commissions and fees to Cowen. Due to the SEC s baby shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, we are unable to issue more shares in our at-the-market program at this time. 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.

On November 3, 2017, the Company entered into the Purchase Agreement with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park, from time-to-time over a 30-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus, up to $15,000,000 in shares of the Company s common stock.

**Cash Flows**

| | Six Months Ended June 30, | |
|---|---|---|
| | 2017 | 2016 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | $ (22,311) | $ (31,187) |
| Investing activities | (45) | (729) |
| Financing activities | 224 | 11,296 |
| Net increase (decrease) in cash and cash equivalents | $ (22,132) | $ (20,620) |

***Net Cash Used in Operating Activities***

Net cash used in operating activities for the six months ended June 30, 2017 was $22.3 million, consisting primarily of a net loss of $28.1 million and an increase in net operating assets of $2.8 million, offset by non-cash charges of $8.6 million. The increase in net operating assets was due to an increase in inventories, prepaid expenses and other current assets, decreases in accounts payable, accrued compensation and accrued expenses and other current liabilities, was due to our workforce reduction in April 2017 and efforts to reduce operating expenses, decreases in other liabilities related to the repayment of assigned interest to PDL, partially offset by a decrease in accounts receivable. 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 the six months ended June 30, 2016 was $31.2 million, consisting primarily of a net loss of $29.7 million and an increase in net operating assets of $7.1 million, offset by non-cash charges of $5.6 million. The increase in net operating assets was primarily due to the commercial launch of Pantheris in March 2016 resulting

Table of Contents

in an increase in accounts receivable and inventories. The increase in net operating assets was also due to an increase in prepaid expenses and other current assets, and decreases in accounts payable and accrued expenses and other current liabilities, due to timing of payments, 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 Investing Activities***

Net cash used in investing activities in the six months ended June 30, 2017 was $45,000 consisting of purchases of property and equipment.

Net cash used in investing activities in the six months ended June 30, 2016 was $0.7 million consisting of purchases of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities in the six months ended June 30, 2017 of $0.2 million primarily relates to proceeds from purchases under our employee stock purchase plan.

Net cash provided by financing activities in the six months ended June 30, 2016 of $11.3 million primarily relates to net proceeds of $9.7 million from the debt financing under the Loan Agreement with CRG, net proceeds of $1.3 million from the issuance of common stock under the Sales Agreement with Cowen and $0.5 million proceeds from purchases under our employee stock purchase plan and proceeds from the exercise of stock options, partially offset by the cash paid for deferred offering costs of $0.2 million.

**Off-Balance Sheet Arrangements**

We currently have no off-balance sheet arrangements, such as the use of 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.

In October 2017, we entered into an agreement to sublease one of our facilities. The sublease agreement is effective in November 2017 and is scheduled to expire on November 15, 2019 (which is 15 days prior to the expiration of the facility lease). The sublessee will pay a base rent of $3.25 per rentable square foot or $79,950 per month, increasing to $3.35 per rentable square foot or $82,410 per month as of December 1, 2018. In addition to the base rent, the sublessee will pay us the Landlord s operating expenses and property taxes due and payable with respect to the subleased facility.

There have been no other material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 14, 2017.

**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 and June 30, 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.

Table of Contents

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, or as of June 30, 2017.

***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.

**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 of contingent assets and liabilities. 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. There have been no significant and material changes in our critical accounting policies during the three months ended June 30, 2017, as compared to those disclosed in Management s Discussion and Analysis of Financial Conditions and Results of Operations - Critical accounting policies and significant judgments and estimates in our most recent Annual Report on Form 10-K, as filed with the SEC on March 14, 2017.

**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 June 30, 2017. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2017, our disclosure controls and procedures were effective.

**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 second quarter of 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

# 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 significantly 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, 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 United States and select European countries promptly thereafter. We also offer the Wildcat and Kittycat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

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 stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all 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 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 allows 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 $11.2 million in 2014, $10.7 million in 2015 and $19.2 million in 2016.

**Our Products**

Our current products include our Lightbox imaging console and our various catheters used in PAD treatment. All of our revenues are currently derived from sales of our Lightbox imaging 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.

Table of Contents

**LUMIVASCULAR PRODUCTS**

| Name | Clinical Indication | Size (Length, Diameter) | Regulatory Status | Original Clearance Date |
|---|---|---|---|---|
| **Lightbox(1)** | OCT Imaging | N/A | FDA Cleared<br>CE Mark | November 2012<br>September 2011 |
| **Pantheris 8F** | Atherectomy | 110cm, 8 French (F) | FDA Cleared<br>CE Mark | October 2015<br>June 2015 |
| **Pantheris 7F** | Atherectomy | 110cm, 7F | FDA Cleared<br>CE Mark | March 2016<br>June 2015 |
| **Ocelot(2)** | CTO Crossing | 110cm, 6F | FDA Cleared<br>CE Mark | November 2012<br>September 2011 |
| **Ocelot MVRX(2)** | CTO Crossing | 110cm, 6F | FDA Cleared | December 2012 |
| **Ocelot PIXL(2)** | CTO Crossing | 135/150cm, 5F | FDA Cleared<br>CE Mark | December 2012<br>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<br>CTO Crossing | 110cm, 6F<br>110cm, 6F | FDA Cleared<br>FDA Cleared<br>CE Mark | February 2009(3)<br>August 2011<br>May 2011 |
| Kittycat 2(2) | CTO Crossing | 150cm, 5F | FDA Cleared<br>CE Mark | October 2011<br>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

Table of Contents

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 healthy arterial structures 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 provides 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 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.

Table of Contents

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 were reported separately in our 510(k) submission to the 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 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 required 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 are 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% |

Table of Contents

Although the original VISION study protocol was not designed to follow patients beyond six months, in 2016 we 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 was completed in May 2017, and we released the final 12- and 24-month results for a total of 73 patients and 89 lesions in July 2017. The key metrics reported for this group were freedom from target lesion revascularization, or TLR, at 12 months and 24 months, which were 82% and 74% by patient and 83% and 76% by lesion, respectively, based on Kaplan-Meier curve assessments.

***INSIGHT (Pantheris)***

INSIGHT is a prospective, global, single-arm, multi-center study to evaluate the safety and effectiveness of Pantheris for treating in-stent restenosis in lower extremity arteries. In-stent restenosis occurs when a blocked artery previously treated with a stent becomes narrowed again, thereby reducing blood flow. Physicians often face challenges when treating in-stent restenosis both in terms of safety and efficacy. From a safety standpoint, limitations in imaging techniques, such X-ray fluoroscopy, and the inability to control the directionality of other atherectomy devices create concerns with impacting the integrity of the stent during the procedure. In terms of efficacy, current therapies for in-stent restenosis, such as balloon angioplasty, have high rates of recurrent narrowing within stents.

The INSIGHT trial allows for up to 140 patients to be treated at up to 20 sites in the United States and Europe. Patient enrollment began in October 2017 and is expected to continue through at least the first quarter of 2018. Patient outcomes will be evaluated at thirty days, six months and one year following treatment. We plan to submit a 510(k) application with the FDA seeking a specific indication for treating in-stent restenosis with Pantheris once the trial is fully enrolled and follow-up data through six months are available and analyzed.

**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 a Vice President, Regional and Territory Sales Managers, Clinical 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 Clinical 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 our marketing team, which focuses primarily on clinical training and education, marketing communications and product management. We also have a small team of field engineers responsible for installation, service and maintenance of our Lightbox consoles.

As of October 15, 2017, we had 24 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 2014, 2015, 2016 and for the six months ended June 30, 2017 were $18.5 million,

Table of Contents

$29.2 million, $40.0 million and $6.2 million, respectively. No single customer accounted for more than 10% of our revenues during 2014, 2015, 2016 or for the six months ended June 30, 2017.

**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 and Philips. Some competitors have attempted to combine intravascular imaging with atherectomy and although we are not aware of any active initiatives in this area, these and other companies may attempt to incorporate on-board visualization into their products in the future or may have ongoing programs of which we are not aware. 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 June 30, 2017, we held 15 issued U.S. patents and had 22 U.S. utility patent applications and 7 PCT applications pending. As of June 30, 2017, we also had 24 issued patents from outside of the United States. As of June 30, 2017, we had 48 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

Table of Contents

expire between the years 2028 and 2035.

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 June 30, 2017, 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 granted 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 we are also developing next-generation CTO crossing devices 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 October 15, 2017, we had 13 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, 2014, 2015, 2016 and the six months ended June 30, 2017 were $11.2 million, $15.7 million, $15.5 million and $3.1 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 through at least 2019.

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.

Table of Contents

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. 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.

Other than current accepted purchase orders, 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 Public Health, or CDPH. 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 was a surveillance audit conducted in January 2017 by BSI, our European Notified Body, under the Medical Device Single Audit Program, or MDSAP. The audit 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

Table of Contents

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 CDPH. 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 CDPH 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

Table of Contents

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

Table of Contents

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.

Table of Contents

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;

Table of Contents

- 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 inpatient PAD procedures for fiscal year 2018 went into effect as of October 1, 2017 and range between $10,928 and $19,492. Medicare reimbursement for outpatient PAD procedures for 2018 go into effect on January 1, 2018 and are expected to range between $7,023 and $16,019. 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 October 15, 2017, we had 73 employees, including 18 in manufacturing and operations, 24 in sales and marketing, 13 in research and development and clinical and regulatory affairs, 7 in quality assurance and 11 in finance, general administrative and executive administration. All 73 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.

**Legal Proceedings**

Except as set forth below, we are not involved in any pending legal proceedings that we believe could have a material adverse effect on our financial condition, results of operations or cash flows. From time to time we may be involved in legal proceedings or investigations, which could harm our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Between May 22, 2017 and May 25, 2017, three purported class actions were filed in the Superior Court of the State of California, County of San Mateo ( State Court ), against us and certain of our officers and directors. The underwriters of our IPO in January 2015 are also named as defendants. The actions were captioned Grotewiel v. Avinger, Inc., et al., No. 17-CIV-02240, Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, and Olberding v. Avinger, Inc., et al., No. 17-CIV-02307. These lawsuits allege that the registration statement for our IPO made false and misleading statements and omissions in violation of the Securities Act of 1933. Plaintiffs seek to represent a class of purchasers of our common stock in and/or traceable to our IPO. Plaintiffs seek, among other things, unspecified compensatory damages, interest, costs, recission, and attorneys fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California ( Federal Court ), where they were captioned Grotewiel v. Avinger, Inc., No. 17-cv-03400, Gonzalez v. Avinger, Inc., No. 17-cv-03401, and Olberding v. Avinger, Inc., No. 17-cv-03398, and where the actions were related and assigned to the same judge.

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Grotewiel action ( Federal Action ). An amended complaint in the Federal Action is due on November 21, 2017. On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted the motions to remand the Olberding and Gonzalez actions to the State Court. On August 9, 2017, the State Court consolidated the Olberding and Grotewiel actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284 ( State Action ). On September 22, 2017, an amended

Table of Contents

complaint was filed in the State Action. On October 31, 2017, the parties in the State Action stipulated to a stay of proceedings until judgment is entered in the Federal Action. On November 2, 2017, pursuant to stipulation of the parties, the State Court entered an order staying proceedings in the State Action until judgment is entered in the Federal Action.

We and our directors believe that the foregoing lawsuits are entirely without merit and intend to vigorously defend against the actions.

**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.

Table of Contents

## MANAGEMENT

### Executive Officers, Directors and Key Employees

The following table sets forth information, as of October 15, 2017, regarding our executive officers, directors and key employees.

| Name | Age | Title |
|---|---|---|
| Jeffrey M. Soinski | 55 | President, Chief Executive Officer and Director |
| John B. Simpson, Ph.D., M.D.(1) | 73 | Director and Executive Chairman of the Board of Directors |
| Matthew B. Ferguson | 49 | Chief Business Officer and Chief Financial Officer |
| Sougata Banerjee | 51 | Senior Vice President, Operations |
| Himanshu N. Patel | 57 | Chief Technology Officer |
| James G. Cullen(2)(3) | 75 | Director |
| Donald A. Lucas(1)(2)(3) | 55 | Director |
| James B. McElwee(1)(2)(3) | 65 | Director |

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and governance committee.

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

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

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

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

*James B. McElwee* has served as a member of our board of directors since March 2011. Mr. McElwee has served as an independent venture capital investor since 2010. Mr. McElwee served as general partner of Weston Presidio, a private equity and venture capital firm, from 1992 to 2010. During his tenure as a general partner and member of the investment committee, Weston Presidio led the start up financing of JetBlue Airways and made investments in Fender Musical Instruments, The Coffee Connection, Guitar Center, Mapquest, Party City, Petzazz, RE/MAX, and

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

Table of Contents

*John B. Simpson, Ph.D., M.D.* founded our company in March 2007 and has served as a member of our board of directors since March 2007 and as our Executive Chairman since December 2014. From March 2007 to December 2014, Dr. Simpson served as our Chief Executive Officer. Since March 2000 Dr. Simpson has served in various positions at De Novo Ventures, a venture capital fund, including managing director and clinical director. Since 1983, Dr. Simpson has been a partner at Cardiovascular Medicine and Coronary Interventions, a cardiology physician group. Prior to founding our company, Dr. Simpson founded several other interventional cardiology companies, including Perclose, a manufacturer of femoral artery access site closure devices, Devices for Vascular Intervention, a manufacturer of atherectomy devices, Advanced Cardiovascular Systems, a manufacturer of balloon angioplasty devices and FoxHollow Technologies, a manufacturer of atherectomy devices. Dr. Simpson holds a B.S. in Agriculture from Ohio State University, an M.D. from the Duke University School of Medicine and an M.S. and a Ph.D. in Biomedical Science from the University of Texas.

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

*Jeffrey M. Soinski* has served as our President, Chief Executive Officer and a member of our Board of Directors since December 2014. From its formation in September 2009 until the acquisition of its Unisyn business by GE Healthcare in May 2013, Mr. Soinski served as Chief Executive Officer of Medical Imaging Holdings and its primary operating company Unisyn Medical Technologies, a national provider of technology-enabled products and services to the medical imaging industry. Mr. Soinski was a Director of Medical Imaging Holdings and its remaining operating company Consensys Imaging Service from September 2009 until its sale in October 2017. Mr. Soinski served periodically as a Special Venture Partner from July 2008 to June 2013 and as a Special Investment Partner since October 2016 for Galen Partners, a leading healthcare-focused private equity firm, which has Medical Imaging Holdings as one of its portfolio companies. From 2001 until its acquisition by C.R. Bard in 2008, Mr. Soinski was President and CEO of Specialized Health Products International, a publicly-traded manufacturer and marketer of proprietary safety medical products. Mr. Soinski served as a consultant to BLOXR Corporation, a venture-backed medical device company, from October 2013 until September 2014. He served on the board of directors of Merriman Holdings, parent of Merriman Capital, a San Francisco-based investment banking and brokerage firm, from 2008 until March 2016. Mr. Soinski holds a B.A. degree from Dartmouth College.

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

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

Mr. Ferguson holds a B.S. in Civil Engineering from Stanford University, an M.S. in Mechanical Engineering from the University of Pennsylvania and an M.B.A. from the University of California at Berkeley.

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

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

Table of Contents

**Director Independence**

Our common stock is listed on The NASDAQ Global Select Market. Under the listing standards of The NASDAQ Stock Market, independent directors must comprise a majority of a listed company s board of directors. In addition, the listing standards of The NASDAQ Stock Market require that, subject to specified exceptions, each member of a listed company s audit, compensation, and nominating and corporate governance committees be independent. Under the listing standards of The NASDAQ Stock Market, a director will only qualify as an independent director if, in the opinion of that listed company s board of directors, that director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the additional independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the Exchange Act ), and the listing standards of The NASDAQ Stock Market. Compensation committee members must also satisfy the additional independence criteria set forth in Rule 10C-1 under the Exchange Act and the listing standards of The NASDAQ Stock Market.

Our board of directors has undertaken a review of the independence of each of our directors. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that Messrs. Cullen, Lucas and McElwee do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent as that term is defined under the listing standards of The NASDAQ Stock Market. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled Related Person Transactions.

**Board Leadership Structure and Lead Independent Director**

We believe that the structure of our board of directors and its committees provides strong overall management of our company. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our board of directors should be separate. While the Executive Chairman of our board of directors and our Chief Executive Officer roles are separate, our current Executive Chairman, John B. Simpson, is not independent under the listing standards of The NASDAQ Stock Market as a result of his employment with us. Our board of directors believes that, given the perspective and experience Dr. Simpson brings as one of our founders, Dr. Simpson s service as our Executive Chairman is appropriate and is in the best interests of our board of directors, our company and our stockholders.

Our Chief Executive Officer, Jeffrey M. Soinski, is responsible for setting the strategic direction of our company, the general management and operation of the business and the guidance and oversight of senior management. In his capacity as Executive Chairman of our board of directors, Dr. Simpson is also responsible for operation of the business and the guidance and oversight of senior management, monitors the content, quality and timeliness of information sent to our board of directors and is available for consultation with our board of directors regarding the oversight of our business affairs.

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

**Board Meetings and Committees**

During our fiscal year ended December 31, 2016, our board of directors held twelve meetings (including regularly scheduled and special meetings), and each director attended at least 75% of the aggregate of (i) the total number of meetings of our board of directors held during the period for which he has been a director and (ii) the total number of meetings held by all committees of our board of directors on which he served during the periods that he served. Five of our directors attended our 2016 annual meeting of stockholders, either in person or telephonically.

Although we do not have a formal policy regarding attendance by members of our board of directors at annual meetings of stockholders, we strongly encourage our directors to attend.

Table of Contents

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members will serve on these committees until their resignation or until as otherwise determined by our board of directors.

***Audit Committee***

Messrs. Lucas, McElwee and Cullen serve on our audit committee. Mr. Lucas serves as the chair of the audit committee. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of The NASDAQ Stock Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that Messrs. Lucas, McElwee and Cullen have met the financial literacy and financial sophistication requirements and that Messrs. Lucas, McElwee and Cullen are independent under SEC and The NASDAQ Stock Market rules. In addition, our board of directors has determined that Mr. Cullen is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act of 1933, as amended. The audit committee s primary responsibilities include:

- appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is Moss Adams, LLP;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- monitoring our internal control over financial reporting, disclosure controls and procedures;
- reviewing our risk management status;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management; and
- monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of The NASDAQ Stock Market. A copy of the charter of our audit committee is available on our website at *www.avinger.com* under Investors Governance. During our fiscal year ended December 31, 2016, our audit committee held nine meetings.

***Compensation Committee***

Messrs. Lucas, Cullen and McElwee serve on our compensation committee. Mr. McElwee serves as the chair of the compensation committee. Each member of our compensation committee meets the requirements for independence for compensation committee members under the listing standards of The NASDAQ Stock Market and SEC rules and regulations, including Rule 10C-1 under the Exchange Act. Each member of our compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code. Our compensation committee is responsible for, among other things:

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

Our Chief Executive Officer and Chief Financial Officer make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee. From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, we have periodically engaged Radford, a business unit of Aon Hewitt, to help develop our compensation philosophy, select a group of peer companies to use for compensation benchmarking purposes and advise on cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of The NASDAQ Stock Market. A copy of the charter of our compensation committee is available on our website at *www.avinger.com* under Investors Governance. During our fiscal year ended December 31, 2016, our compensation committee held six meetings.

Table of Contents

***Nominating and Corporate Governance Committee***

Messrs. Lucas, Cullen and McElwee serve on our nominating and governance committee. Mr. Cullen serves as the chair of the nominating and governance committee. Each member of our nominating and corporate governance committee meets the requirements for independence under the listing standards of The NASDAQ Stock Market and SEC rules and regulations. Our nominating and corporate governance committee is responsible for, among other things:

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

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable listing standards of The NASDAQ Stock Market. A copy of the charter of our nominating and corporate governance committee is available on our website at *www.avinger.com* under Investors Governance. During our fiscal year ended December 31, 2016, our nominating and corporate governance committee held no meetings.

**Compensation Committee Interlocks and Insider Participation**

During the last fiscal year, Messrs. Cullen, Lucas, and McElwee served as members of our compensation committee. None of the members of our compensation committee is or has been an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions) of any entity that has one or more of its executive officers serving on our board of directors or compensation committee.

**Considerations in Evaluating Director Nominees**

Our nominating and corporate governance committee uses a variety of methods for identifying and evaluating director nominees. In its evaluation of director candidates, our nominating and corporate governance committee will consider the current size and composition of our board of directors and the needs of our board of directors and the respective committees of our board of directors. Some of the qualifications that

our nominating and corporate governance committee considers include, without limitation, issues of character, integrity, judgment, diversity of experience, independence, area of expertise, corporate experience, length of service, potential conflicts of interest and other commitments. Nominees must also have the ability to offer advice and guidance to our Chief Executive Officer based on past experience in positions with a high degree of responsibility and be leaders in the companies or institutions with which they are affiliated. Director candidates must have sufficient time available in the judgment of our nominating and corporate governance committee to perform all board of director and committee responsibilities. Members of our board of directors are expected to prepare for, attend and participate in all board of director and applicable committee meetings. Other than the foregoing, there are no stated minimum criteria for director nominees, although our nominating and corporate governance committee may also consider such other factors as it may deem, from time to time, are in our and our stockholders best interests.

Although our board of directors does not maintain a specific policy with respect to board diversity, our board of directors believes that our board of directors should be a diverse body, and our nominating and corporate governance committee considers a broad range of backgrounds and experiences. In making determinations regarding nominations of directors, our nominating and corporate governance committee may take into account the benefits of diverse viewpoints. Our nominating and corporate governance committee also considers these and other factors as it oversees the annual board of director and committee evaluations. After completing its review and evaluation of director candidates, our nominating and corporate governance committee recommends to our full board of directors the director nominees for selection.

**Stockholder Recommendations for Nominations to the Board of Directors**

Our nominating and corporate governance committee will consider candidates for director recommended by stockholders, so long as such recommendations comply with our amended and restated certificate of incorporation, amended and restated bylaws and applicable laws, rules and regulations, including those promulgated by the SEC. Our nominating and corporate governance committee will evaluate such recommendations in accordance with its charter, our amended and restated bylaws, our policies and procedures for director candidates, as well as the regular director nominee criteria described

Table of Contents

above. This process is designed to ensure that our board of directors includes members with diverse backgrounds, skills and experience, including appropriate financial and other expertise relevant to our business. Eligible stockholders wishing to recommend a candidate for nomination should contact our Secretary in writing. Such recommendations must include information about the candidate, a statement of support by the recommending stockholder, evidence of the recommending stockholder s ownership of our common stock and a signed letter from the candidate confirming willingness to serve on our board of directors. Our nominating and corporate governance committee has discretion to decide which individuals to recommend for nomination as directors.

Under our amended and restated bylaws, stockholders may also nominate candidates for our board of directors. Any nomination must comply with the requirements set forth in our amended and restated bylaws and should be sent in writing to our Secretary at 400 Chesapeake Drive, Redwood City, California 94063. To be timely for our 2018 annual meeting of stockholders, our Secretary must receive the nomination no earlier than February 9, 2018 and no later than March 11, 2018.

**Communications with the Board of Directors**

Interested parties wishing to communicate with our board of directors or with an individual member or members of our board of directors may do so by writing to our board of directors or to the particular member or members of our board of directors and mailing the correspondence to our Secretary at Avinger, Inc., 400 Chesapeake Drive, Redwood City, California 94063. Our Secretary, in consultation with appropriate members of our board of directors as necessary, will review all incoming communications and, if appropriate, all such communications will be forwarded to the appropriate member or members of our board of directors, or if none is specified, to the Executive Chairman of our board of directors.

**Corporate Governance Guidelines and Code of Business Conduct**

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

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, we have established charters for the audit committee, compensation committee and nominating and governance committee, as well as a code of business conduct that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of business conduct is posted on the Corporate Governance portion of our website at *www.avinger.com* under Investors Governance. We will post amendments to our code of business conduct or waivers of our code of business conduct for directors and executive officers on the same website.

**Limitation on Liability and Indemnification Matters**

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified

Table of Contents

exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors and officers liability insurance.

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

**Risk Management**

Risk is inherent with every business, and we face a number of risks, including strategic, financial, business and operational, political, regulatory, legal and compliance, and reputational risk. We have designed and implemented processes to manage risk in our operations. Management is responsible for the day-to-day management of risks the company faces, while our board of directors, as a whole and assisted by its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are appropriate and functioning as designed.

Our board of directors believes that open communication between management and our board of directors is essential for effective risk management and oversight. Our board of directors meets with our Chief Executive Officer and other members of the senior management team at quarterly meetings of our board of directors, where, among other topics, they discuss strategy and risks facing the company, as well as at such other times as they deem appropriate.

While our board of directors is ultimately responsible for risk oversight, our board committees assist our board of directors in fulfilling its oversight responsibilities in certain areas of risk. Our audit committee assists our board of directors in fulfilling its oversight responsibilities with respect to risk management in the areas of internal control over financial reporting and disclosure controls and procedures, legal and regulatory compliance, and discusses with management and the independent auditor guidelines and policies with respect to risk assessment and risk management. Our audit committee also reviews our major financial risk exposures and the steps management has taken to monitor and control these exposures. Our audit committee also monitors certain key risks on a regular basis throughout the fiscal year, such as risk associated with internal control over financial reporting and liquidity risk. Our nominating and corporate governance committee assists our board of directors in fulfilling its oversight responsibilities with respect to the management of risk associated with board organization, membership and structure, and corporate governance. Our compensation committee assesses risks created by the incentives inherent in our compensation policies. Finally, our full board of directors reviews strategic and operational risk in the context of reports from the management team, receives reports on all significant committee activities and evaluates the risks inherent in significant transactions.

**Director Compensation**

Our board of directors approved our Outside Director Compensation Policy in January 2015 to compensate each non-employee director for his or her service. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or

appropriate. Under our Outside Director Compensation Policy, non-employee directors will receive compensation in the form of equity and cash, as described below:

*Cash Compensation.* All non-employee directors will be entitled to receive the following cash compensation for their services:

- $35,000 per year for service as a board member;
- $15,000 per year additionally for service as lead independent director;
- $20,000 per year additionally for service as chairman of the audit committee;
- $10,000 per year additionally for service as an audit committee member;
- $15,000 per year additionally for service as chairman of the compensation committee;
- $7,500 per year additionally for service as a compensation committee member;
- $10,000 per year additionally for service as chairman of the nominating and corporate governance committee; and
- $5,000 per year additionally for service as a nominating and corporate governance committee member.

Table of Contents

All cash payments to non-employee directors, or the Retainer Cash Payments, will be paid semiannually with the first semiannual installment payable on the date of our annual meeting of stockholders or, if no annual meeting occurs in a given year, May 1, and the second semiannual installment payable on November 1 of each year.

*Election to Receive Stock Options in Lieu of Cash Payments.* All non-employee directors may elect to convert a Retainer Cash Payment into a nonstatutory stock option, or a Retainer Option, with a grant date fair value equal to the applicable Retainer Cash Payment. Each Retainer Option will be granted on the date that the applicable Retainer Cash Payment was scheduled to be paid, and all of the shares underlying the Retention Option will vest and become exercisable one year from the date of grant, subject to continued service as a director through the applicable vesting date. The Retainer Option will be subject to certain terms and conditions as described below under the section titled Equity Compensation.

Elections to convert a Retainer Cash Payment into a Retainer Option must generally be made on or prior to December 31 of the year prior to the year in which the Retainer Cash Payment is scheduled to be paid, or such earlier deadline as is established by our board of directors or compensation committee. A newly appointed non-employee director will be permitted to elect to convert Retainer Cash Payments payable in the same calendar year into Retainer Options, provided that such election is made prior to the date the individual becomes a non-employee director.

*Equity Compensation.* Nondiscretionary, automatic grants of nonstatutory stock options will be made to our non-employee directors.

- *Initial option.* Each person who first becomes a non-employee director will be granted an option to purchase shares having a grant date fair value equal to $115,000, or the Initial Option. The Initial Option will be granted on the date of the first meeting of our board of directors or compensation committee occurring on or after the date on which the individual first became a non-employee director. The shares underlying the Initial Option will vest and become exercisable as to one thirty-sixth (1/36th) of the shares subject to such Initial Option on each monthly anniversary of the commencement of the non-employee director s service as a director, subject to the continued service as a director through the applicable vesting date.

- *Annual Option.* On the date occurring once each calendar year on the same date that our board of directors grants annual equity awards to our senior executives, each non-employee director will be granted an option to purchase shares having a grant date fair value equal to $75,000, or the Annual Option. All of the shares underlying the Annual Option will vest and become exercisable one year from the date of grant, subject to continued service as a director through the applicable vesting date.

The exercise price per share of each stock option granted under our outside director compensation policy, including Retainer Options, Initial Options and Annual Options, will be the fair market value of a share of our common stock, as determined in accordance with our 2015 Equity Incentive Plan, which we refer to as the 2015 Plan, on the date of the option grant. The grant date fair value is computed in accordance with the

Black-Scholes option valuation methodology or such other methodology as our board of directors or compensation committee may determine.

Any stock option granted under our outside director compensation policy will fully vest and become exercisable in the event of a change in control, as defined in our 2015 Plan, provided that the optionee remains a director through such change in control. Further, our 2015 Plan provides that in the event of a merger or change in control, as defined in our 2015 Plan, each outstanding equity award granted under our 2015 Plan that is held by a non-employee director will fully vest, all restrictions on the shares subject to such award will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels, and all of the shares subject to such award will become fully exercisable, if applicable, provided such optionee remains a director through such merger or change in control.

*Compensation for Fiscal Year 2016*

The following table sets forth a summary of the compensation received by our non-employee directors who received compensation during our fiscal year ended December 31, 2016:

Table of Contents

| Name | Fees earned or paid in cash(1) | Option awards (2)(3) | Total |
|---|---|---|---|
| James G. Cullen | $ 82,500 | $ 75,000 | $ 157,500 |
| Thomas J. Fogarty(4) | $ 40,000 | $ 75,000 | $ 115,000 |
| Donald A. Lucas | $ 67,500 | $ 75,000 | $ 142,500 |
| James B. McElwee | $ 65,000 | $ 75,000 | $ 140,000 |

(1) Messrs. Cullen and Lucas respectively elected to convert $62,500 and $33,750 of their Retainer Cash Payments for 2016 into Retainer Options.

(2) During 2016, all non-employee directors received an Annual Option grant.

(3) As of December 31, 2016, Messrs. Cullen, Lucas, McElwee and Dr. Fogarty had outstanding options to purchase a total of 61,212, 54,620, 43,888 and 37,222 shares of our common stock, respectively.

(4) Dr. Fogarty resigned from our board of directors in August 2017.

Directors who are also our employees receive no additional compensation for their service as directors. During 2016, John B. Simpson and Jeffrey M. Soinski, two of our directors, were also our employees. See Executive Compensation Fiscal 2016 Summary Compensation Table for additional information about the compensation for Dr. Simpson and Mr. Soinski.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC reports regarding their ownership and changes in ownership of our securities. We believe that, during fiscal 2016, our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements.

Table of Contents

## EXECUTIVE COMPENSATION

### Processes and Procedures for Compensation Decisions

Our compensation committee is responsible for the executive compensation programs for our executive officers and reports to our board of directors on its discussions, decisions and other actions. Our compensation committee reviews and approves corporate goals and objectives relating to the compensation of our Chief Executive Officer, evaluates the performance of our Chief Executive Officer in light of those goals and objectives and determines and approves the compensation of our Chief Executive Officer based on such evaluation. Our compensation committee has the sole authority to determine our Chief Executive Officer s compensation. In addition, our compensation committee, in consultation with our Chief Executive Officer, reviews and approves all compensation for other officers, including the directors. Our Chief Executive Officer and Chief Financial Officer also make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee.

The compensation committee is authorized to retain the services of one or more executive compensation and benefits consultants or other outside experts or advisors as it sees fit, in connection with the establishment of our compensation programs and related policies.

### Fiscal 2016 Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our Chief Executive Officer and our two other most highly compensated executive officers in our fiscal year ended December 31, 2016. The individuals listed in the table below are our named executive officers for our fiscal year ended December 31, 2016.

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Awards ($)(1) | Option Awards ($)(1) | Non-Equity Incentive Plan Compensation ($) | All Other Compensation ($)(3) | Total ($) |
|---|---|---|---|---|---|---|---|---|
| John B. Simpson, Ph.D., M.D.(2) | 2016 | 390,000 | | 342,511 | 334,360 | 91,134 | | 1,158,005 |
| *Executive Chairman* | 2015 | 335,000 | | | | 141,841 | | 476,841 |
| Jeffrey M. Soinski(2) | 2016 | 390,000 | | 342,511 | 334,360 | 91,134 | 105,891 | 1,263,896 |
| *President and Chief Executive Officer* | 2015 | 375,000 | | | | 114,000 | 3,000 | 492,000 |
| Matthew B. Ferguson | 2016 | 300,000 | | 143,043 | 139,286 | 56,083 | 3,000 | 641,412 |
| *Chief Financial Officer and Chief Business Officer* | 2015 | 275,000 | | | | 62,699 | 3,000 | 340,699 |

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officer in 2015 and 2016, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in the section of our Annual Report on Form 10-K titled Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-Based

Compensation.

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

(3) The amounts reported for Mr. Soinski represent reimbursed relocation expenses, of $102,891 for 2016, pursuant to his employment offer letter and funds contributed to his health savings account of $3,000 for each of 2015 and 2016. The amount reported for Mr. Ferguson represents funds contributed to his health savings account.

Table of Contents

**Executive Employment Letters**

***John B. Simpson***

We entered into an employment offer letter in November 2014 with John B. Simpson. The letter has no specific term and provides for at-will employment. The letter does not provide for any bonus. Effective January 1, 2016, Dr. Simpson s annual base salary is $390,000.

***Jeffrey M. Soinski***

We entered into an employment offer letter in December 2014 with Jeffrey M. Soinski, our President and Chief Executive Officer. The letter has no specific term and provides for at-will employment. The letter also provides that, in 2015, Mr. Soinski is eligible to receive an annual performance bonus of up to 40% of his annual salary based on the achievement of certain goals mutually agreed upon by him and our board of directors. Effective January 1, 2016, Mr. Soinski s annual base salary is $390,000 and his target bonus percentage was increased from 40% to 50%.

Pursuant to Mr. Soinski s employment offer letter, if, within the 12-month period following a change in control, we terminate Mr. Soinski s employment without cause, or Mr. Soinski resigns for good reason (as such terms are defined in Mr. Soinski s employment offer letter), Mr. Soinski will receive accelerated vesting as to 100% of his outstanding unvested stock options. If we experience a change in control, and Mr. Soinski remains our employee through such date, Mr. Soinski will receive accelerated vesting as to 50% of his outstanding unvested stock options and/or restricted stock.

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

The letter provided that Mr. Soinski receive payments or reimbursements from us for up to $30,000 of reasonable and documented expenses related to temporary lodging, travel, and commuting costs incurred by Mr. Soinski prior to August 2015 in connection with his transition from Utah to Redwood City, California, and reimbursements of up to $100,000 related to the sale of Mr. Soinski s home in Utah and relocation to California. All relocation benefits owed to Mr. Soinski have been paid, as is more fully described above under Fiscal 2016 Summary Compensation Table, and no further obligations exist under these provisions.

***Matthew B. Ferguson***

We entered into an employment offer letter in December 2010 with Matt Ferguson, our Chief Financial Officer and Chief Business Officer. The letter has no specific term and provides for at-will employment. The letter did not provide for any bonus. Effective January 1, 2016, Mr. Ferguson s annual base salary is $300,000.

**401(k) Plan**

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. We may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. To date, we have not made any matching or profits sharing contributions into the 401(k) plan. All participants interests in our matching and profit sharing contributions, if any, vest pursuant to a four-year graded vesting schedule from the time of contribution. Pre-tax contributions are allocated to each participant s individual account and are then invested in selected investment alternatives according to the participants directions. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan, and all contributions are deductible by us when made.

**Pension Benefits and Nonqualified Deferred Compensation**

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2016.

**Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding equity awards held by our named executive officers at December 31, 2016.

Table of Contents

| | | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options (#) Exercisable (3) | Number of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price ($)(4) | Option Expiration Date | Number of Shares or Units of Stock That Have Not Vested (#) | Market Value of Shares or Units of Stock That Have Not Vested ($)(5) |
| John B. Simpson | 5/1/2013(1)(6) | 28,888 | | 22.50 | 5/1/2018 | | |
| | 12/31/2014(1)(7) | 838,250 | | 4.95 | 12/31/2024 | | |
| | 3/7/2016(1)(7) | | 60,000 | 12.96 | 3/7/2026 | | |
| | 3/7/2016(2)(8) | | | | | 30,000 | 111,000 |
| Jeffrey M. Soinski | 12/31/2014(1)(7) | 619,385 | | 4.50 | 12/31/2024 | | |
| | 3/7/2016(1)(7) | | 60,000 | 12.96 | 3/7/2026 | | |
| | 3/7/2016(2)(8) | | | | | 30,000 | 111,000 |
| Matthew B. Ferguson | 7/29/2011(1)(9) | 33,965 | | 12.60 | 7/29/2021 | | |
| | 5/1/2013(1)(6) | 6,816 | | 20.25 | 5/1/2023 | | |
| | 12/31/2014(1)(7) | 95,482 | | 4.50 | 12/31/2024 | | |
| | 3/3/2016(1)(7) | | 25,000 | 12.99 | 3/3/2026 | | |
| | 3/3/2016(2)(8) | | | | | 12,500 | 46,250 |

(1) Each of the outstanding equity awards was granted pursuant to our 2009 Stock Plan. Effective as of January 29, 2015, no additional awards will be granted under the 2009 Stock Plan, and all awards granted under the 2009 Stock Plan that are repurchased, forfeited, expire, are cancelled or otherwise not issued will become available for grant under the 2015 Plan in accordance with its terms.

(2) Each of the outstanding equity awards was granted pursuant to our 2015 Equity Incentive Plan.

(3) All of our options granted pursuant to our 2009 Stock Plan are early exercisable subject to the Company s right to repurchase any unvested shares.

(4) This column represents the fair value of a share of our common stock on the date of grant, as determined by our board of directors.

(5) This column represents the market value of the unvested shares of our common stock underlying the RSUs as of December 30, 2016, based on the closing price of our common stock, as reported on the Nasdaq Global Select Market, of $3.70 per share.

(6) 25% of the shares of our common stock subject to this option vested on January 1, 2014, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.

(7) 25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.

(8) 25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, and the balance vests in 3 successive equal annual installments, subject to continued service through each such vesting date.

(9) 25% of the shares of our common stock subject to this option vested on December 31, 2011, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.

**Potential Payments upon Termination or Change of Control**

In March 2012, we entered into change of control and severance agreements with each of John B. Simpson and Matt Ferguson that superseded all previous severance and change of control arrangements we had entered into with these employees. Under each of these agreements, if, within the 18 month period following a change of control, we terminate the employment of the applicable employee other than for cause, death or disability, or the employee resigns for good reason (as such terms are defined in the employee s employment agreement) and, within 60 days following the employee s termination, the employee executes an irrevocable separation agreement and release of claims, the employee is entitled to receive (i) continuing payments of severance pay at a rate equal to the employee s base salary and target bonus, as then in effect, for 12 months, (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for employee and employee s dependents for up to 12 months, (iii) accelerated vesting as to 100% of the

Table of Contents

employee s outstanding unvested stock options and/or restricted stock, and (iv) the extension of the post-termination exercise period of any options held by the employee for a period of 1 year. Additionally, if we experience a change in control, 50% of the employee s outstanding unvested stock options and/or restricted stock will vest.

Potential payments upon termination or change of control for Mr. Soinski are described above, see Executive Employment Letters.

**Executive Incentive Compensation Plan**

Our board of directors has adopted an Executive Incentive Compensation Plan, or the Bonus Plan, that is administered by our compensation committee. The Bonus Plan allows our compensation committee to provide cash incentive awards to selected employees, including our named executive officers, based upon performance goals established by our compensation committee.

Under the Bonus Plan, our compensation committee determines the performance goals applicable to any award, which goals may include, without limitation: attainment of research and development milestones, sales bookings, business divestitures and acquisitions, cash flow, cash position, earnings (which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation and amortization and net earnings), earnings per share, net income, net profit, net sales, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total stockholder return, working capital, and individual objectives such as peer reviews or other subjective or objective criteria. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

Our compensation committee may, in its sole discretion and at any time, increase, reduce or eliminate a participant s actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant s target award, in the compensation committee s discretion. Our compensation committee may determine the amount of any reduction on the basis of such factors as it deems relevant, and it is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards are paid in cash only after they are earned, which usually requires continued employment through the date a bonus is paid. Our compensation committee has the authority to amend, alter, suspend or terminate the Bonus Plan provided such action does not impair the existing rights of any participant with respect to any earned bonus.

**Equity Compensation Plan Information**

All of our equity compensation plans have been approved by our stockholders. 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 Securities Reflected in Column (a)) |
|---|---|---|---|
| Equity compensation plans approved by stockholders (1) | 6,074,304 | $ 9.60 | 1,727,816 |

Table of Contents

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

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

Table of Contents

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our capital stock as of October 15, 2017 for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors and nominees for director; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of our capital stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 31,539,117 shares of our common stock outstanding as of October 15, 2017. In computing the number of shares of capital stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of our capital stock subject to options held by the person that are currently exercisable or exercisable within 60 days of October 15, 2017. However, we did not deem such shares of our capital stock outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Avinger, Inc., 400 Chesapeake Drive, Redwood City, California 94063. The information provided in the table is based on our records, information filed with the SEC and information provided to us, except where otherwise noted.

| | Shares Beneficially Owned | |
|---|---|---|
| **Name of Beneficial Owner** | **Number of Shares** | **Percentage** |
| **5% and Greater Stockholders** | | |

| | | |
|---|---|---|
| Entities affiliated with John B. Simpson(1) | 2,278,229 | 7.0% |
| | | |
| **Named Executive Officers and Directors** | | |
| Jeffrey M. Soinski(2) | 718,679 | 2.2% |
| John B. Simpson, Ph.D., M.D.(1) | 2,278,229 | 7.0% |
| Matthew Ferguson(3) | 188,405 | * |
| James G. Cullen(4) | 173,010 | * |
| Donald A. Lucas(5) | 77,849 | * |
| James B. McElwee(6) | 20,611 | * |
| All executive officers and directors as a group (8 individuals)(7) | 3,885,761 | 12.3% |

* Represents ownership of less than 1%

(1) Consists of (i) 7,541 shares of common stock held of record by Dr. Simpson, (ii) 893,388 shares subject to options to purchase common stock that were fully exercisable within 60 days of October 15, 2017 held of record by Dr. Simpson, (iii) 1,074,130 shares of common stock held of record by the Simpson Family Trust Dated 1/12/90, for which Dr. Simpson and his spouse serve as trustees, (iv) 222,220 shares subject to warrants to purchase common stock held of record by the Simpson Family Trust Dated 1/12/90, for which Dr. Simpson and his spouse serve as trustees, (v) 47,618 shares of common stock held of record by Dr. Simpson s spouse and (vi) 33,332 shares subject to warrants to purchase common stock held of record by Dr. Simpson s spouse. Dr. Simpson has shared voting and dispositive power with respect to shares held by the Simpson Family Trust Dated 1/12/90 and Dr. Simpson s spouse.

Table of Contents

(2) Consists of (i) 67,044 shares of common stock held of record by Mr. Soinski and (ii) 645,635 shares issuable upon exercise of options exercisable within 60 days of October 15, 2017.

(3) Consists of (i) 31,552 shares of common stock held of record by Mr. Ferguson, (ii) warrants to purchase 9,653 shares of common stock and (iii) 147,200 shares of common stock issuable upon exercise of options exercisable within 60 days of October 15, 2017.

(4) Consists of (i) 73,835 shares of common stock held by Gilbert Investments, LLC, (ii) warrants to purchase 24,862 shares of common stock held by Gilbert Investments, LLC, (iii) 13,101 shares held by 2000 James Cullen Generation Skipping Family Trust and (iv) 61,212 shares of common stock issuable upon exercise of options exercisable within 60 days of October 15, 2017. Mr. Cullen has sole voting and dispositive power with respect to shares held by Gilbert Investments, LLC and James Cullen Generation Skipping Family Trust. Mr. Cullen does not have a pecuniary interest in the James Cullen Generation Skipping Family Trust and disclaims beneficial ownership in Gilbert Investments, LLC except to the extent of his pecuniary interest therein.

(5) Consists of (i) 23,229 shares of common stock held of record by Lucas Venture Group III, LP and (ii) 54,620 shares of common stock issuable upon exercise of options exercisable within 60 days of October 15, 2017.

(6) Consists of (i) 15,090 shares of common stock held of record by Mr. McElwee, (ii) warrants to purchase 5,521 shares of common stock and (iii) 43,888 shares issuable upon exercise of options exercisable within 60 days of October 15, 2017.

(7) Consists of (i) 1,666,596 shares of common stock outstanding, (ii) warrants to purchase 313,909 shares of common stock (iii) 2,156,560 shares issuable upon exercise of options exercisable within 60 days of October 15, 2017.

Table of Contents

## RELATED PERSON TRANSACTIONS

We describe below transactions and series of similar transactions, since the beginning of our last fiscal year, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and

- any of our directors, nominees for director, executive officers or beneficial holders of more than 5% of our outstanding common stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities (each, a related person), had or will have a direct or indirect material interest.

**Master Consulting Agreement**

We entered into a Master Consulting Agreement in November 2013 with Recreation, Inc., a brand strategy and design agency, for marketing services. John D. Simpson is the founder and was the Chief Executive Officer of Recreation at the time we entered into the Master Consulting Agreement and until March 2017, was also our Senior Vice President, Sales and Marketing. Pursuant to this Consulting Agreement, as amended, the Statement of Work in effect from March 2015 through February 2016 and Statement of Work No. 2 in effect from June 1, 2016 through December 31, 2016, Recreation provided marketing services to us at a fixed $35,000 per month fee with an aggregate cap of $245,000 for the contract period. Under the prior Statement of Work in effect from March 2015 through February 2016, Recreation provided marketing services to us at a fixed $20,000 per month fee for the first 100 hours of services performed in such month, with any excess hours within such month charged at an hourly rate of $200 per hour, subject to our written approval. The total amount we paid to Recreation in 2016 was $697,000.

**Master Services Agreement**

We entered into a Master Services Agreement effective September 1, 2015 ( MSA ) with Consensys Imaging Service, Inc. ( Consensys ). Jeffrey M. Soinski, our President, Chief Executive Officer and member of our Board of Directors was also a member of the Board of Directors of Consensys until October 2017. Under the MSA, we may enter into any number of Statements of Work, each of which is governed by the general terms of the MSA. We entered into a Statement of Work effective as of January 15, 2016, pursuant to which Consensys provides field engineers to assist with the installation, service and maintenance of our Lightbox consoles for a fixed fee depending on the type of service. The Statement of Work has no expiration date and remains in effect. The total amount we paid to Consensys in 2016 was $123,000.

**Employment of Related Persons**

Through March 2017, we employed John D. Simpson most recently as our Senior Vice President, Sales and Marketing, who is the son of John B. Simpson, our Executive Chairman. Mr. Simpson became an employee in August 2009, and in this capacity Mr. Simpson s compensation totaled $338,000 in 2016. We believe that Mr. Simpson s compensation was comparable with compensation paid to other employees with similar levels of responsibility and years of experience.

**Other Transactions**

We have entered into employment arrangements with certain current and former executive officers. See Executive Compensation Executive Officer Employment Letters.

We have entered into indemnification agreements with our directors and executive officers. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law.

**Policies and Procedures for Related Party Transactions**

Our board of directors has adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock or any member of the immediate family of any of the foregoing persons in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person s interest in the transaction.

Table of Contents

## DESCRIPTION OF SECURITIES

The following description summarizes the most important terms of our capital stock and does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which documents are incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and the applicable provisions of the Delaware General Corporation Law (the DGCL ).

### General

Our authorized capital stock consists of one hundred million (100,000,000) shares of common stock, $0.001 par value per share, and five million (5,000,000) shares of undesignated preferred stock, $0.001 par value per share.

### Common Stock

#### *Outstanding Shares*

On October 15, 2017, there were 31,539,117 shares of common stock outstanding, held of record by 188 stockholders. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

As of October 15, 2017, there were 2,152,117 shares of common stock subject to outstanding warrants, and 3,585,745 shares of common stock subject to outstanding options.

#### *Dividend Rights*

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. We have never declared or paid cash dividends on any of our capital stock and currently do not anticipate paying any cash dividends after this offering or in the foreseeable future.

#### *Voting Rights*

There are 100,000,000 shares of common stock authorized for issuance. Pursuant to our amended and restated certificate of incorporation, each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of stockholders; provided, however, that, except as otherwise required by law, holders of our common stock, as such, shall not be entitled to vote on any amendment to our amended and restated certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to our amended and restated certificate of incorporation. Pursuant to our amended and restated certificate of incorporation and amended and restated bylaws, corporate actions can generally be taken by a majority of our board and/or stockholders holding a majority of our outstanding shares, except as otherwise indicated in the section entitled Anti-takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws, where certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws require the vote of at least 662/3% of our then outstanding voting securities. Additionally, our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a plurality of the votes cast at a meeting of stockholders will be able to elect all of the directors then standing for election.

***Right to Receive Liquidation Distributions***

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our

Table of Contents

common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering, when paid for, will be fully paid and nonassessable.

**Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock by us could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of our company or other corporate action. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

**Stock Options**

As of June 30, 2017, there were 4,071,506 shares of our common stock issuable upon exercise of outstanding stock options, at a weighted-average exercise price of $6.29 per share.

**Warrants**

As of June 30, 2017, we had outstanding warrants to purchase an aggregate of 2,152,117 shares of our common stock at an exercise price of $12.60 per share. These warrants are immediately exercisable and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control.

**Exclusive Jurisdiction**

Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for:

- any derivative action or proceeding brought on behalf of us;

- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders;

- any action asserting a claim against us arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws;

- any action asserting a claim against us governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

**Registration Rights Under our Amended and Restated Investors Rights Agreement**

The holders of an aggregate of up to 2,270,729 shares of our common stock, as of October 15, 2017, including shares of common stock issuable upon the exercise of outstanding options and warrants, or their permitted transferees, are entitled to rights with respect to the registration of such shares under the Securities Act. We refer to these shares as registrable securities. These rights are provided under the terms of our amended and restated investors rights agreement between us and the holders of registrable securities, and include demand registration rights, piggyback registration rights and Form S-3 registration rights.

Table of Contents

These registration rights will terminate as to a given holder of registrable securities upon the earliest of (a) five (5) years following the consummation of our initial public offering (b) such time after our initial public offering at which such holder (i) can sell all shares held by it in compliance with Rule 144(b)(1)(i) or (ii) holds one percent (1%) or less of our outstanding Common Stock and all registrable securities held by such holder can be sold in any three (3) month period without registration in compliance with Rule 144 or (c) after the consummation of a Liquidation Event, as that term is defined in our amended and restated certificate of incorporation.

Generally, we are required to pay the registration expenses (other than underwriters and brokers discounts and commissions) in connection with the registrations described below, including the reasonable fees and disbursements of one counsel for the selling holder or holders of registrable securities. In an underwritten offering, the underwriters have the right to limit the number of shares registered by the holders of registrable securities for marketing reasons, subject to certain limitations.

***Demand Registration Rights***

Upon the written request of 50% or more of the then outstanding registrable securities that we file a registration statement under the Securities Act (provided that the anticipated aggregate offering price of such shares is greater than $25 million), we will be obligated to notify all holders of registrable securities of such request and to use our reasonable best efforts to register the sale of all registrable securities that holders may request to be registered. We are only obligated to file up to two registration statements which are declared or ordered effective in connection with the exercise of these demand registration rights. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

***Piggyback Registration Rights***

If we propose to register any of our securities under the Securities Act in connection with the public offering of such securities, the holders of registrable securities will be entitled to certain piggyback registration rights allowing such holders to include their shares in such registration, subject to certain limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to either to the sale of securities to our employees pursuant to a stock plan, stock purchase or similar plan or a registration related to a corporate reorganization or transaction under Rule 145 of the Securities Act of registrable securities are entitled to notice of the registration and have the right to include their shares in the registration. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances.

***Form S-3 Registration Rights***

Upon the written request from the holders of at least 30% of the outstanding shares of registrable securities, holders of registrable securities have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of shares to be offered and sold under such registration statement on Form S-3 is at least $5 million (net of any underwriters discounts or commissions). We are not required to effect a registration on Form S-3 if we have already effected two registrations on Form S-3 for the holders pursuant to Form S-3 registration rights within the twelve-month period preceding the date of the request. Additionally, we are not required to effect such registration in any jurisdiction in which we would be required to qualify to do business or execute a general consent of process in effecting such registration.

**Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Table of Contents

***Delaware Law***

We are governed by the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns, or within three years of the date on which it is sought to be determined whether such person is an interested stockholder, did own, 15% or more of the corporation s outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaw Provisions***

Our amended and restated certificate of incorporation and our amended and restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our management team, including the following:

- *Board of directors vacancies.* Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by our board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- *Classified board.* Our amended and restated certificate of incorporation and amended and restated bylaws provide that our board is classified into three classes of directors. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

- *Stockholder action; special meeting of stockholders.* Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock may not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws. Our amended and restated bylaws further provide that special meetings of our stockholders may be called only by our board of directors, the Chairman of our Board of Directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance notice requirements for stockholder proposals and director nominations*. Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder s notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer s own slate of directors or otherwise attempting to obtain control of our company.

- *No cumulative voting.* The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation s certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation does not provide for cumulative voting.

- *Directors removed only for cause*. Our amended and restated certificate of incorporation provides that stockholders may remove directors only for cause.

- *Amendment of charter provisions*. Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least 662/3% of the voting power of our then outstanding voting securities.

Table of Contents

- *Issuance of undesignated preferred stock*. Our board of directors will have the authority, without further action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare, N.A. The transfer agent and registrar s address is 250 Royall Street, Canton, MA 02021. Our shares of common stock are issued in uncertificated form only, subject to limited circumstances.

**Market Listing**

Our common stock is listed on The NASDAQ Global Market under the symbol AVGR.

Table of Contents

**PLAN OF DISTRIBUTION**

The common stock offered by this prospectus may be sold by the Selling Stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the Selling Stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- at the market into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state s registration or qualification requirement is available and complied with.

Lincoln Park is an underwriter within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of the shares offered by this prospectus may receive compensation in the form of commissions, discounts, or concessions from the purchasers, for whom the broker-dealers may act as agent, of the common stock sold by Lincoln Park through this prospectus. The compensation paid to any such particular broker-dealer by any such purchasers of common stock sold by Lincoln Park may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of

compensation that any agent will receive from any purchasers of common stock sold by Lincoln Park.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus.

We may from time to time file with the SEC one or more supplements to this prospectus or amendments to the registration statement of which this prospectus forms a part to amend, supplement or update information contained in this prospectus, including, if and when required under the Securities Act, to disclose certain information relating to a particular sale of shares offered by this prospectus by the Selling Stockholder, including the names of any brokers, dealers, underwriters or agents participating in the distribution of such shares by the Selling Stockholder, any compensation paid by Lincoln Park to any such brokers, dealers, underwriters or agents, and any other required information.

We will pay the expenses incident to the registration under the Securities Act of the offer and sale of the shares covered by this prospectus by Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which

Table of Contents

establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park.

Our common stock is quoted on The NASDAQ Global Market under the symbol AVGR .

Table of Contents

## LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California will pass upon certain legal matters relating to the issuance of the securities offered by this prospectus. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, P.C. own an interest representing less than 1% of the shares of our common stock.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2016 and 2015, and for each of the two years in the period ended December 31, 2016, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company s ability to continue as a going concern as described in Note 1 to the financial statements) which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC s website at http://www.sec.gov. You may also read and copy any document we file at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge through the Internet. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We have filed with the SEC a registration statement, of which this prospectus forms a part, under the Securities Act of 1933 relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under Information Incorporated by Reference are also available on our Internet website, www.avinger.com. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

## INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except for any information that is superseded by other information that is included in this prospectus.

We incorporate by reference the documents listed below that we have previously filed with the SEC (excluding any portions of any Form 8-K that are not deemed filed pursuant to the General Instructions of Form 8-K):

- our Annual Report on Form 10-K, for the year ended December 31, 2016, filed with the SEC on March 15, 2017;

- the information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, from our definitive proxy statement on Schedule 14A which was filed on April 25, 2017;

- our Quarterly Report on Form 10-Q, for the quarter ended March 31, 2017, filed with the SEC on May 10, 2017;

- our Quarterly Report on Form 10-Q, for the quarter ended June 30, 2017, filed with the SEC on August 9, 2017;

- our Quarterly Report on Form 10-Q, for the quarter ended September 30, 2017, filed with the SEC on November 14, 2017;

- our Current Reports on Form 8-K filed with the SEC on April 24, 2017, May 31, 2017, June 15, 2017, August 8, 2017, October 16, 2017, October 23, 2017, October 27, 2017, November 6, 2017 and November 9, 2017, only to the extent that the items therein are specifically stated to be filed rather than furnished for the purposes of Section 18 of the Exchange Act; and

- the description of our common stock set forth in our registration statement on Form 8-A, filed with the SEC on January 27, 2015, including any amendment or report filed for the purpose of updating such description.

Table of Contents

We also incorporate by reference into this prospectus additional documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits on such form that are related to such items) that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information deemed furnished and not filed with the SEC.

Any statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained herein or in any subsequently filed document that is also incorporated by reference in this prospectus modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

We will provide to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this prospectus.

Requests for such documents should be directed to:

Avinger, Inc.

400 Chesapeake Drive

Redwood City, CA 94063

Attention: Secretary

You may also access the documents incorporated by reference in this prospectus through our website at www.avinger.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

Table of Contents

**up to 9,950,000 Shares**

**of Common Stock**

---

**PROSPECTUS**

---

**November 17, 2017**