

Avinger Inc

Form 424B4

October 30, 2018

**Filed Pursuant to Rule 424(b)(4)**

**Registration No. 333-227689**

**3,535,000 Class A Units consisting of common stock and warrants and**

**8,586 Class B Units consisting of shares of Series C preferred stock and warrants**

**(and 46,465,000 shares of common stock underlying shares of Series C preferred stock and warrants)**

Avinger, Inc. is offering 3,535,000 Class A Units, with each Class A Unit consisting of one share of common stock, par value \$0.001 per share, or the common stock, and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the Class A Units) at a public offering price of \$0.40 per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of common stock at an exercise price per share of \$0.40.

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, if they so choose, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%), 8,586 Class B Units. Each Class B Unit consists of one share of Series C preferred stock, par value \$0.001 per share, or the Series C preferred stock, convertible into 2,500 shares of common stock and warrants to purchase 2,500 shares of our common stock (together with the shares of common stock underlying such shares of Series C preferred stock and such warrants, the "Class B Units" and, together with the Class A Units, the "units") at a public offering price of \$1,000 per Class B Unit and a Series C preferred stock conversion price of \$0.40 per share. Each warrant included in the Class B Units entitles its holder to purchase 2,500 shares of common stock at an exercise price per share of \$0.40.

The Class A Units and Class B Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of common stock, Series C preferred stock and warrants comprising such units are immediately separable and will be issued separately in this offering. The warrants offered hereby may be exercised from time to time beginning on the closing date of this offering and expire on the five year anniversary of the closing. The underwriter has the option to purchase up to 3,750,000 additional shares of common stock and/or warrants to purchase up to 3,750,000 shares of common stock solely to cover overallocments, if any, at the price to the public less the underwriting discounts and commissions. The overallocation option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series C preferred stock) and warrants sold in the primary offering. The

overallotment option is exercisable for 45 days from the date of this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol “AVGR”. The closing price of our common stock on October 29, 2018, as reported by The Nasdaq Capital Market, was \$0.59 per share. We do not intend to apply for listing of the warrants offered hereby or the shares of Series C preferred stock on any securities exchange or trading system.

**Investing in our securities involves a high degree of risk. Before making any investment in these securities, you should consider carefully the risks and uncertainties in the section entitled “Risk Factors” beginning on page 11 of this prospectus, any applicable prospectus supplement and in any applicable free writing prospectuses, and under similar headings in the documents that are incorporated by reference into this prospectus.**

|   | <b>Per<br/>Class<br/>A Unit</b> | <b>Per Class<br/>B Unit</b> | <b>Total</b>    |
|---|---------------------------------|-----------------------------|-----------------|
| Public offering price(1)                    | \$0.400                         | \$1,000.00                  | \$10,000,000.00 |
| Underwriting discount(2)(3)                 | \$0.032                         | \$80.00                     | \$800,000.00    |
| Proceeds, before expenses, to Avinger, Inc. | \$0.368                         | \$920.00                    | \$9,200,000.00  |

(1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$0.3588 and (ii) a public offering price per warrant of \$0.0092 and (y) in respect of the Class B Units (i) a public offering price per share of Series C preferred stock of \$897.00 and (ii) a public offering price per warrant of \$0.0092 per whole share of common stock.

(2) We have also agreed to reimburse for certain expenses. See the section entitled “Underwriting.”

(3) We have granted a 45-day option to the underwriter to purchase up to 3,750,000 additional shares of common stock and/or warrants to purchase up to 3,750,000 shares of common stock (up to 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series C preferred stock) and warrants sold in the primary offering) solely to cover overallotments, if any.

**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 securities are not being offered in any jurisdiction where the offer is not permitted.**

The underwriter expects to deliver the securities to purchasers in the offering on or about November 1, 2018.

*Sole Book-Running Manager*

**Ladenburg Thalmann**

**The date of this prospectus is October 30, 2018**

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**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. We have not 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 securities 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 securities.**

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 “Information Incorporated by Reference” in this prospectus.

For investors outside the United States, we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the U.S. Persons who come into possession of this prospectus and any free writing prospectus related to this offering in jurisdictions outside the U.S. are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.



## PROSPECTUS SUMMARY

*This summary description about us and our business highlights selected information contained elsewhere in this prospectus supplement or the accompanying prospectus, or incorporated in this prospectus supplement or the accompanying prospectus by reference. This summary does not contain all of the information you should consider before buying securities in this offering. You should carefully read this entire prospectus supplement and the accompanying prospectus, including each of the documents incorporated herein or therein by reference, before making an investment decision. Unless the context otherwise requires, the terms “Avinger,” “the Company,” “we,” “us” and “our” in this prospectus supplement and accompanying prospectus refer to Avinger, Inc., and its subsidiaries.*

### Company 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. 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 additional 510(k) clearances for enhanced versions of Pantheris in March 2016 and May 2018, and commenced sales of Pantheris in the United States and select European countries promptly thereafter. We also offer the Wildcat and Kittykat 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 Lumivasular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography, or OCT, a high resolution, light-based, radiation-free imaging technology. Our Lumivasular 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 Lumivasular 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 EEL 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 20 VISION sites to re-solicit consent from previous clinical trial patients in order to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the 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 in-stent restenosis.

| <b><u>Name</u></b>              | <b>Clinical Indication</b> | <b>Regulatory Status</b>    | <b>Original Clearance Date</b>  |
|---------------------------------|----------------------------|-----------------------------|---------------------------------|
| <b>NEXT GENERATION PRODUCTS</b> |                            |                             |                                 |
| <b>Pantheris SV</b>             | Atherectomy                | FDA 510(k) filed<br>CE Mark | October 2018                    |
| <b>PRODUCTS</b>                 |                            |                             |                                 |
| <b>Lightbox(1)</b>              | OCT Imaging                | FDA Cleared<br>CE Mark      | November 2012<br>September 2011 |
| <b>Pantheris 3.0</b>            | Atherectomy                | FDA Cleared<br>CE Mark      | May 2018<br>December 2017       |
| <b>Pantheris 8F</b>             | Atherectomy                | FDA Cleared<br>CE Mark      | October 2015<br>June 2015       |
| <b>Pantheris 7F</b>             | Atherectomy                | FDA Cleared<br>CE Mark      | March 2016<br>June 2015         |
| <b>Ocelot(2)</b>                | CTO Crossing               | FDA Cleared<br>CE mark      | November 2012<br>September 2011 |
| <b>Ocelot MVRX(2)</b>           | CTO Crossing               | FDA Cleared                 | December 2012                   |
| <b>Ocelot PIXL(2)</b>           | CTO Crossing               | FDA Cleared<br>CE Mark      | December 2012<br>October 2012   |

We are developing a next-generation version of our Pantheris atherectomy device, Pantheris SV, a lower profile Pantheris, that has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels. We submitted a 510(k) submission for Pantheris SV for smaller vessels in August 2018. We received CE Marking approval for Pantheris SV in October 2018.



We have assembled a team with extensive medical device development and commercialization capabilities. 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 \$10.7 million in 2015, \$19.2 million in 2016, \$9.9 million in 2017, and \$3.9 million for the six months ended June 30, 2018.

## **Recent Developments**

### **Common Stock Offering**

On July 12, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 2,166,180 shares of our common stock at an offering price of \$1.6425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 1,083,091 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately \$3.2 million after deducting placement agent fees and other expenses payable by us and the conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to \$1.58 per share as a result. The warrants have an exercise price of \$1.58 per share of our common stock and may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021.

### **Series B Preferred Stock Financing**

In February 2018, we consummated an \$18 million public offering of a newly authorized Series B convertible preferred stock, or the Series B preferred stock, and warrants to purchase common stock underwritten by Ladenburg Thalmann and Co. Inc.

### **CRG Debt Conversion**

In connection with our February 2018 offering of Series B preferred stock and warrants to purchase common stock, we entered into an agreement with CRG Partners III L.P. and certain of its affiliated funds, which we collectively refer to as CRG, pursuant to which CRG converted \$38.0 million of the outstanding principal amount of our senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock, or the Series A preferred stock.

In connection with this offering, CRG has agreed to suspend the conversion of its Series A convertible preferred stock into common stock until such time as our stockholders have approved an amended and restated certificate of incorporation authorizing at least 125 million shares of common stock. We have created a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, in the form filed as Exhibit 3.7 to the registration statement of which this prospectus forms a part, for filing with the

Secretary of State for the state of Delaware to effect this change. Following the filing of this amendment, the Company has agreed to call a meeting of the Company's stockholders on or before June 30, 2019, and to use reasonable best efforts (including the hiring of a proxy solicitor), to obtain approval from the stockholders of the Company for an amended and restated certificate of incorporation that increases the number of authorized shares to at least 125 million shares (or such larger number of shares as is necessary) in order to allow for the conversion of the outstanding Series A convertible preferred stock into common stock. In this regard, the Company shall include approval of an amended and restated certificate of incorporation as a proposal to be voted on by the stockholders in such stockholders meeting. If such proposal is not approved in the next stockholders meeting the Company shall include a similar proposal on its agenda for following stockholders meetings and continue to use reasonable best efforts to obtain its approval until such proposal is approved.

### **Reverse Stock Split**

In December 2017 and January 2018, our board of directors and stockholders, respectively, approved a reverse stock split of our shares of common stock at a ratio of between one-for-twenty and one-for-forty, with the exact ratio to be chosen within that range at the discretion of our board of directors. On January 30, 2018, we effected a one-for-40 reverse stock split of our shares of common stock, or the 2018 Reverse Stock Split, at the direction of our board of directors. As a result of the 2018 Reverse Stock Split, every forty (40) shares of our common stock outstanding was automatically changed and reclassified into one (1) new share of common stock. Stockholders of fractional shares of common stock otherwise issuable pursuant to the 2018 Reverse Stock Split were paid cash in lieu of such fractional shares. The 2018 Reverse Stock Split did not change the par value of our stock or the number of common shares or preferred shares authorized by our certificate of incorporation. All share and per share amounts in this prospectus have been retroactively adjusted to reflect the 2018 Reverse Stock Split for all periods presented. As of January 31, 2018, we had 877,159 shares of common stock outstanding, as adjusted by the 2018 Reverse Stock Split. The 2017 financial statements incorporated by reference herein have been adjusted to reflect the 2018 Reverse Stock Split.

### **Lincoln Park Purchase Agreement**

We entered into a purchase agreement, or the Purchase Agreement with Lincoln Park Capital Fund, L.P., or Lincoln Park, on November 3, 2017, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of \$15.0 million of our common stock (subject to certain limitations) from time to time over the thirty-month term of the Purchase Agreement. At the time we signed the Purchase Agreement, we issued 23,584 shares of our common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement. Our board of directors unanimously approved this transaction in November 2017, and our stockholders approved the issuance under the Purchase Agreement of more than 19.99% of our outstanding common stock at a special meeting of stockholders on January 29, 2018. The Purchase Agreement may be terminated by us at any time at our discretion without any cost to us. As of the date of this prospectus supplement, we have sold an aggregate of 65,000 shares of our common stock under the Purchase Agreement for approximately \$0.5 million of gross proceeds.

## **Nasdaq Compliance**

As previously disclosed, on April 20, May 24, and October 24, 2017, we received letters from the Listing Qualifications Department of Nasdaq notifying us that we were not in compliance with applicable listing rules. On March 1, 2018, Nasdaq informed us that we had regained compliance with the applicable requirements for listing on the Nasdaq Capital Market.

## **Resale S-1 Registration Statement for July 2018 Warrants**

On September 12, 2018, we filed a registration statement on Form S-1 to fulfill our contractual obligations under a securities purchase agreement that we entered into on July 12, 2018 in a registered direct offering, an aggregate of 2,166,180 shares of our common stock at an offering price of \$1.6425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants, which we refer to as the July 2018 Warrants, exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 1,083,091 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately \$3.2 million after deducting placement agent fees and other expenses payable by us. The conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to \$1.58 per share as a result. The warrants have an exercise price of \$1.58 per share of our common stock, may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021. The registration statement was declared effective by the SEC on September 28, 2018. Subject to certain exceptions, we will be obligated to use our commercially reasonable efforts to keep such registration statement effective until no purchaser owns any July 2018 Warrants or shares issuable upon exercise of the July 2018 Warrants.

## **Preliminary September 30, 2018 Financial Results**

A brief summary of certain of our consolidated preliminary unaudited financial results for the quarter ended September 30, 2018 is set forth below. This summary is not meant to be a comprehensive statement of our consolidated financial results for this period. The following financial data for the quarter ended September 30, 2018 is preliminary and based upon our estimates, and actual results may differ from these estimates following the completion of our financial closing procedures and related adjustments.

In the three and nine months ended September 30, 2018, our revenue is expected to be approximately \$2.0 million and approximately \$5.9 million, respectively, as compared to \$2.1 million and \$8.0 million, respectively, for the three and nine months ended September 30, 2017. In the three and nine months ended September 30, 2018, our net cash used in operating activities is expected to be approximately \$3.5 million and \$14.8 million, respectively, as compared to \$7.0

million and \$29.3 million, respectively, for the three and nine months ended September 30, 2017. As of September 30, 2018, our cash and cash equivalents balance is expected to be approximately \$10.0 million and the principal and interest outstanding under our credit facilities is expected to be approximately \$8.1 million.

You should read this data together with our financial statements and related notes incorporated by reference in this prospectus, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018. The preliminary financial data included in this registration statement has been prepared by, and is the responsibility of, our management. Moss Adams LLP has not audited, reviewed, compiled or performed any procedures with respect to the accompanying preliminary financial data. Accordingly, Moss Adams LLP does not express an opinion or any other form of assurance with respect thereto.

### **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:

• 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.

- 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.

CRG has the right to acquire a significant percentage of our stock upon conversion of its Series A preferred stock and has the ability to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement.

The Series A preferred stock has a liquidation preference senior to our common stock, the Series B preferred stock and the Series C preferred stock.

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

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.

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

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.

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

We have limited long-term data regarding the safety and efficacy of our Lumivasular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivasular 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.

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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.

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

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

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 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.

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

• 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.

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

• 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 Lumivasular platform products.

• 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 Lumivasular platform products.

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

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

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

• Material modifications to our Lumivasular platform products may require new 510(k) clearances or pre-market approvals or may require us to recall or cease marketing our Lumivasular platform products until clearances or approvals are obtained.

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

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

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

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



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

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

Our 2017 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.

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

The Series C preferred stock and warrants are unlisted securities and there is no public market for these securities.

The warrants may not have any value.

## 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 <sup>TM</sup> 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.

## 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 \$1.07 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.

### **Available Information**

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act. We make available on our website at [www.avinger.com](http://www.avinger.com), free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

The information in or accessible through the websites referred to above are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

## THE OFFERING

**Class A Units offered by us** We are offering 3,535,000 Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants).

**Offering price per Class A Unit** \$0.40

**Class B Units offered by us** We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, 8,586 Class B Units. Each Class B Unit consists of one share of Series C preferred stock, par value \$0.001 per share, convertible into a number of shares of common stock equal to 2,500 (at a conversion price of \$0.40 per share) and a warrant to purchase 2,500 shares of our common stock (together with the shares of our common stock underlying such shares of Series C preferred stock and warrants).

**Offering price per Class B Unit** \$1,000

**Overallotment option** The underwriter has the option to purchase up to 3,750,000 additional shares of common stock, and/or warrants to purchase up to 3,750,000 shares of common stock solely to cover overallotments, if any, at the price to the public less the underwriting discounts and commissions. The overallotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series C preferred stock) and warrants sold in the primary offering. The overallotment option is exercisable for 45 days from the date of this prospectus.

**Description of warrants** The warrants will be exercisable beginning on the date of issuance and expire on the five (5) year anniversary of the date of issuance at an initial exercise price per share equal to \$0.40, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.

**Description of Series C preferred stock** Each share of Series C preferred stock is convertible at any time at the holder's option into 2,500 shares of common stock (at a conversion price of \$0.40 per share). Notwithstanding the foregoing, we shall not effect any conversion of Series C preferred stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series C preferred stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For

additional information, see the section entitled “Description of Securities—Preferred Stock.”

|   |                   |
|---|-------------------|
| Shares of<br>common stock<br>outstanding<br>before this<br>offering | 11,554,149 shares |
|---|-------------------|

Shares of common stock  
outstanding after this offering 15,089,149 shares

Shares of Series  
C preferred stock  
outstanding after this offering 8,586 shares

Use of proceeds We estimate that the net proceeds to us from this offering will be approximately \$8.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use net proceeds from this offering for working capital, payment of interest on our debt and general corporate purposes, which may include research and development of our Lumivasular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. 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. See the section entitled “Use of Proceeds” on page 39 of this prospectus.

Risk factors This investment involves a high degree of risk. You should carefully read and consider the information set forth under “Risk Factors” on page 11 of this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.

Nasdaq Capital Market  
common stock symbol AVGR

No listing of Series  
C preferred stock or  
warrants There is no established public trading market for the Series C preferred stock or the warrants, and we do not intend to apply for listing of the shares of the Series C preferred stock or warrants on any securities exchange or trading system. Without an active trading market, the liquidity of the warrants and the Series C preferred stock will be limited.

There were 41,800 shares of Series A preferred stock, 1,701 shares of Series B preferred stock and no shares of Series C preferred stock outstanding prior to this offering. The number of shares of common stock that will be outstanding after this offering is based on 9,305,872 shares outstanding as of June 30, 2018, and excludes:

84,842 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2018 with a weighted average exercise price of \$194.72 per share;

18,825,306 shares of common stock issuable upon exercise of outstanding warrants, including those issuable upon exercise of the July 2018 Warrants;

8,306 unvested restricted stock units;

3,090,775 shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, or our 2015 Plan, and any additional shares that become available under our 2015 Plan pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

27,515 shares of common stock reserved for future issuance under our 2015 Employee Stock Purchase Plan, or ESPP, and any additional shares that become available under our ESPP pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

197,903 shares of common stock reserved for future issuance under our Officer and Director Share Purchase Plan, or ODPP;

- shares of common stock issuable under the Purchase Agreement with Lincoln Park;
- shares of common stock issuable upon conversion of the Series A preferred stock;
- shares of common stock issuable upon conversion of the Series B preferred stock; and
- shares of common stock issuable upon conversion of the Series C preferred stock.

Except as otherwise indicated, all information in this prospectus assumes:

- the issuance of 80,000 shares of common stock to a vendor in July 2018;
- the issuance of 2,166,180 shares of common stock in July 2018;
- the issuance of 2,097 shares of common stock pursuant to our ODPP;
- the “full-ratchet” anti-dilution adjustment of the conversion price of our outstanding Series B preferred stock to \$1.58 in connection with the Private Placement Transaction;
- no exercise of outstanding options and warrants; and
- no exercise of the underwriter’s overallotment option to purchase additional shares of common stock and/or warrants.



## RISK FACTORS

*Investing in our securities 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 the section entitled “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 flows, may vary significantly in the future and period-to-period comparisons of our results of operations 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 cost and potential outcomes of existing and future litigation;

• 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 \$16.1 million for the six months ended June 30, 2018, \$48.7 million in 2017, \$56.1 million in 2016 and \$47.3 million in 2015. As of June 30, 2018, we had an accumulated deficit of approximately \$317.4 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivasular 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 this offering, together with the recently completed offerings of our Series B preferred stock and common stock, our cash and cash equivalents at June 30, 2018 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations for at least the next twelve months. Even though we sold \$18.0 million in Series B preferred stock and warrants in our February 2018 offering, and \$3.5 million of common stock and warrants in our July 2018 offering, we will need to raise additional funds through future equity or debt financings within the next twelve 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 twelve 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 offerings. The warrants issued pursuant to the Series B Purchase Agreement entered into in connection with the Series B preferred stock follow-on in February 2018, or the Series B Offering, prohibit us from entering into certain transactions involving the issuance of securities for a price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case for a period of three years from the closing date of the Series B Offering (and excluding purchases pursuant to the Series B Purchase Agreement, which may be made on the 120 day anniversary of the closing date of the offering). This

prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivasular 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 Lumivasular platform products, particularly Pantheris 3.0 and Pantheris SV, and any future 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 Lumivasular platform products, especially Pantheris and, if necessary, obtaining FDA clearance of such variations;

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

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

• the costs of defending ourselves against existing and future litigation;

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

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

We may raise 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, 2018, we had \$7.8 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, collectively the CRG. This amount reflects the completion of the Series B Offering and CRG's conversion of \$38 million in outstanding principal and interest into Series A preferred stock, or the CRG Conversion. 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.

*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, investments 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 Loan Agreement, as amended, includes a covenant that we maintain a minimum of \$3.5 million of cash and certain cash equivalents, and we will have to achieve minimum revenue of \$15.0 million in 2020, \$20.0 million in 2021 and \$25.0 million in 2022. 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. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended.

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, including in the event of a material adverse change, 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. The existing collateral pledged under the Loan Agreement 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 and are unable to cure the default within the relevant cure period, we would need relief from default or else our creditors could exercise their remedies. There can be no assurance that our debtholders would accord any relief from default. 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.



***We may not be able to generate sufficient cash to service our credit facility with CRG. If we fail to comply with the obligations under our credit facility, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.***

Borrowings under our credit facility are secured by substantially all of our personal property, including our intellectual property. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated. If we fail to comply with our obligations under the Loan Agreement, the lender would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets securing our obligations under the Loan Agreement.

***CRG has the right to acquire a significant percentage of our stock upon conversion of its Series A preferred stock and has the ability to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement.***

Even though Series A preferred stock is non-voting stock, and has beneficial ownership restrictions, the Series A Certificate of Designations has protective provisions that will require CRG to consent to certain significant Company events. For example, CRG's consent would be necessary to create additional shares of Series A preferred stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock.

***The Series A preferred stock has a liquidation preference senior to our common stock, the Series B preferred stock and the Series C preferred stock.***

Series A preferred stock has a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise warrants), the Series B preferred stock and the Series C preferred stock. As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately \$41,800,000 from any such transaction before any amount is paid to the holders of our Series B preferred stock or common stock or pursuant to the

redemption rights in the warrants for fundamental transactions. The payment of the liquidation preferences could result in common stockholders, Series B preferred stockholders, Series C preferred stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. Furthermore, any conversion of Series A preferred stock into common stock will cause substantial dilution to our common stock holders.

***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 current version of Pantheris, Pantheris 3.0, received FDA clearance in May 2018. 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 attempted to address certain of these concerns with Pantheris 3.0. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. 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 Lumivasular 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 Lumivasular 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 the next-generation versions of Pantheris and our other current and future Lumivasular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivasular 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 enhanced versions of Pantheris in March 2016 and May 2018, and those versions of 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 Lumivasular 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. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivasular 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 Lumivasular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivasular 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 Lumivasular platform products. Any studies we may conduct comparing our Lumivasular 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 Lumivasular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivasular 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.***

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.

***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 was (5%) for the three months ended June 30, 2018 compared to (59%) for the three months ended June 30, 2017. Our gross margin was 7% for the six months ended June 30, 2018 compared to (34%) for the six months ended June 30, 2017. Gross margin for the three and six month periods ended June 30, 2017 was negatively impacted by increases in charges related to excess and obsolete Lightbox and Pantheris inventories.

Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. To the extent that our revenue does not grow 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 Lumivasular 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 Lumivasular platform. If physicians do not value the benefits of on-board imaging and the enhanced visualization enabled by our products during an endovascular intervention as compared to our competitor's products, or do not believe that such benefits improve clinical outcomes, our Lumivasular platform products may not be widely adopted.

***The use, misuse or off-label use of the products in our Lumivasular 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 Lumivasular platform products because we market primarily to physicians who are experienced in the interventional techniques required to use our device. If demand for our Lumivasular 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 Lumivasular 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 Lumivasular 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 Lumivasular 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 Lumivasular platform products for these off-label applications. The application of our Lumivasular 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 Lumivasular 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 Lumivasular 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 results of operations.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of our Lumivasular 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 Lumivasular platform products and potential customers may opt against purchasing our Lumivasular 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 Lumivasular platform products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our Lumivasular 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 a next-generation version of our Pantheris atherectomy device, Pantheris SV, a lower profile Pantheris. We anticipate that the lower profile Pantheris will translate into revenue growth and achieve increased physician acceptance. Because we believe new products and enhancements 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 the lower profile Pantheris, is lower than we expect, fail to gain anticipated market acceptance or cause 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.

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 Lumivasular platform from our competitors and their products, and includes such factors as:

• procedural safety and efficacy;

• acute and long-term outcomes;

• ease of use and procedure time;

• price;

• size and effectiveness of sales force;

• radiation exposure for physicians, hospital staff and patients; and

• third-party reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

trouble in managing multiple clinical sites;

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

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

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

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

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

***We have limited long-term data regarding the safety and efficacy of our Lumivasular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivasular 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 Lumivasular 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 Lumivasular 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 Lumivasular platform products. The long-term clinical benefits of procedures that use our Lumivasular platform products, including Pantheris, are not known.

The results of short-term clinical experience of our Lumivasular 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 Lumivasular 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 Lumivasular 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 Lumivasular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivasular 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 Lumivasular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

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

Our current products are cleared in the United States only for crossing sub-total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These clearances prohibit our ability to market or advertise our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off-label uses of medical devices are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use.

We are not allowed to actively promote or advertise our products for off-label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to FDA warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot or Pantheris in the United States for use in other applications for which we do not currently have clearance, such as the coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues.

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

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

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

Because we have only limited experience in manufacturing our Lumivasular 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 Lumivasular 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 Lumivasular platform products.

If we are unable to keep up with demand for our Lumivasular platform products, our revenues could be impaired, market acceptance for our Lumivasular platform products could be harmed and our customers might instead purchase our competitors' products. Our inability to successfully manufacture our Lumivasular 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 Lumivasular platform products and to pursue our research and development efforts may be jeopardized.***

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

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

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

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components;
  - price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;



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

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

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

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

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

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

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

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

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

We educate physicians on the capabilities of our Lumivasular 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 Lumivasular platform products, they may not refer patients to interventional cardiologists, vascular surgeons and interventional radiologists for treatment using our Lumivasular 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 Lumivasular platform products, our ability to increase our revenues may be impaired.

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

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

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 Lumivasular platform internationally, which will limit our potential revenues from our Lumivasular platform products.***

Marketing our Lumivasular 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 Lumivasular 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 Lumivasular platform products or other products internationally.

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

As of December 31, 2017, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of \$258.4 million and \$191.9 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2018 for state purposes. Generally, subject to certain limitations, 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 Capital Fund, LLC, or Lincoln Park, pursuant to the Purchase Agreement, dated as of November 3, 2017, between us and Lincoln Park, or the Purchase Agreement, and the sale of Series B preferred stock and warrants pursuant to the Series B Offering 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. On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Act, was enacted into law with many significant changes to the U.S. tax laws. The Tax Act limits the utilization of NOLs arising in tax years beginning after December 31, 2017 to 80% of taxable income per year. However, existing NOLs that arose in years prior to December 31, 2017 are not affected by these provisions. Our ability to utilize NOLs arising in future tax periods may be limited by the Tax Act.

***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 results of operations.***

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 results of operations. In addition, if an acquired business fails to meet our expectations, our results of operations, 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 Lumivasular 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 Lumivasular 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 Lumivasular platform products or using product names, which would have a significant adverse impact on our business.

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

***We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivasular 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, 2018, we held 21 issued and allowed U.S. patents and had 25 U.S. utility patent applications and 6 PCT applications pending. As of June 30, 2018, we also had 34 issued and allowed patents outside of the United States. As of June 30, 2018, we had 41 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business. We use certain open source software in Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re-engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations.

## **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, results of operations 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, results of operations 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;



pre-marketing 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 pre-marketing 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 obtained 510(k) clearance for Pantheris 3.0 in May 2018, and we submitted for FDA clearance of Pantheris SV in August 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. 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 pre-market approval of new products, new intended uses or modifications to existing products;

- withdrawing 510(k) clearance or pre-market 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 pre-market 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 pre-market 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 pre-market approval. We may not be able to obtain additional 510(k) clearances or pre-market 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 results of operations and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. We plan to make further modifications to the design of Pantheris to enhance cutting efficiency and access smaller vessels. Future versions of Pantheris incorporating these enhancements may require additional regulatory clearances or approvals.

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. BSI, our European Notified Body, inspected our facility in 2014 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. The BSI audit performed in January 2017 resulted in zero non-conformances. We can provide no assurance that we will continue to remain in substantial compliance with the QSR. If the FDA, CDHS or BSI inspect our facility and discover compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility we may be unable to produce our Lumivasular platform products, which would harm our business.

***Our Lumivasular 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 Lumivasular 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 Lumivasular platform products could affect the adoption of our Lumivasular platform and our future revenues.***

Currently, our Lumivasular 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 Lumivasular platform products, they are significantly less likely to use our Lumivasular 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. Although this tax has been suspended through 2019, it is expected to apply to sales of our products in 2020 and thereafter. 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 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 results of operations.

***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 Securities

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

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

• sales of stock by our existing stockholders, including our affiliates;

- market acceptance of our Lumivascular platform and products, including Pantheris;

• the results of our clinical trials;

• changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' and our own estimates;

• the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;

- actual or anticipated fluctuations in our financial condition and results of operations;

• 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. 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 have a significant number of outstanding warrants and shares of convertible preferred stock, some of which contain full-ratchet anti-dilution protection, which may cause significant dilution to our stockholders, have a material adverse impact on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings.***

As of September 30, 2018, we had outstanding 11,554,149 shares of common stock. In addition, as of that date we had outstanding warrants to acquire 18,825,306 shares of common stock and shares of Series B convertible preferred stock convertible into an aggregate of 1,076,582 shares of common stock. The issuance of shares of common stock upon the exercise of warrants or conversion of the Series B preferred stock would dilute the percentage ownership interest of all stockholders, might dilute the book value per share of our common stock and would increase the number of our publicly traded shares, which could depress the market price of our common stock.

In addition, the shares of Series B preferred stock contain full-ratchet anti-dilution provisions which, subject to limited exceptions, would reduce the conversion price of the Series B preferred stock (and increase the number of shares issuable) in the event that we in the future issue common stock, or securities convertible into or exercisable to purchase common stock, at price per share lower than the conversion price then in effect, to such lower price. Of our outstanding 1,701 shares of Series B preferred stock convertible into 1,076,582 shares of common stock at a conversion price of \$1.58 per share contained a full-ratchet anti-dilution provision. Because the public offering price per Class A Unit sold in this offering is lower than \$1.58, the anti-dilution provision will be triggered in connection with this offering will cause shares of our Series B preferred stock convertible before the offering into 1,076,582 shares of common stock at a conversion price of \$1.58 per share to become convertible after the offering into approximately 4,252,500 shares of common stock at a conversion price of \$0.40 per share (the public offering price per Class A Unit in this offering). This full ratchet anti-dilution provision would be triggered by the future issuance by us of shares of our common stock or common stock equivalents at a price per share below the then-conversion price of the Series B preferred stock, subject to limited exceptions.

In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants and shares of Series B preferred stock may cause our common stockholders to be more inclined to sell their shares, which would contribute to a downward movement in the price of our common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our common stock price could encourage investors to engage in short sales of our common stock, which could further contribute to price declines in our common stock. The fact that our stockholders and warrant holders can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, as well as the existence of full-ratchet anti-dilution provisions in our Series B preferred stock, could make it more difficult for us to raise additional funds through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

***The Series C preferred stock and warrants are unlisted securities and there is no public market for them.***

There is no established public trading market for the Series C preferred stock or warrants, and we do not expect a market to develop. In addition, the Series C preferred stock and warrants are not listed, and we do not intend to apply for listing of the Series C preferred stock and warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series C preferred stock and warrants will be limited, and investors may be unable to liquidate their investments in the Series C preferred stock and warrants.

***The warrants may not have any value.***

The warrants will be exercisable for five years from the closing date at an initial exercise price per share of \$0.40. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

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

We have provided in the past and may provide guidance in the future about our business and future results of operations. 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 results of operations. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future results of operations fails to meet expectations of securities analysts, investors or other interested parties, the price of our common stock would decline.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. The analysts who previously published research reports on our stock following our IPO have discontinued coverage. Although one new analyst initiated coverage of our business in March 2018, if additional analysts do not begin regularly publishing reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If our results of operations 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 twelve 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. On February 3, 2016, we filed a universal shelf registration statement, or the 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 200,000 shares of common stock having an aggregate offering value of approximately \$8.7 million between the Shelf Registration Statement’s effectiveness on March 8, 2016 and September 2017. In July 2018, we sold a further 2,166,180 shares of our common stock (excluding the July 2018 Warrants to purchase an additional 1,083,091 shares of our common stock issued in a concurrent private placement) pursuant to the Shelf Registration Statement, for gross proceeds of approximately \$3.5 million. In addition, in August 2016, we issued and sold 200,000 shares of our common stock in our follow-on public offering at a public offering price of \$140.00 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 Shelf Registration Statement. During the year ended December 31, 2016, we sold 27,374 shares of common stock under our “at-the-market” program with Cowen at an average price of \$194.74 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the three and six months ended June 30, 2018, we sold no shares of common stock through the “at-the-market” program. 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 using the Shelf Registration Statement at this time. Accordingly, it was necessary to register the shares sold pursuant to the Purchase Agreement, the CRG Conversion and Series B Purchase Agreement on Form S-1. This has increased our transaction expenses and the number of shares required to be sold to finance our operations.

In addition, pursuant to our Securities Purchase Agreement with CRG, the Shelf Registration Statement also registered for resale 8,705 shares of common stock held by CRG, which may be sold freely in the public market. On November 3, 2017, we also entered into the Lincoln Park Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park is obligated to purchase, at our request, up to \$15.0 million of our common stock over a 30-month period, subject to certain limitations set forth in the Purchase Agreement. The warrants issued in connection with the Series B preferred stock prohibits us from entering into certain transactions involving the issuance of securities for a price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case for a period of three years from the closing date of the Series B Offering, other than purchases pursuant to the Series B Purchase Agreement, which may be made on the 120 day anniversary of the closing date of the Series B Offering. This prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. 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 any 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.

***Our 2017 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 included in its auditors' report on our 2017 financial statements, included in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2018, an explanatory paragraph that substantial doubt exists relating to our ability to continue as a "going concern," meaning that as of the date of the audit report, due to our recurring losses from operations and negative cash flows from operations, substantial doubt regarding our ability to continue as a going concern has not been alleviated. 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 2017 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 results of operations. 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 results of operations. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due

to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.



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

As a result of disclosure of information in this Quarterly Report on Form 10-Q and in filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations 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 results of operations.

***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 \$1.07 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 the Nasdaq Capital Market, which has qualitative and quantitative listing criteria.

On March 1, 2018, we regained compliance with all applicable Nasdaq listing criteria; however, there can be no assurance that we will continue to be compliant with such listing criteria. 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 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, results of operations 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, except the cumulative dividend payable on our Series A preferred stock. The payment of all other 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. The terms of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock provide that we may not pay dividends on our common stock without concurrently declaring dividends on each. 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. For more information on restrictions governing our ability to pay dividends, see the section entitled "Dividend Policy" in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2018.

## 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, contain 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,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the outcome of and expectations regarding our 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 remain in compliance with the listing requirements of the Nasdaq Capital Market;

- our ability to retain and recruit key personnel, including the continued development of 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 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 acquire new products;

our financial performance;

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

developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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 and any free writing prospectus that we have authorized for use in connection with this offering with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

## **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 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

We estimate that the net proceeds from this offering will be approximately \$8.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any additional proceeds from any future conversions of the Series C preferred stock. We will only receive additional proceeds from the exercise of the warrants issuable in connection with this offering if the warrants are exercised and the holders of such warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the warrants.

We intend to use net proceeds from this offering for working capital, payment of interest on our debt and general corporate purposes, which may include research and development of our Lumivascular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. We have not yet determined the amount of net proceeds to be used specifically for any particular purpose or the timing of these expenditures. 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. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities.

**PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY**

Our common stock began trading on the Nasdaq Global Market on January 30, 2015 and was transferred to the Nasdaq Capital Market on January 19, 2018, where it trades under the symbol “AVGR”. In our IPO, our common stock priced at \$520.00 (as adjusted for the reverse split) per share on January 29, 2015. The following table sets forth for the periods indicated the high and low sales prices per share (as adjusted for the reverse split) of our common stock as reported by Nasdaq:

|   | <b>Low</b> | <b>High</b> |
|---|------------|-------------|
| <b>Fiscal Year ending December 31, 2016</b> |            |             |
| First Quarter                               | \$340.40   | \$818.40    |
| Second Quarter                              | \$396.80   | \$548.80    |
| Third Quarter                               | \$146.40   | \$479.60    |
| Fourth Quarter                              | \$140.00   | \$202.00    |
| <b>Fiscal Year ending December 31, 2017</b> |            |             |
| First Quarter                               | \$64.00    | \$146.40    |
| Second Quarter                              | \$14.40    | \$67.20     |
| Third Quarter                               | \$8.80     | \$38.40     |
| Fourth Quarter                              | \$6.80     | \$16.40     |
| <b>Fiscal Year ending December 31, 2018</b> |            |             |
| First Quarter                               | \$0.95     | \$9.76      |
| Second Quarter                              | \$1.09     | \$2.44      |
| Third Quarter                               | \$1.01     | \$1.80      |
| Fourth Quarter (through October 29, 2018)   | \$0.57     | \$1.42      |

As of October 29, 2018, the last reported sale price of our common stock on the Nasdaq Capital Market was \$0.59.

As of June 30, 2018, there were 9,305,872 shares of our common stock held by 175 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. The terms of the Series A preferred stock also limit our ability to pay dividends.



**CAPITALIZATION**

The following table sets forth our capitalization as of June 30, 2018:

on an actual basis; and

on a pro forma as adjusted basis, after giving effect to the sale of common stock issued to a vendor in July 2018, our July 2018 common stock issuance, the July 2018 Warrants, the issuance of 2,097 shares of common stock under the ODPP, 3,535,000 Class A Units at the public offering price of \$0.40 per unit and 8,586 Class B Units, at the public offering price of \$1,000 per unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The as adjusted information in the balance sheet data below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering that will be determined at pricing. You should read this table together with the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, which is incorporated by reference into this prospectus.

|   | <b>As of June 30, 2018</b> |  |
|---|----------------------------|--|
|   | <b>Actual</b>              | <b>Pro<br/>Forma<br/>As<br/>Adjusted</b> |
| Cash and cash equivalents   | \$ 10,144                  | \$ 18,909                                |
| Borrowings  | \$ 7,823                   | \$ 7,823                                 |
| Stockholders’ equity (deficit):   |                            |  |
| Preferred stock, \$0.001 par value; 5,000,000 shares authorized, 43,501 shares issued and outstanding, actual; 5,000,000 shares authorized, 52,087 shares issued and outstanding, pro forma as adjusted         | —                          | —  |
| Common stock, \$0.001 par value; 100,000,000 shares authorized, 9,305,872 shares issued and outstanding, actual; 100,000,000 shares authorized, 15,097,735 shares issued and outstanding, pro forma as adjusted | 8                          | 14                                       |
| Additional paid-in capital  | 323,991                    | 332,750                                  |
| Accumulated deficit   | (317,407)                  | (317,407)                                |
| Total stockholders’ equity (deficit)  | 6,592                      | 15,357                                   |
| Total capitalization  | \$ 14,415                  | \$ 23,180                                |

There were 41,800 shares of Series A preferred stock, 1,701 shares of Series B preferred stock and no shares of Series C preferred stock outstanding prior to this offering. The number of shares of common stock in the table above is based

on 9,305,872 shares outstanding as of June 30, 2018, and excludes:

84,842 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2018 with a weighted average exercise price of \$194.72 per share;

18,825,306 shares of common stock issuable upon exercise of outstanding warrants, including those issuable upon exercise of the July 2018 Warrants;

8,306 unvested restricted stock units;

3,090,775 shares of common stock reserved for future issuance under our 2015 Plan and any additional shares that become available under our 2015 Plan pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

27,515 shares of common stock reserved for future issuance under our ESPP and any additional shares that become available under our ESPP pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

197,903 shares of common stock reserved for future issuance under our ODPP;

shares of common stock issuable under the Purchase Agreement with Lincoln Park;

shares of common stock issuable upon conversion of the Series A preferred stock;

shares of common stock issuable upon conversion of the Series B preferred stock; and

shares of common stock issuable upon conversion of the Series C preferred stock.

## **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 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 additional 510(k) clearances for enhanced versions of Pantheris in March 2016 and May 2018 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. We also offer the Wildcat and Kittykat 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 through 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 20 VISION sites to re-solicit consent from previous clinical trial patients in order to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the 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 Lumivasular 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 in-stent restenosis.

We are developing a next-generation version of our Pantheris atherectomy device, Pantheris SV, a lower profile Pantheris. The lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels. We submitted a 510(k) application for Pantheris SV in smaller vessels in August 2018 and received CE Marking approval in October 2018. In addition, we completed development of Pantheris 3.0 which we believe represents a significant improvement over our prior product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe improves usability and reliability. On January 3, 2017, we announced the successful treatment of the first seven patients to be treated with Pantheris 3.0 by a vascular surgeon in Münster, Germany. Pantheris 3.0 received CE Marking approval in December 2017 and was cleared by the FDA in May 2018. The Pantheris 3.0 is available for commercial sale in the EU and United States.

We have assembled a team with extensive medical device development and commercialization capabilities. 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 \$10.7 million in 2015, \$19.2 million in 2016, \$9.9 million in 2017 and \$3.9 million for the six months ended June 30, 2018.

## 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.

## LUMIVASCULAR PRODUCTS

| <u>Name</u>                     | <u>Clinical Indication</u> | <u>Size (Length, Diameter)</u> | <u>Regulatory Status</u>    | <u>Original Clearance Date</u>  |
|---------------------------------|----------------------------|--------------------------------|-----------------------------|---------------------------------|
| <b>NEXT GENERATION PRODUCTS</b> |                            |                                |                             |                                 |
| Pantheris SV                    | Atherectomy                |                                | FDA 510(k) filed<br>CE Mark | October 2018                    |
| <b>PRODUCTS</b>                 |                            |                                |                             |                                 |
| Lightbox(1)                     | OCT Imaging                | N/A                            | FDA Cleared<br>CE Mark      | November 2012<br>September 2011 |
| Pantheris 3.0                   | Atherectomy                |                                | FDA Cleared<br>CE Mark      | May 2018<br>December 2017       |
| 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   |

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



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 (2) 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

| <b>Name</b>      | <b>Indication</b> | <b>Size<br/>(Length, Diameter)</b> | <b>Regulatory<br/>Status</b> | <b>Original<br/>Clearance Date</b> |
|------------------|-------------------|------------------------------------|------------------------------|------------------------------------|
| Wildcat(1)       | Guidewire Support | 110cm, 6F                          | FDA Cleared                  | February 2009(3)                   |
|                  | CTO Crossing      | 110cm, 6F                          | FDA Cleared<br>CE Mark       | August 2011<br>May 2011            |
| Kittycat<br>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 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 version of Pantheris in March 2016. We first

received CE Mark for Pantheris in June 2015.

We are developing a next-generation version of our Pantheris atherectomy device, Pantheris SV, a lower profile Pantheris. The lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels. We submitted a 510(k) application for Pantheris SV in smaller vessels in August 2018 and received CE Marking approval in October 2018. In addition, we completed development of Pantheris 3.0 which we believe represents a significant improvement over our prior product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe improves usability and reliability. We received 510(k) clearance for Pantheris 3.0 in May 2018.

***Ocelot, Ocelot PIXL and Ocelot MVRX***

Ocelot is the first CTO crossing catheter to incorporate real-time OCT imaging, which allows physicians to see the inside of an artery during a CTO crossing procedure. Physicians have traditionally relied solely on fluoroscopy and tactile feedback to guide catheters through complicated blockages. Ocelot allows physicians to accurately navigate through CTOs by utilizing the OCT images to precisely guide the device through the arterial blockage, while minimizing disruption to the healthy arterial structures. We received CE Mark for Ocelot in September 2011 and received FDA 510(k) clearance in November 2012.

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

### ***Other Products***

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

### **Clinical Development**

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

#### ***CONNECT (Wildcat)***

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

#### ***CONNECT II (Ocelot)***

Our clinical trial for Ocelot, known as CONNECT II, was a prospective, multi-center, non-randomized trial that evaluated the safety and efficacy of Ocelot in crossing CTOs in arteries of the upper leg using OCT intravascular imaging. The CONNECT II trial enrolled 100 patients with CTOs at 14 centers in the United States and two centers in Europe. Patients were followed for 30 days post-procedure and an independent group of physicians verified the results

to confirm the primary efficacy and safety endpoints. Results from the CONNECT II trial demonstrated that Ocelot surpassed its primary efficacy endpoint by successfully crossing the CTO in 97% of the cases following unsuccessful attempts to cross with standard guidewire techniques. Ocelot achieved these rates with 98% freedom from MAEs.

### *VISION (Pantheris)*

VISION was our pivotal, non-randomized, prospective, single-arm trial to evaluate the safety and effectiveness of Pantheris across 20 sites within the United States and Europe. The objective of the clinical trial was to demonstrate that Pantheris can be used to effectively remove plaque from diseased lower extremity arteries while using on-board visualization as an adjunct to fluoroscopy. Two groups of patients were treated in VISION: (1) optional roll-ins, which are typically the first two procedures at a site, and (2) the primary cohort, which are the analyzable group of patients. The data for these two groups 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.

VISION'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.

|   | <b>Roll-In<br/>Cohort</b> | <b>Primary<br/>Cohort</b> | <b>Total</b>        |
|---|---------------------------|---------------------------|---------------------|
| Patients Treated  | 28                        | 130                       | 158                 |
| Lesions treated   | 34                        | 164                       | 198                 |
| <b>Primary Efficacy Endpoint</b>  |                           |                           |                     |
| 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 %<br>(34/34 )         | 96.3 %<br>(158/164)       | 97 %<br>(192/198)   |
| <b>Primary Safety Endpoint (MAEs through 6 months)</b>  |                           |                           |                     |
| Total MAEs Reported   | 3                         | 22                        | 25                  |
| Reported MAEs as a percentage of patients enrolled  | 11.5 %<br>(3/26 )         | 17.6 %<br>(22/125 )       | 16.6 %<br>(25/151 ) |
| <b>Histopathology Results (Non-Endpoint Data)</b>   |                           |                           |                     |
| Lesions with histopathology results   | 34                        | 162                       | 196                 |
| Average percent area of adventitia in all lesions with histopathology results                           | 0.56 %                    | 1.02 %                    | 0.94 %              |

Although the original VISION study protocol was not designed to follow patients beyond six months, 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 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 as 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 early 2019. 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 have partnered with a third party field service firm for the installation, service and maintenance of our Lightbox consoles.

As of December 31, 2017, we had 23 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 2015, 2016, 2017 and for the six months ended June 30, 2018 were \$29.2 million, \$40.0 million, \$25.1 million and \$8.5 million, respectively. No single customer accounted for more than 10% of our revenues during 2015, 2016 and 2017, or for the six months ended June 30, 2018.

## **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, Becton Dickinson, Boston Scientific, Cardinal Health, Cook Medical, Medtronic and Philips. 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, 2018, we held 21 issued and allowed U.S. patents and had 25 U.S. utility patent applications and 6 PCT applications pending. As of June 30, 2018, we also had 34 issued and allowed patents outside of the United States. As of June 30, 2018, we had 41 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. As we continue to research and develop our products and technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our devices. Our issued patents expire between the years 2028 and 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, 2018, we held five registered U.S. trademarks and one pending U.S. trademark application. In Europe, we hold two 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 intend to further develop 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 June 30, 2018, we had 10 employees focused on research and development. In addition to our internal team, we retain third-party contractors from time to time to provide us with assistance on specialized projects. We also work closely with experts in the medical community to supplement our internal research and development resources. Research and development expenses for the years ended December 31, 2015, 2016, and 2017 were \$15.7 million, \$15.5 million, and \$11.3 million, respectively. Research and development expenses for the three and six months ended June 30, 2018 were \$1.2 million and \$2.9 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 facility 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.

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 PMA if it cannot receive authorization through a 510(k). The FDA has established three different classes of medical devices that indicate the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy. Class I and Class II devices are considered lower risk and often can gain approval for commercial distribution by submitting an application to the FDA, generally known as the 510(k) process. The devices regarded as the highest risk by the FDA are designated Class III status and generally require the submission of a PMA application for approval to commercialize a product. These generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA.

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

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

A PMA application must include reasonable scientific and clinical data that demonstrates the device is safe and effective for the intended uses and indications being sought. The application must also include preclinical testing, technical, manufacturing and labeling information. If the FDA determines the application can undergo substantive review, it has 180 days to review the submission, but it can typically take longer (up to several years) as this regulatory body can request additional information or clarifications. The FDA may also impose additional regulatory

hurdles for a PMA, including the institution of an advisory panel of experts to assess the application or provide recommendations as to whether to approve the device. Although the FDA in the end approves or disapproves the device, in nearly all cases the FDA follows the recommendation from the advisory panel. As part of this process, the FDA will usually inspect the manufacturing facilities and operations prior to approval to verify compliance with quality control regulations. Significant changes in the manufacturing of a device, or changes in the intended use, indications and labeling or design of a product require new PMA applications or PMA supplements for a product originally approved under a PMA. This creates substantial regulatory risk for devices undergoing the PMA route.

***Pervasive and Continuing Regulation***

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

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

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

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

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

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the 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 times between 2010 and 2015 and found zero non-conformances. BSI conducted a recertification audit (for EU) in 2016 followed by surveillance audits in 2017 and 2018, and found no major non-conformances. Additionally, BSI also audited the Company for QSR compliance under MDSAP for the FDA in July 2016, and found no major non-conformances.

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

- warning letters, adverse publicity, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;



- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

- withdrawing 510(k) clearance or premarket approvals that have already been granted; and

- criminal prosecution.

### ***Regulatory System for Medical Devices in Europe***

The European Union consists of 28 member states and has a coordinated system for the authorization of medical devices. The E.U. Medical Devices Directive, or MDD, sets out the basic regulatory framework for medical devices in the European Union. This directive has been separately enacted in more detail in the national legislation of the individual member states of the European Union.

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for CE mark varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.

***Federal, State and Foreign Fraud and Abuse Laws***

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

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

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

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

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

programs.

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

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

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

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

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

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

and to devise and maintain an adequate system of internal accounting controls for international operations.

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

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

### ***U.S. Healthcare Reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changed 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 may again attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the United States may have on our business.

### **Third-Party Reimbursement**

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

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

•Type of procedure performed—angioplasty, stent or atherectomy;

•Patient-specific complexities and comorbidities;

•Type of facility—hospital, teaching hospital or office-based lab;

•Inpatient or outpatient status; and

•Geographic region.

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

Medicare reimbursement levels for inpatient PAD procedures for fiscal year 2018 went into effect as of October 1, 2017 and range between approximately \$10,000 and \$18,000. Medicare reimbursement for outpatient PAD procedures for 2018 went into effect on January 1, 2018 and range between approximately \$7,000 and \$16,000. 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 June 30, 2018, we had 63 employees, including 17 in manufacturing and operations, 18 in sales and marketing, 10 in research and development and clinical and regulatory affairs, 2 in quality assurance and 8 in finance, general administrative and executive administration. 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 class actions were filed in the Superior Court of the State of California, County of San Mateo, or the 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, rescission, and attorneys' fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California, or Federal Court.

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 Gonzalez actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, or State Action. On September 22, 2017, an amended 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 Grotewiel action, or Federal Action. On June 20, 2018, the State Court dismissed the State Action pursuant to the proposed settlement described below.

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Federal Action. On November 21, 2017, an amended complaint was filed in the Federal Action. Defendants filed a motion to dismiss that complaint on January 26, 2018. On March 19, 2018, plaintiff in the Federal Action filed a further amended complaint, on behalf of a class of purchasers of our common stock in and/or traceable to our IPO, as



well as purchasers of our common stock during the period January 30, 2015, to April 10, 2017.

The Company and its directors believe that the foregoing lawsuits were without merit; however, in the interest of avoiding the cost and disruption of continuing to defend against these lawsuits, the Company entered into a settlement of the actions. The settlement is for a total of \$5 million. The Company's total contribution to the settlement fund is \$1.76 million, which the Company paid in March 2018. On October 24, 2018, the court approved the settlement.

## **Other Information**

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](http://www.sec.gov). Our common stock is traded on the Nasdaq Capital 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 \$1.07 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.

**MANAGEMENT****Executive Officers, Directors and Key Employees**

The following table sets forth information, as of June 30, 2018, regarding our executive officers, directors and key employees.

| <b><u>Name</u></b>        | <b><u>Age</u></b> | <b><u>Title</u></b>                             |
|---------------------------|-------------------|---|
| Jeffrey M. Soinski        | 56                | President, Chief Executive Officer and Director |
| Mark Weinswig             | 45                | Chief Financial Officer                         |
| Himanshu N. Patel         | 58                | Chief Technology Officer                        |
| James G. Cullen(1)(2)(3)  | 75                | Director and Chairman of the Board of Directors |
| Donald A. Lucas(1)(2)(3)  | 56                | Director  |
| James B. McElwee(1)(2)(3) | 66                | Director  |

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(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, as our Lead Independent Director since January 2015 and as our Non-Executive Chairman since December 2017. During the last five years, Mr. Cullen has held board and committee positions with various companies. Mr. Cullen is currently a director of Agilent Technologies, Inc. Mr. Cullen previously served as a director and chairman of the audit committee of Johnson & Johnson and as a director and member of the investment and finance committees of Prudential Financial. 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, Katerra, Bossa Nova Robotics, Fild, Berkeley Lights Inc, and Palantir. 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 others.

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.

*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 Consensus 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 included 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.

*Mark Weinswig* has served as our Chief Financial Officer since June 2018. From August 2017 to March 2018, Mr. Weinswig formerly served as the Chief Financial Officer of Aqua Metals, Inc., a heavy metal recycling company. From July 2016 to July 2017, Mr. Weinswig served as Chief Financial Officer of One Workplace, a designer and manufacturer of customized workspaces. From October 2010 to June 2016, Mr. Weinswig served as Chief Financial Officer of Emcore Corporation, a Nasdaq-listed designer and manufacturer of indium phosphide optical chips, components, subsystems and systems for the broadband and specialty fiber optics market. From September 2009 to October 2010, Mr. Weinswig served as International Finance Director at Coherent, Inc., a Nasdaq-listed designer and manufacturer of photonics solutions. Earlier in his career Mr. Weinswig worked at Morgan Stanley and PricewaterhouseCoopers. He received an M.B.A. from the University of Santa Clara and a B.S. in business administration with an accounting major from Indiana University. He has earned the CFA and CPA designations.

*Himanshu N. Patel* co-founded Avinger in 2007 and has served as our Chief Technology Officer from January 2011 to November 2011 and since October 2013. From September 1999 to February 2007, Mr. Patel held various research and development positions, including Director of Advanced Technologies, at FoxHollow Technologies. Mr. Patel previously held research and development positions at EndoTex Interventional Systems and General Surgical Innovations. 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.

## **Director Independence**

Our common stock is listed on The Nasdaq Capital 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, or 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 entitled “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. The Chairman of our board of directors and our Chief Executive Officer roles are separate, and our current Non-Executive Chairman, James G. Cullen, is independent under the listing standards of The Nasdaq Stock Market and thus also serves as our lead independent director.

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. As lead independent director, Mr. Cullen is expected to preside over periodic meetings of our independent directors, to serve as a liaison between our Chief Executive Officer 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 present. Following each meeting, Mr. Cullen is expected to provide feedback to Mr. Soinski on his 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, 2017, our board of directors held seventeen 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 2017 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.

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](http://www.avinger.com) under “Investors—Governance.” During our fiscal year ended December 31, 2017, our audit committee held seven 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](http://www.avinger.com) under “Investors—Governance.” During our fiscal year ended December 31, 2017, our compensation committee held two meetings.

### *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](http://www.avinger.com) under "Investors—Governance." During our fiscal year ended December 31, 2017, 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 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 2019 annual meeting of stockholders, our Secretary must receive the nomination no earlier than February 11, 2019 and no later than March 13, 2019.

### **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](http://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 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, and amended it in August 2018. 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;

\$25,000 per year additionally for service as chairman of the board;

\$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.

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 Restricted Stock Units in Lieu of Cash Payments.* All non-employee directors may elect to convert a Retainer Cash Payment into restricted stock units with a grant date fair value equal to the applicable Retainer Cash Payment, or a Retainer Award. Each Retainer Award will be granted on the date that the applicable Retainer Cash Payment was scheduled to be paid, and the Retainer Award will vest and settle six months from the date of grant, subject to continued service as a director through the applicable vesting date. The Retainer Award will be subject to certain terms and conditions as described below under the section entitled "Equity Compensation."

Elections to convert a Retainer Cash Payment into a Retainer Award 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 Awards, provided that such election is made prior to the date the individual becomes a non-employee director.

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

*Initial Award.* Each person who first becomes a non-employee director will be granted restricted stock units having a grant date fair value equal to \$115,000, or the Initial Award. The Initial Award 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 Award will vest and settle as to one thirty-sixth (1/36th) of the shares subject to such Initial Award 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 Award.* 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 restricted stock units covering a number of shares having a grant date fair value equal to \$75,000, or the Annual Award. All of the shares underlying the Annual Award will vest and settle 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 award granted under our outside director compensation policy, including Retainer Awards, Initial Awards and Annual Awards, 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 award.

Any restricted stock unit granted under our outside director compensation policy will fully vest and settle in the event of a change in control, as defined in our 2015 Plan, provided that the recipient 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 2017*

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, 2017:



| <u>Name</u>       | <b>Fees<br/>Earned<br/>or Paid<br/>in<br/>Cash(1)</b> | <b>Option<br/>Awards(2)(3)</b> | <b>Total</b> |
|-------------------|---|--------------------------------|--------------|
| James G. Cullen   | \$ 77,500   | \$ 75,000                      | \$ 152,500   |
| Thomas J. Fogarty | \$—   | \$ 115,000                     | \$ 115,000   |
| Donald A. Lucas   | \$ 67,500   | \$ 75,000                      | \$ 142,500   |
| James B. McElwee  | \$ 65,000   | \$ 75,000                      | \$ 140,000   |

(1) Dr. Fogarty elected to convert \$40,000 of his Retainer Cash Payments for 2017 into Retainer Options. Dr. Fogarty retired from our board of directors in August 2017.

(2) During 2017, all non-employee directors received an annual option grant, prior to the revision of the outside director compensation policy to provide for the grant of restricted stock units.

(3) As of December 31, 2017, Messrs. Cullen, Lucas, McElwee and Dr. Fogarty had outstanding options to purchase a total of 130,685, 124,093, 113,361 and no shares of our common stock, respectively.

Directors who are also our employees receive no additional compensation for their service as directors. During 2017, John B. Simpson, our founder and former Executive Chairman of our board of directors, and Jeffrey M. Soinski, our President, Chief Executive Officer and a director, were also our employees. See the section entitled “Executive Compensation—Fiscal 2017 Summary Compensation Table” for additional information about the compensation for Dr. Simpson and Mr. Soinski. Dr. Simpson resigned as director and Executive Chairman in December 2017.

## **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 2017, our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements.

## **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 2017 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, 2017. The individuals listed in the table below are our named executive officers for our fiscal year ended December 31, 2017.

| <u>Name and Principal Position</u>   | <u>Year</u> | <u>Salary</u><br>(\$) | <u>Bonus</u><br>(\$) | <u>Stock Awards</u><br>(\$)(1) | <u>Option Awards</u><br>(\$)(1) | <u>Non-Equity Incentive Plan Compensation</u><br>(\$) | <u>All Other Compensation</u><br>(\$) | <u>Total</u><br>(\$) |
|--|-------------|-----------------------|----------------------|--------------------------------|---------------------------------|---|---------------------------------------|----------------------|
| John B. Simpson, Ph.D., M.D.<br><i>Executive Chairman</i>                        | 2017        | 363,500               | —                    | 61,500                         | 67,161                          | —   | 232,500                               | 724,661              |
|  | 2016        | 390,000               | —                    | 342,511                        | 334,360                         | 91,134  | —                                     | 1,158,005            |
| Jeffrey M. Soinski<br><i>President and Chief Executive Officer</i>               | 2017        | 390,000               | —                    | 61,500                         | 67,161                          | —   | 3,000                                 | 521,661              |
|  | 2016        | 390,000               | —                    | 342,511                        | 334,360                         | 91,134  | 105,891                               | 1,263,896            |
| Matthew B. Ferguson<br><i>Chief Financial Officer and Chief Business Officer</i> | 2017        | 300,000               | —                    | 51,250                         | 55,967                          | —   | 3,000                                 | 410,217              |
|  | 2016        | 300,000               | —                    | 143,043                        | 139,286                         | 56,083  | 3,000                                 | 641,412              |

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officer in 2016 and 2017, 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 entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Stock-Based Compensation.”

(2) In 2017, the amounts reported in All Other Compensation for Dr. Simpson include a cash severance payment of \$195,000 and reimbursement for accrued paid time off of \$37,500. Dr. Simpson resigned as a director and Executive Chairman from our board of directors and as an employee in December 2017.

(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 2016 and 2017.

(4) The amounts reported for Mr. Ferguson represent funds contributed to his health savings account of \$3,000 for each of 2016 and 2017. Mr. Ferguson resigned in June 2018.

## **Executive Employment Letters**

### ***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 2017 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 former 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 was \$300,000. Mr. Ferguson

resigned as director and Chief Financial Officer in June 2018. In connection with Mr. Ferguson's resignation, we and Mr. Ferguson entered into a Separation Agreement and Release, dated as of August 1, 2018, and a Consulting Agreement, dated as of August 1, 2018. Pursuant to the terms of the Separation Agreement, Mr. Ferguson will release all claims he may have against the Company and affirm his obligations regarding Company confidential information. As consideration for the release of claims, Mr. Ferguson's employment status at the time the Company pays bonuses for the first half of 2018 will not be considered with respect to his eligibility to receive such bonus payments. Pursuant to the Consulting Agreement, Mr. Ferguson will provide up to twenty hours per week of service to the Company during the period from August 1, 2018 to December 31, 2018, for which he will be entitled to receive total payments of \$62,500.

***Mark Weinswig***

We entered into an employment offer letter in June 2018 with Mark Weinswig, our Chief Financial Officer. The letter has no specific term and provides for at-will employment. Effective June 11, 2018, Mr. Weinswig's annual base salary is \$300,000. The letter also provides that Mr. Weinswig is eligible to receive a discretionary bonus of up to 40% of his base salary payable semi-annually based on the achievement of certain goals mutually agreed upon by him and our board of directors.

We also entered into a Change of Control and Severance Agreement in June 2018 with Mr. Weinswig. Pursuant to the Severance Agreement, if, within the 18-month period following a "change of control," we terminate Mr. Weinswig's employment without "cause," or Mr. Weinswig resigns for "good reason" (as such terms are defined in Mr. Weinswig's employment offer letter), Mr. Weinswig will receive accelerated vesting as to 100% of his outstanding unvested stock options and/or restricted stock.

**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 2017.

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

The following table provides information regarding equity awards held by our named executive officers at December 31, 2017.

| <u>Name</u> | <b>Grant Date</b> | <b>Option Awards</b>  |   |                                      | <b>Stock Awards</b>           |  |  |
|-------------|-------------------|---|---|--------------------------------------|-------------------------------|--|--|
|             |                   | <b>Number of Securities Underlying Unexercised Options (#) Exercisable(3)</b> | <b>Number of Securities Underlying Unexercised Options (#) Unexercisable(3)</b> | <b>Option Exercise Price (\$)(4)</b> | <b>Option Expiration Date</b> | <b>Number of Shares or Units of Stock That Have Not Vested</b> | <b>Market Value of Shares or Units of Stock That Have Not Vested</b> |
|             |                   |   |   |                                      |                               |  |  |

|                     |                  |        |       |        |            | (#) | Vested<br>(\$)(5) |
|---------------------|------------------|--------|-------|--------|------------|-----|-------------------|
| John B. Simpson     | 5/1/2013(1)(6)   | 722    | —     | 900.00 | 5/1/2018   | —   | —                 |
|                     | 12/31/2014(1)(7) | 15,280 | —     | 198.00 | 12/31/2024 | —   | —                 |
|                     | 3/7/2016(2)(7)   | 656    | —     | 518.40 | 3/7/2026   | —   | —                 |
| Jeffrey M. Soinski  | 12/31/2014(1)(7) | 15,484 | —     | 180.00 | 12/31/2024 | —   | —                 |
|                     | 3/7/2016(2)(7)   | 656    | 843   | 518.40 | 3/7/2026   | —   | —                 |
|                     | 3/7/2016(2)(8)   | —      | —     | —      | —          | 562 | 4,046             |
|                     | 3/13/2017(2)(7)  | —      | 1,500 | 82.00  | 3/13/2027  | —   | —                 |
|                     | 3/13/2017(2)(8)  | —      | —     | —      | —          | 750 | 5,400             |
| Matthew B. Ferguson | 7/29/2011(1)(9)  | 849    | —     | 504.00 | 7/29/2021  | —   | —                 |
|                     | 5/1/2013(1)(6)   | 170    | —     | 810.00 | 5/1/2023   | —   | —                 |
|                     | 9/2/2014(1)      | 241    | —     | 504.00 | 9/2/2019   | —   | —                 |
|                     | 12/31/2014(1)(7) | 2,387  | —     | 180.00 | 12/31/2024 | —   | —                 |
|                     | 3/3/2016(2)(7)   | 273    | 351   | 519.60 | 3/3/2026   | —   | —                 |
|                     | 3/3/2016(2)(8)   | —      | —     | —      | —          | 234 | 1,685             |
|                     | 3/13/2017(2)(7)  | —      | 1,250 | 82.00  | 3/13/2027  | —   | —                 |
|                     | 3/13/2017(2)(8)  | —      | —     | —      | —          | 625 | 4,500             |

(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 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 which, prior to our initial public offering in January 2015, was determined by our board of directors. Subsequently, the fair value of our common stock is determined based on the closing price of our common stock, as reported on the Nasdaq Global Market or Nasdaq Capital Market, as applicable.

(5) This column represents the market value of the unvested shares of our common stock underlying the RSUs as of December 29, 2017, based on the closing price of our common stock, as reported on the Nasdaq Global Market, of \$7.20 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.

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

25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, (8) 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 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. Dr. Simpson resigned as director and Executive Chairman in December 2017 and is no longer eligible for any change of control payments.

Potential payments upon termination or change of control for Mr. Soinski are described above, see the section entitled “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, except our Officer and Director Share Purchase Plan adopted in August 2018. The following table provides information as of December 31, 2017, with respect to the shares of our common stock that may be issued under our existing equity compensation plans. The following table does not reflect (i) annual “evergreen” increases to our 2015 Plan and 2015 Employee Stock Purchase Plan on January 1, 2018, (ii) the reservation of an additional 3,000,000 shares of common stock under the 2015 Plan following our 2018 annual meeting of stockholders or (iii) the adoption of our Officer and Director Share Purchase Plan in August 2018.

| <u>Plan Category</u>                                  | (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) | 135,448   | \$ 379.19  | 88,736  |

(1) Includes the following plans: our 2009 Stock Plan, our 2015 Plan and our 2015 Employee Stock Purchase Plan. Our 2015 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) 42,250 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) 12,325 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.

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## 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 September 30, 2018 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
- 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 11,554,149 shares of our common stock outstanding as of September 30, 2018. 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 September 30, 2018. 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**

| <b><u>Name of Beneficial Owner</u></b>   | <b>Number<br/>of<br/>Shares</b> | <b>Percentage</b> |
|--|---------------------------------|-------------------|
| <b>Named Executive Officers and Directors</b>                                  |                                 |                   |
| Jeffrey M. Soinski <sup>(1)</sup>  | 21,577                          | *                 |
| Mark Weinswig <sup>(2)</sup>   | 1,456                           | *                 |
| James G. Cullen <sup>(3)</sup>   | 6,058                           | *                 |
| Donald A. Lucas <sup>(4)</sup>   | 3,680                           | *                 |
| James B. McElwee <sup>(5)</sup>  | 3,346                           | *                 |
| All executive officers and directors as a group (6 individuals) <sup>(6)</sup> | 45,679                          | *                 |

\* Represents ownership of less than 1%

(1) Consists of (i) 4,469 shares directly owned and (ii) 17,108 shares of common stock upon exercise of options exercisable within 60 days of September 30, 2018.

(2) Consists of 1,456 shares directly owned.

Consists of (i) 1,845 shares of common stock held by Gilbert Investments, LLC, (ii) warrants to purchase 621 shares of common stock held by Gilbert Investments, LLC, (iii) 327 shares held by 2000 James Cullen Generation Skipping Family Trust and (iv) 3,265 shares of common stock issuable upon exercise of options exercisable within (3) 60 days of September 30, 2018. 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.

(4) Consists of (i) 580 shares of common stock held of record by Lucas Venture Group III, LP and (ii) 3,100 shares of common stock issuable upon exercise of options exercisable within 60 days of September 30, 2018.

Consists of (i) 377 shares of common stock held of record by Mr. McElwee, (ii) warrants to purchase 138 shares of (5) common stock and (iii) 2,831 shares issuable upon exercise of options exercisable within 60 days of September 30, 2018.

(6) Consists of (i) 12,995 shares of common stock outstanding, and (ii) warrants to purchase 759 shares of common stock and (iii) 31,925 shares issuable upon exercise of options exercisable within 60 days of September 30, 2018.

## DESCRIPTION OF SECURITIES

The following description summarizes the most important terms of our capital stock and the securities we are offering 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, or the DGCL.

### Units

We are offering 3,535,000 Class A Units, with each Class A Unit consisting of one share of common stock and a warrant to purchase one share of our common stock at an exercise price per share of \$0.40, together with the shares of common stock underlying such warrants, at a public offering price of \$0.40 per Class A Unit. The Class A Units will not be certificated and the shares of common stock and warrants part of such units are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%), 8,586 Class B Units. Each Class B Unit consists of one share of Series C preferred stock, par value \$0.001 per share, convertible into 2,500 shares of common stock and a warrant to purchase 2,500 shares of our common stock at an exercise price per share of \$0.40, together with the shares of common stock underlying such shares of Series C preferred stock and warrants, at a public offering price of \$ 1,000 per Class B Unit and a Series C preferred stock conversion price of \$0.40 per share. The Class B Units will not be certificated and the shares of Series C preferred stock and the warrants part of such units are immediately separable and will be issued separately in this offering.

## **Description of Capital Stock**

Our authorized capital stock consists of 100,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. Of our 5,000,000 shares of authorized preferred stock, 60,000 shares have been designated as Series A preferred stock, 18,000 have been designated as Series B preferred stock, 8,586 have been designated as Series C preferred stock and the remainder are as-yet undesignated.

## **Common Stock**

### *Outstanding Shares*

On June 30, 2018, there were 9,305,872 shares of common stock outstanding, held of record by 175 stockholders. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

As of June 30, 2018, there were 17,742,215 shares of common stock subject to outstanding warrants and 84,842 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 66<sup>2</sup>/<sub>3</sub>% 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 common stock are subject to, and may be adversely affected by, the rights of the holders of our outstanding preferred stock and 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**

Under our restated certificate of incorporation, we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares (less any Series A preferred stock and Series B preferred stock issued) of preferred stock, par value \$0.001 per share, in one or more series. As of June 30, 2018, 60,000 shares of preferred stock were designated Series A preferred stock, 18,000 shares of preferred stock were designated Series B preferred stock and no shares of preferred stock were designated Series C preferred stock. As of June 30, 2018, 41,800 shares of Series A preferred stock were issued and outstanding and 1,701 shares of Series B preferred stock were issued and outstanding.

Pursuant to our restated certificate of incorporation, we are authorized to issue “blank check” preferred stock, which may be issued from time to time in one or more series upon authorization by our board of directors. Our board of directors, without further approval of the stockholders, is authorized to fix the designation, powers, preferences, relative, participating optional or other special rights, and any qualifications, limitations and restrictions applicable to each series of the preferred stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes could, among other things, adversely affect the voting power or rights of the holders of our common stock and, under certain circumstances, make it more difficult for a third party to gain control of us, discourage bids for our common stock at a premium or otherwise adversely affect the market price of the common stock.

### **Series A Preferred Stock**

The preferences and rights of the Series A preferred stock are as set forth in a Certificate of Designation of Series A preferred stock, or the Series A Certificate of Designation, filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on February 23, 2018. The following is a summary of the material terms of our Series A Preferred stock and is qualified in its entirety by the Series A Certificate of Designation. Please refer to the Series A Certificate of Designation for more information on the preferences, rights and limitations of Series A preferred stock.

*Liquidation.* Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series A preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of the greater of (i) an amount equal to \$1,000 per share plus accrued and unpaid dividends thereon or (ii) such amount as would be payable if the Series A preferred stock had been converted to common stock. Amounts payable to the Series A preferred stock upon any dissolution, liquidation or winding up are payable prior and in preference to the payment of any amounts to the holders of Series B preferred stock or common stock.

*Dividends.* Holders of the Series A preferred stock are entitled to receive accruing dividends of 8% per annum, which dividends are cumulative and annually compounded. The holders of Series A preferred stock will be entitled to receive an amount equal (on an “as converted to common stock” basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. We have an option to pay the Series A preferred stock’s accruing dividend in additional shares of Series A preferred stock.

*Conversion.* Each share of Series A preferred stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing \$1,000 by the conversion price of \$2.00 (subject to adjustment as described below). This right to convert is limited by the beneficial ownership limitation described below.

In connection with this offering, CRG has agreed to suspend the conversion of its Series A convertible preferred stock into common stock until such time as our stockholders have approved an amended and restated certificate of incorporation authorizing at least 125 million shares of common stock. We have created a Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, in the form filed as Exhibit 3.7 to the registration statement of which this prospectus forms a part, for filing with the Secretary of State for the state of Delaware to effect this change. Following the filing of this amendment, the Company has agreed to call a meeting of the Company’s stockholders on or before June 30, 2019, and to use reasonable best efforts (including the hiring of a proxy solicitor), to obtain approval from the stockholders of the Company for an amended and restated certificate of incorporation that increases the number of authorized shares to at least 125 million shares (or such larger number of shares as is necessary) in order to allow for the conversion of the outstanding Series A convertible preferred stock into common stock. In this regard, the Company shall include approval of an amended and restated certificate of incorporation as a proposal to be voted on by the stockholders in such stockholders meeting. If such proposal is not approved in the next stockholders meeting the Company shall include a similar proposal on its agenda for following stockholders meetings and continue to use reasonable best efforts to obtain its approval until such proposal is approved.

*Forced Conversion.* Beginning on January 1, 2019, if the Company’s average market capitalization is at least \$100,000,000 both (i) on a given date, based on the closing price and number of shares outstanding and (ii) for the prior quarter, based on the volume-weighted average closing price during such quarter and number of shares outstanding on the last day of such quarter, the Series A preferred stock is subject to mandatory conversion (subject to the beneficial ownership limitation below).

*Beneficial Ownership Limitation.* A holder shall have no right to convert any portion of Series A preferred stock, to the extent that, after giving effect to such conversion, such holder, together with such holder’s affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% (or, upon election by a holder any higher or lower percentage) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion. A holder of Series A preferred stock may adjust the percentage of the beneficial ownership upon not less than 61 days prior notice. Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series B preferred stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as

amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series A preferred stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

*Optional Redemption.* Subject to the terms of the certificate of designation, the Company holds an option to redeem some or all the Series A preferred stock for the amount per share otherwise payable upon a liquidation, dissolution or winding up of the Company, upon 30 days prior written notice to the holder of the Series A preferred stock.

*Stock Dividends and Stock Splits.* If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then effective conversion price by a fraction, the numerator of which shall be the number of shares of common stock (including shares issuable upon conversion of the Series B preferred stock) outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event (assuming conversion of the Series B preferred stock).

*Fundamental Transaction.* In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series A preferred stock will be entitled to receive upon conversion of the Series A preferred stock the same kind and amount of securities, cash or property which the holders would have received had they converted the Series A preferred stock immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series A preferred stock.

*Voting Rights, etc.* Except as otherwise provided in the Series A Certificate of Designation or required by law, the Series A preferred stock has no voting rights. However, as long as any shares of Series A preferred stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A preferred stock, (i) liquidate, dissolve, or wind up the Company; (ii) alter or amend the certificate of incorporation, Series A Certificate of Designation or bylaws of the Company in a manner adverse to the Series A preferred stock; (iii) create or amend the terms of any securities so as to create, securities pari passu or senior to the Series A preferred stock; (iv) purchase, redeem or make any dividend upon shares of capital stock other than certain limited exceptions; or (v) issue any additional Series A preferred stock.

*Fractional Shares.* No fractional shares of common stock will be issued upon conversion of Series A preferred stock. Rather, we shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the fair market value of a share of common stock.

The Series A preferred stock was issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and was initially represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for

the Series A preferred stock and we do not expect a market to develop. We do not plan on applying to list the Series A preferred stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

The transfer agent for our Series A preferred stock is American Stock Transfer & Trust Company, LLC.

### **Series B Preferred Stock**

The preferences and rights of the Series B preferred stock are as set forth in a Certificate of Designation of Series B preferred stock, or the Series B Certificate of Designation, filed as Exhibit 3.2 to our Current Report on Form 8-K, filed with the SEC on February 23, 2018. The following is a summary of the material terms of our Series B Preferred stock and is qualified in its entirety by the Series B Certificate of Designation. Please refer to the Series B Certificate of Designation for more information on the preferences, rights and limitations of Series B preferred stock.

*Liquidation.* Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series B preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series B preferred stock before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series B preferred stock, but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness.

*Dividends.* Holders of the Series B preferred stock will be entitled to receive dividends equal (on an “as converted to common stock” basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series B preferred stock.

*Conversion.* Each share of Series B preferred stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing \$1,000 by the conversion price of \$1.58 (subject to adjustment as described below). This right to convert is limited by the beneficial ownership limitation described below.

*Forced Conversion.* Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds \$500,000 per trading day, we shall have the right to force the conversion of the Series B preferred stock into common stock.

*Beneficial Ownership Limitation.* A holder shall have no right to convert any portion of Series B preferred stock, to the extent that, after giving effect to such conversion, such holder, together with such holder’s affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% (or, upon election by a holder prior to the issuance of any shares of Series B preferred stock, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series B preferred stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series B preferred stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

*Optional Redemption.* Subject to the terms of the certificate of designation, the Company holds an option to redeem some or all the Series B preferred stock six months after its issuance date at a 200% premium to the stated value of the Series B preferred stock subject to the redemption, upon 30 days prior written notice to the holder of the Series B preferred stock. The Series B preferred stock would be redeemed by the Company for cash.

*Subsequent Equity Sales.* The Series B preferred stock has full-ratchet price based anti-dilution protection, subject to customary carve outs, in the event of a down-round financing at a price per share below the conversion price of the Series B preferred stock. If during any 20 of 30 consecutive trading days the volume weighted average price of our common stock exceeds 300% of the then-effective conversion price of the Series B preferred stock and the daily dollar trading volume for each trading day during such 30 day period exceeds \$500,000, the anti-dilution protection in the Series B preferred stock will expire and cease to apply.

*Stock Dividends and Stock Splits.* If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

*Fundamental Transaction.* In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series B preferred stock will be entitled to receive upon conversion of the Series B preferred stock the same kind and amount of securities, cash or property which the holders would have received had they converted the Series B preferred stock immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series B preferred stock.



*Voting Rights, etc.* Except as otherwise provided in the Series B Certificate of Designation or required by law, the Series B preferred stock has no voting rights. However, as long as any shares of Series B preferred stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B preferred stock, alter or change adversely the powers, preferences or rights given to the Series B preferred stock, amend the Series B Certificate of Designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series B preferred stock, or enter into any agreement with respect to any of the foregoing. The Series B Certificate of Designation provides that if any party commences an action or proceeding to enforce any provisions thereunder, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and Delaware general corporation law.

*Fractional Shares.* No fractional shares of common stock will be issued upon conversion of Series B preferred stock. Rather, we shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price.

The Series B preferred stock was issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and was initially represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series B preferred stock and we do not expect a market to develop. We do not plan on applying to list the Series B preferred stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

The transfer agent for our Series B preferred stock is American Stock Transfer & Trust Company, LLC.

### **Series C Preferred Stock Included in the Class B Units**

The preferences and rights of the Series C preferred stock are as set forth in a Certificate of Designation of Series C preferred stock, or the Series C Certificate of Designation, filed as Exhibit 3.1 to this prospectus. The following is a summary of the material terms of our Series C Preferred stock and is qualified in its entirety by the Series C Certificate of Designation. Please refer to the Series C Certificate of Designation for more information on the preferences, rights and limitations of Series C preferred stock.

*Liquidation.* Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series C preferred stock will be entitled to receive distributions out of our assets, whether capital or surplus, of an amount equal to \$0.001 per share of Series C preferred stock before any distributions shall be made on the common stock or any series of preferred stock ranked junior to the Series C preferred stock, but after distributions shall be made on any outstanding Series A preferred stock and any of our existing or future indebtedness.

*Dividends.* Holders of the Series C preferred stock will be entitled to receive dividends equal (on an as-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of our common stock when, as and if such dividends are paid on shares of our common stock. No other dividends will be paid on shares of Series C preferred stock.

*Conversion.* Each share of Series C preferred stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing \$1,000 by the conversion price of \$0.40 (subject to adjustment as described below). This right to convert is limited by the beneficial ownership limitation described below.

*Forced Conversion.* Subject to certain ownership limitations as described below and certain equity conditions being met, until such time that during any 30 consecutive trading days, the volume weighted average price of our common stock exceeds 300% of the conversion price and the daily dollar trading volume during such period exceeds \$500,000 per trading day, we shall have the right to force the conversion of the Series C preferred stock into common stock.

*Beneficial Ownership Limitation.* A holder shall have no right to convert any portion of Series C preferred stock, to the extent that, after giving effect to such conversion, such holder, together with such holder's affiliates, and any persons acting as a group together with such holder or any such affiliate, would beneficially own in excess of 4.99% (or, upon election by a holder prior to the issuance of any shares of Series C preferred stock, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon such conversion (subject to the right of the holder to increase such beneficial ownership limitation upon not less than 61 days prior notice provided that such limitation can never exceed 9.99% and such 61 day period cannot be waived). Beneficial ownership of the holder and its affiliates will be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder. Holders of Series C preferred stock who are subject to such beneficial ownership limitation are and will remain responsible for ensuring their own compliance with Regulation 13D-G promulgated under the Securities Exchange Act of 1934, as amended, consistent with their individual facts and circumstances. In addition, pursuant to Rule 13d-3(d)(1)(i) promulgated under the Securities Exchange Act of 1934, as amended, any person who acquires Series C preferred stock with the purpose or effect of changing or influencing the control of our company, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition will be deemed to be the beneficial owner of the underlying common stock.

*Stock Dividends and Stock Splits.* If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents, subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

*Fundamental Transaction.* In the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series C preferred stock will be entitled to receive upon conversion of the Series C preferred stock the same kind and amount of securities, cash or property which the holders would have received had they converted the Series C preferred stock immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series C preferred stock.

*Voting Rights, etc.* Except as otherwise provided in the Series C Certificate of Designation or required by law, the Series C preferred stock has no voting rights. However, as long as any shares of Series C preferred stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series C preferred stock, alter or change adversely the powers, preferences or rights given to the Series C preferred stock, amend the Series C Certificate of Designation, amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders, increase the number of authorized shares of Series C preferred stock, or enter into any agreement with respect to any of the foregoing. The Series C Certificate of Designation provides that if any party commences an action or proceeding to enforce any provisions thereunder, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other

costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding. This provision may, under certain circumstances, be inconsistent with federal securities laws and Delaware general corporation law.

*Fractional Shares.* No fractional shares of common stock will be issued upon conversion of Series C preferred stock. Rather, we shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price.

The Series C preferred stock will be issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and will initially be represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. There is no established public trading market for the Series C preferred stock and we do not expect a market to develop. We do not plan on applying to list the Series C preferred stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

The transfer agent for our Series C preferred stock is American Stock Transfer & Trust Company, LLC.

### **Description of Warrants Included in the Units**

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus forms a part. Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian, on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock and each Class B Unit issued in this offering includes a warrant to purchase 2,500 shares of our common stock at an exercise price equal to \$0.40 per share at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised.

Subject to certain limitations as described below the warrants are immediately exercisable upon issuance on the closing date and expire on the five year anniversary of the closing date. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants. On the expiration date, unexercised warrants will automatically be exercised via the "cashless" exercise provision.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person

acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of such warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants. Additionally, as more fully described in the warrants, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the warrants on the date of consummation of such transaction.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement, of which this prospectus forms a part, effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a "cashless" exercise provision).

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding, if, after the closing date, (i) the volume weighted average price of our common stock for each of 30 consecutive trading days, or the Measurement Period, which Measurement Period commences on the closing date, exceeds 300% of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions after the initial exercise date), (ii) the average daily trading volume for such Measurement Period exceeds \$500,000 per trading day and (iii) certain other equity conditions are met, and subject to the Beneficial Ownership Limitation, then we may, within one trading day of the end of such Measurement Period, upon notice, or a Call Notice, call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered, or a Call, for consideration equal to \$0.001 per warrant share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is sent by the Company (such date and time, the Call Date). Our right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants. We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

### Outstanding Warrants

Prior to this offering, as of June 30, 2018 (on a pro forma basis to give effect to our July 2018 financing), we had outstanding warrants to purchase common stock as follows:

|   | <b>Total<br/>Outstanding<br/>and<br/>Exercisable</b> | <b>Exercise<br/>price<br/>per<br/>Share</b> | <b>Expiration Date</b> |
|---|--|---|------------------------|
| Series 1 Warrants issued in February 2018 financing | 8,979,500  | \$2.00                                      | February, 2025         |
| Series 2 Warrants issued in February 2018 financing | 8,709,500  | \$2.00                                      | February, 2025         |
| Warrants issued in July 2018 financing              | 1,083,091  | \$1.58                                      | July, 2021             |
| Series E Warrants                                   | 53,803   | \$504.00                                    | September 2019         |

### Certain Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved preferred stock may enable our board of directors to issue shares of preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue additional preferred stock, the issuance could adversely affect the voting power of holders of

common stock and the likelihood that holders of common stock will receive dividend payments or payments upon liquidation.

### **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.

#### *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 66 2/3% of the voting power of our then outstanding voting securities.

*Issuance of undesignated preferred stock.* Our board of directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of undesignated preferred stock (less any shares of Series A preferred stock, Series B preferred stock and Series C preferred shares already issued) 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 American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219. 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 Capital Market under the symbol "AVGR".

**UNDERWRITING**

We have entered into an underwriting agreement dated October 30, 2018 with Ladenburg Thalmann & Co. Inc., as the underwriter and the sole book-running manager of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of our securities set forth opposite its name below.

| <b>Underwriter</b>            | <b>Class A<br/>Units</b> | <b>Class<br/>B<br/>Units</b> |
|-------------------------------|--------------------------|------------------------------|
| Ladenburg Thalmann & Co. Inc. | 3,535,000                | 8,586                        |
| Total                         | 3,535,000                | 8,586                        |

A copy of the underwriting agreement has been filed as Exhibit 1.1 to the registration statement of which this prospectus is part.

We have been advised by the underwriter that they propose to offer the securities directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of \$0.01872 per share and \$0.00048 per warrant.

The underwriting agreement provides that subject to the satisfaction or waiver by the representative of the conditions contained in the underwriting agreement, the underwriter is obligated to purchase and pay for all of the securities offered by this prospectus.

No action has been taken by us or the underwriter that would permit a public offering of the units in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offered hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that it does not intend to confirm sales to any account over which it exercises discretionary authority.

### Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

|   | <b>Class<br/>A<br/>Units</b> | <b>Class B<br/>Units</b> | <b>Total</b>  |
|---|------------------------------|--------------------------|---------------|
| Public offering price                                     | 0.400                        | 1,000.00                 | 10,000,000.00 |
| Underwriting discount to be paid to the underwriter by us | 0.032                        | 80.00                    | 800,000.00    |
| Proceeds to us (before expenses)                          | 0.368                        | 920.00                   | 9,200,000.00  |

We estimate the total expenses payable by us for this offering to be approximately \$1,335,000 which amount includes (i) the underwriting discount of \$800,000, (ii) reimbursement of the accountable expenses of the representative equal to \$100,000 including the legal fees of the representative being paid by us and (iii) other estimated company expenses of approximately \$435,000 which includes legal accounting printing costs and various fees associated with the registration of our securities.

### Determination of Offering Price

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "AVGR." On October 29, 2018 the closing price of our common stock was \$0.59 per share. We do not intend to apply for listing of the Series C Preferred Stock or warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the shares of preferred stock and warrants were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of Series C preferred stock and warrants sold in this offering can be resold at or above the public offering price.

### **Lock-up Agreements**

Our officers, directors and each of their respective affiliates and associated persons have agreed with the representative to be subject to a lock-up period of ninety (90) days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions.

We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

### **Other Relationships**

Upon completion of this offering, we have granted the representative a right of first refusal to act as lead bookrunner, lead placement agent or financial advisor in connection with any subsequent public or private offering of

equity securities or other capital markets financing by us. This right of first refusal extends until February 16, 2019. The terms of any such engagement of the representative will be determined by separate agreement.

### **Stabilization, Short Positions and Penalty Bids**

The underwriter may engage in stabilizing transactions for the purpose of pegging, fixing or maintaining the price of our common stock. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum. These stabilizing transactions may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect that stabilizing transactions may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriter make any representations or predictions as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representations that the underwriter will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

### **Indemnification**

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriter may be required to make for these liabilities.

## **CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS**

The following is a general discussion of certain material U.S. federal income considerations relating to the purchase, ownership and disposition of our common stock. This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service, or the IRS, or opinion of counsel, regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate taxes. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

• insurance companies;

• tax-exempt organizations;

• banks or other financial institutions;

• brokers or dealers in securities;

• regulated investment companies or mutual funds;

• pension plans;

• controlled foreign corporations;

• passive foreign investment companies;

- persons that own (directly, indirectly or constructively) more than 5% of our common stock;

• corporations that accumulate earnings to avoid U.S. federal income tax;

• certain former citizens or long-term residents of the United States;

• persons that have a “functional currency” other than the U.S. dollar;

• persons that acquire our stock or warrants as compensation for services;

• owners that hold our stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and

• partnerships or other entities treated as partnerships for U.S. federal income tax purposes.

If any entity taxable as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. A partner in a partnership or other transparent entity that holds our common stock should consult his, her or its own tax advisor regarding the applicable tax consequences.

For purposes of this discussion, the term “U.S. holder” means a beneficial owner of our common stock that is, for U.S. federal income tax purposes:

• an individual who is a citizen or resident of the United States;

• a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;



an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust, if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A “non-U.S. holder” is a beneficial owner of our common stock that is neither a U.S. holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

**Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, holding and disposing of our common stock.**

## **U.S. Holders**

### *Distributions on Common Stock*

If we pay distributions of cash or property with respect to our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder’s investment, up to such holder’s tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading “—Gain on Sale, Exchange or Other Taxable Disposition.”

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder generally will constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains.

### *Gain on Sale, Exchange or Other Taxable Disposition*

Upon the sale or other taxable disposition of common shares, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such common shares sold or otherwise disposed of. Such gain or loss generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares have been held by the U.S. holder for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. Deductions for capital losses are subject to significant limitations.

## **Non-U.S. Holders**

### *Distributions on Common Stock*

If we pay distributions of cash or property with respect to our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

#### ***Gain on Sale, Exchange or Other Taxable Disposition***

Subject to the discussion below in "—Information Reporting and Backup Withholding" and "—Foreign Account Tax Compliance Act," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our common stock unless:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or

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our common stock constitutes “U.S. real property interests” by reason of our being or having been a “U.S. real property holding corporation” during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock, Series B preferred stock or warrants. Generally, a domestic corporation is a “U.S. real property holding corporation” if the fair market value of its “U.S. real property interests” (within the meaning of the Internal Revenue Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a “U.S. real property holding corporation” for U.S. federal income tax purposes. However, because the determination of whether we are a U.S. real property holding corporation depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other business assets, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we become a U.S. real property holding corporation, as long as our common stock is regularly traded on an established securities market, common stock held by a non-U.S. holder will be treated as U.S. real property interests only if such non-U.S. holder actually (directly or indirectly) or constructively holds more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding such non-U.S. holder’s disposition of, or holding period for, our common stock.

### **Information Reporting and Backup Withholding**

Distributions on, and the payment of the proceeds of a disposition of, our common stock generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements. Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder’s U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

## **Foreign Account Tax Compliance Act**

Legislation commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities (including certain intermediaries) unless such persons comply with FATCA's information reporting and withholding regime. This regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. The FATCA withholding rules apply to dividend payments and, in the case of certain sales or other dispositions occurring after December 31, 2018 (including a distribution to the extent it is treated as a return of capital or capital gain), the gross proceeds of such disposition.

The United States has entered into, and continues to negotiate, intergovernmental agreements, each, an IGA, with a number of other jurisdictions to facilitate the implementation of FATCA. An IGA may significantly alter the application of FATCA and its information reporting and withholding requirements with respect to any particular investor. FATCA is particularly complex and its application remains uncertain. Prospective investors should consult their own tax advisors regarding how these rules may apply in their particular circumstances.

## **LEGAL MATTERS**

Certain legal matters relating to the issuance of the securities offered by this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California. 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. The underwriter has been represented by Ellenoff Grossman & Schole LLP, New York, New York.

## **EXPERTS**

The financial statements of Avinger, Inc. as of December 31, 2017, and for the year then ended, have been audited by Moss Adams LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such consolidated financial statements have been so incorporated in reliance upon the report of such firm (which report expresses an unqualified opinion and includes an explanatory paragraph regarding a going concern emphasis) given upon their authority as experts in accounting and auditing.

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements (and schedule) at December 31, 2016, and for the year then ended, as set forth in their report, which is incorporated by

reference in this prospectus and elsewhere in the registration statement. Our financial statements (and schedule) 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 is also available on our Internet website, [www.avinger.com](http://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, 2017, filed with the SEC on March 30, 2018, as amended by the Form 10-K/A, filed with the SEC on April 26, 2018;

• the information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, from our definitive proxy statement on Schedule 14A which was filed on April 27, 2018;

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our Quarterly Report on Form 10-Q, for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018;

our Quarterly Report on Form 10-Q, for the quarter ended June 30, 2018, filed with the SEC on August 13, 2018;

our Current Reports on Form 8-K filed with the SEC on January 19, 2018, January 30, 2018, February 2, 2018, February 15, 2018, February 23, 2018, March 21, 2018, June 5, 2018, June 11, 2018, June 13, 2018, July 13, 2018, August 8, 2018 and August 24, 2018, 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.

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

(650) 241-7900

You may also access the documents incorporated by reference in this prospectus through our website at [www.avinger.com](http://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.

**3,535,000 Class A Units consisting of common stock and warrants and  
8,586 Class B Units consisting of shares of Series C preferred stock and warrants  
(and 46,465,000 shares of common stock underlying shares of Series C preferred stock and warrants)**

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**PROSPECTUS**

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**Ladenburg Thalmann**

**October 30, 2018**

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