

Avinger Inc  
Form POS AM  
March 14, 2019

As filed with the Securities and Exchange Commission on March 14, 2019

Registration No. 333-222517

333-223023

---

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

POST-EFFECTIVE AMENDMENT NO. 1 TO  
FORM S-1

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**AVINGER, INC.**

---

(Exact name of registrant as specified in its charter)

<b>Delaware</b>	<b>3841</b>	<b>20-8873453</b>
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

**400 Chesapeake Drive**

**Redwood City, California 94063**

**(650) 241-7900**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Jeffrey M. Soinski**

**Chief Executive Officer**

**Avinger, Inc.**

**400 Chesapeake Drive**

**Redwood City, CA 94063**

**(650) 241-7900**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

**Nolan S. Taylor**

**David F. Marx**

**Michael R. Newton**

**Dorsey & Whitney LLP**

**111 S. Main St., 21<sup>st</sup> Floor**

**Salt Lake City, Utah 84111**

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

Edgar Filing: Avinger Inc - Form POS AM

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

---

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

Large accelerated filer  
Non-accelerated filer  
Accelerated filer  
Smaller reporting company  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of Securities Act.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

---

## EXPLANATORY NOTE

On February 16, 2018 Avinger, Inc. (the “Company,” “we,” or “our”) closed a public offering (the “Public Offering”) of 17,979 shares of Series B Preferred Stock, par value \$0.001 per share (the “Series B Preferred Stock”), with each share of Series B Preferred Stock accompanied by one Series 1 warrant to purchase 500 shares of our common stock and one Series 2 warrant to purchase 500 shares of our common stock. The Series B preferred stock issued in the Public Offering is convertible into shares of the Company’s common stock at a conversion price of \$0.40 per share. The securities that we offered in the Public Offering, which included the Series B Preferred Stock, the common stock underlying the Series B Preferred Stock, the Series 1 warrants, the common stock underlying the Series 1 warrants, the Series 2 warrants, and the common stock underlying the Series 2 warrants, were registered on a Registration Statement on Form S-1, which was filed with the Securities and Exchange Commission (the “Commission”) on January 12, 2018 (File No. 333-222517), as amended, which was declared effective by the Commission on February 13, 2018 (the “Initial Registration Statement”), and a Registration Statement on Form S-1, which was filed with the Commission on February 14, 2018 (File No. 333-223023) (the “Rule 462(b) Registration Statement” and, together with the Initial Registration Statement, the “Registration Statements”).

The Series B Preferred Stock, the Series 1 warrants and the Series 2 warrants were issued and sold in the Public Offering and are no longer the subject of this Registration Statement. The securities that were originally registered under the Registration Statements, but have not yet been issued or sold, which include the common stock underlying the Series B Preferred Stock, the Series 1 warrants and the Series 2 warrants, continue to be registered under the Registration Statements, pursuant to this Post-Effective Amendment No. 1 to the Registration Statements (this “Post-Effective Amendment”).

This Post-Effective Amendment is being filed in accordance with Section 10(a)(3) of the Securities Act of 1933, as amended, to update and supplement the information contained in the Registration Statements by (i) incorporating by reference our financial statements for the fiscal year ended December 31, 2018 that were filed with the Commission as part of our Annual Report on Form 10-K on March 6, 2019, (ii) updating certain other disclosures as of and through a more recent practicable date and (iii) incorporating by reference future documents filed with the Commission.

No additional securities are being registered under this Post-Effective Amendment. All applicable registration fees were paid at the time of the original filing of the Registration Statements.

**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, dated March 14, 2019**

## **PROSPECTUS**

**Avinger, Inc.**

**850,500 Shares of Common Stock Underlying the Series B Preferred Stock  
8,979,000 Shares of Common Stock Issuable Upon Exercise of  
Series 1 Warrants**

**8,709,500 Shares of Common Stock Issuable Upon Exercise of  
Series 2 Warrants**

This prospectus relates to the offering of the remaining shares of common stock that are underlying the Series B convertible preferred stock, Series 1 warrants and Series 2 warrants that we issued in our public offering, which closed on February 16, 2018 (the “Public Offering”), including (i) 850,500 shares of our common stock issuable upon the conversion of outstanding shares of our Series B preferred stock, (ii) 8,979,000 shares of our common stock issuable upon the exercise of Series 1 warrants and (iii) 8,709,500 shares of our common stock issuable upon the exercise of Series 2 warrants.

Subject to certain ownership limitations, the Series B preferred stock is currently convertible at any time at the option of the holder into shares of the company’s common stock at a conversion price of \$0.40 per share, which means that each share of Series B preferred stock is convertible into 2,500 shares of common stock without additional consideration. Subject to certain ownership limitations, each Series 1 warrant, which expires on the seventh anniversary of its issuance, is exercisable at any time at the option of the holder to purchase 500 shares of the company’s common stock at an exercise price of \$2.00 per share. Subject to certain ownership limitations, each Series 2 warrant, which expires on the earlier of (i) 60 days following the clearance by the FDA of a new lower-profile version of our Pantheris below-the-knee device (or the same or similar product with a different name) and (ii) the

seventh anniversary of the warrant's issuance, is exercisable at any time at the option of the holder to purchase 500 shares of the company's common stock at an exercise price of \$2.00 per share.

For a more detailed description of the Series B convertible preferred stock, see the section entitled "Description of Capital Stock—Series B Preferred Stock." For a more detailed description of the warrants, see the section entitled "Description of Capital Stock—Series 1 and Series 2 Warrants." For a more detailed description of our common stock, see the section entitled "Description of Capital Stock—Common Stock." We refer to the Series B convertible preferred stock issued hereunder, the warrants to purchase common stock issued hereunder and the shares of common stock issuable upon conversion of the Series B convertible preferred stock and upon exercise of the warrants issued hereunder, collectively, as the securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol "AVGR." On March 13, 2019, the last reported sales price of our common stock was \$0.649 per share.

---

**We are an “emerging growth company” as defined under the federal securities laws. Investing in our securities involves a high degree of risk. Please see the section entitled “Risk Factors” starting on page 7 of this prospectus to read about risks you should consider carefully before making any investment in these securities.**

**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.**

**Ladenburg Thalmann**

**The date of this prospectus is           , 2019**

---



**TABLE OF CONTENTS**

<b>Section</b>	<b>Page</b>
Prospectus Summary	1
Risk Factors	7
Cautionary Notes Regarding Forward-Looking Statements	37
Market, Industry and Other Data	39
Use of Proceeds	40
Plan of Distribution	41
Description of Capital Stock	43
Capitalization	56
Dilution	58
Certain Material U.S. Federal Income Tax Considerations	60
Legal Matters	65
Experts	65
Where You Can Find More Information	65
Information Incorporated by Reference	65

**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.**

**This prospectus contains estimates, projections and other information concerning our industry, our business and the potential markets for our platform, including data regarding the estimated demand in those markets, their projected growth rates, as well as data regarding market research, estimates and forecasts prepared by our management. 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. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. 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.**

Unless the context requires otherwise references to “Avinger”, our “company,” “we,” “us” or “our” refer to Avinger, Inc., a Delaware corporation.

ii

---

## PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference herein and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read the entire prospectus, including “Risk Factors” beginning on page 7, as well as the other information in this prospectus and other information incorporated by reference herein. As used in this prospectus, references to “we,” “our,” “us” and “Avinger” refer to Avinger, Inc. unless the context requires otherwise. This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.*

### 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 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 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 specifically include in-stent restenosis. We received CE Marking in December 2017 and 510(k) clearance in May 2018 for a next-generation version of our Pantheris atherectomy device, which we believe represents a significant improvement over our prior product. This next-generation version of Pantheris includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe improve usability and reliability of the device. The next-generation Pantheris atherectomy device is available for commercial sale in the United States and select international markets. On December 13, 2018 we announced the 500<sup>th</sup> patient treated with the next-generation Pantheris. All previous versions of Pantheris have been discontinued.

We are developing a line extension of our Pantheris image-guided atherectomy platform, Pantheris SV (Small Vessel), a lower profile version of 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 August 2018 and received CE Marking approval in October 2018. On November 15, 2018 we announced the successful treatment of the first patients globally with Pantheris SV by a vascular surgeon in Münster, Germany. Pantheris SV is available in limited supply for commercial sale in the EU; it is not available for commercial sale in the United States at this time.

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-Lumivasular platform products in 2009 and introduced our Lumivasular 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 \$7.9 million in 2018.

## **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](http://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 “Lumivasular” 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 make available, free of charge on our corporate website at [www.avinger.com](http://www.avinger.com), 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).

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

Securities offered by us	We are offering (i) 850,500 shares of our common stock issuable upon the conversion of outstanding shares of Series B preferred stock that we issued in the Public Offering, (ii) 8,979,000 shares of our common stock issuable upon the exercise of outstanding Series 1 warrants that we issued in the Public Offering and (iii) 8,709,500 shares of our common stock issuable upon the exercise of outstanding Series 2 warrants that we issued in the Public Offering.
Shares of common stock underlying the Series B Preferred Stock and the Warrants	18,539,000 shares.
Shares of common stock outstanding before this offering	48,129,047 shares as of March 7, 2019.
Shares of common stock outstanding after this offering	66,668,047 shares (assuming the conversion of the Series B Preferred Stock and exercise of the Series 1 warrants and Series 2 warrants).
Use of proceeds	We will not receive any additional proceeds from any future conversions of the Series B Preferred Stock. Upon the exercise of our outstanding Series 1 warrants and Series 2 warrants, if at all, we may receive up to a total of approximately \$35.4 million in additional net proceeds. However, we cannot predict the timing or the number of Series 1 warrants or Series 2 warrants that may be exercised, if any. We expect to use any net proceeds that we may receive in this offering for general corporate purposes and working capital. See “Use of Proceeds” on page 40 of this prospectus.
Risk Factors	You should carefully read and consider the information set forth under “Risk Factors” on page 7 of this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.
NASDAQ Capital Market symbol for our common stock	“AVGR”.
Limitations on beneficial ownership	Notwithstanding anything herein to the contrary, no holder will be permitted to convert its Series B preferred stock or exercise its warrants if, after such conversion or exercise, such holder would beneficially own more than 4.99% of the shares of common stock then outstanding or, upon election by a holder prior to the issuance of any shares of Series B preferred stock, 9.99%;

Edgar Filing: Avinger Inc - Form POS AM

provided, however, that upon notice to the Company, a holder may increase or decrease its beneficial ownership limitation, provided that in no event shall the beneficial ownership limitation exceed 9.99% and any increase in the beneficial ownership limitation will not be effective until 61 days following notice of such increase from the holder to us.

4

---

Series 1 warrants      The Series 1 warrants will be exercisable beginning on the date of issuance and expire on the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to \$2.00, 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.

Series 2 warrants      The Series 2 warrants will be exercisable beginning on the date of issuance and expire on the earlier of (1) the 60th calendar day following the receipt and announcement of FDA clearance to market our Pantheris BTK device (or the same or similar product with a different name), and (2) the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to \$2.00, 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 Series 1 warrants and the Series 2 warrants are collectively referred to as the "warrants." The forms of each warrant are filed as an exhibit to the registration statement of which this prospectus forms a part.

No listing of Series B Preferred Stock or warrants      We do not intend to apply for listing of the shares of the Series B preferred stock or warrants on any securities exchange or trading system.

The number of shares of common stock that will be outstanding after this offering is based on 48,129,047 shares outstanding as of March 7, 2019, and excludes:

• 77,592 shares of common stock issuable upon the exercise of stock options outstanding as of March 7, 2019 with a weighted average exercise price of \$161.19 per share;

• 24,858,785 shares of common stock issuable upon exercise of outstanding warrants, other than the Series 1 warrants and the Series 2 warrants;

• 2,869,725 unvested restricted stock units;

• 199,201 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;

•

Edgar Filing: Avinger Inc - Form POS AM

113,564 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 Capital Fund, LLC, other than the 23,584 shares we issued to Lincoln Park Capital Fund, LLC as a commitment fee in November 2017 and 65,000 shares we have sold to date under the Purchase Agreement; and

5

---

•shares of common stock issuable upon conversion of our Series A preferred stock.

Except as otherwise indicated, all information in this prospectus assumes a 1-for-40 reverse stock split of our common stock, which became effective as of January 30, 2018.

6

---

## **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 “Cautionary Notes Regarding Forward-Looking Statements.”*

### **Risks Related to Our Business**

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

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

our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, and the timing of such clearances and approvals, particularly with respect to current and future generations of Pantheris;

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

the availability of reimbursement for our Lumivascular platform products;

our ability to attract new customers and increase the amount of business we generate from existing customers;

results of our clinical trials;

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

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

changes in our pricing policies or those of our competitors;

general economic, political, industry and market conditions;

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 \$27.6 million in 2018 and \$48.7 million in 2017. As of December 31, 2018, we had an accumulated deficit of approximately \$328.9 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

We expect our losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will continue to incur significant legal, accounting and other expenses. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

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

We believe that our cash and cash equivalents at December 31, 2018, and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through at least the third quarter of 2019. Even though we received net proceeds of \$10.2 million from the sale of our common stock and Series C convertible preferred stock in our November 2018 offering, net proceeds of \$15.5 million from the sales of our Series B convertible preferred stock and warrants in our February 2018 offering, and net proceeds of \$3.0 million from the sale of our 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 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 in connection with the Series B and Series C preferred stock offering in February 2018 prohibit us from entering into certain transactions involving the issuance of securities for a variable 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 until February 17, 2021. 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 Lumivascular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, and any 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 Lumivasular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;

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

the costs of defending ourselves against existing and future litigation, including pending stockholder class action claims;

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

the extent and scope of our general and administrative expenses.

We 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 December 31, 2018, we had \$7.5 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds (collectively “CRG”). Our significant amount of debt may:

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 of our assets 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 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. 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.

***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 next-generation version of Pantheris 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 our current version of Pantheris. 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 Lumivascular platform products we intend to commercialize in the United States. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of our next-generation Pantheris and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA clearance 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 Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivascular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.





We are also aware of certain characteristics and features of our Lumivasular 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 Lumivasular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye. 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 Lumivasular 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 Lumivasular 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 increased to 17% for the year ended December 31, 2018, compared to -31% for the year ended December 31, 2017. Gross margin for the three months and year ended December 31, 2018 was positively impacted by lower excess and obsolete provisions related to our Lightbox and Pantheris inventories in 2018.

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 Lumivasular platform to physicians, hospitals and patients.***

In order to generate sales, we must be able to clearly demonstrate that our Lumivasular 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 Lumivasular 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 Lumivasular 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 imaging products is lower than with non-imaging 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 competitors' 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 Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

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

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

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

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

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

In order to remain competitive, we must continue to develop new product offerings and enhancements to our existing Lumivascular platform products. In particular, we have developed and are currently developing two next-generation versions of our Pantheris atherectomy device, next-generation Pantheris and Pantheris SV (Small Vessel), a lower profile version of Pantheris. We believe these versions will represent significant improvements in reliability and usability compared to prior versions of our products. We anticipate that our next-generation Pantheris and Pantheris SV will translate into revenue growth and achieve increased physician acceptance. Because we believe they are important to our future revenues, we are devoting a significant portion of our resources to their continued 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 our next-generation Pantheris and Pantheris SV, are 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 FFDCAs prohibit us from marketing or advertising 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 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 Lumivasular platform products in-house. Our products are comprised of components sourced from a variety of contract manufacturers, with final assembly completed at our facility in Redwood City, California. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, terrorism, flooding and power outages. Further, our electronic systems may experience service interruptions, denial-of-service and other cyber-attacks, computer viruses or other events. Any of these may render it difficult or impossible for us to manufacture products, pursue our research and development efforts or otherwise run our business for some period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products.

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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, 2018, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of \$282.7 million and \$199.3 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2018 for state purposes. Out of the total Federal net operating loss carryforwards, \$25.2 million were generated post December 31, 2017 and have no expiration. 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.” A number of our common and preferred stock financings over the past year 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 operating results.***

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

To date, our technology and product development efforts have been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in

dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial condition may suffer.

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

***If our technology infrastructure is compromised, damaged or interrupted by a cybersecurity incident, data security breach or other security problems, our operating results and financial condition could be adversely affected.***

We use technology in substantially all aspects of our business operations, and our ability to serve customers most effectively depends on the reliability of our technology systems. Cybersecurity incidents can include computer viruses, computer denial-of-service attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage.

In addition, our technology infrastructure and systems are vulnerable to damage or interruption from natural disasters, power loss and telecommunications failures. Any such disruption to our systems, or the technology systems of third parties on which we rely, the failure of these systems to otherwise perform as anticipated, or the theft, destruction, loss, misappropriation, or release of sensitive and/or confidential information or intellectual property, could require us to notify affected individuals, federal or state agencies or media outlets of the incident and could result in business disruption, negative publicity, loss of customers, potential liability, including litigation or other legal actions against us or the imposition of penalties, fines, fees or liabilities, which may not be covered by our insurance policies, and competitive disadvantage, any or all of which would potentially adversely affect our customer service, decrease the volume of our business and result in increased costs and lower profits. Moreover, a cybersecurity breach could require us to devote significant management resources to address the problems associated with the breach and to expend significant additional resources to upgrade further the security measures we employ to protect information against cyber-attacks and other wrongful attempts to access such information, which could result in a disruption of our operations.

While we have invested, and continue to invest, in technology security initiatives and other measures to prevent security breaches and cyber incidents, as well as disaster recovery plans, these initiatives and measures may not be entirely effective to insulate us from technology disruption that could result in adverse effects on our results of operations.

### **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 Lumivascular platform products.***

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

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

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2018, we held 23 issued and allowed U.S. patents and had 29 U.S. utility patent applications and 4 PCT applications pending. As of December 31, 2018, we also had 45 issued and allowed patents outside of the United States. As of December 31, 2018, we had 43 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other



trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business.

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

### **Risks Related to Government Regulation**

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

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

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

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

product design, development and manufacture;

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

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 our next-generation Pantheris in May 2018 and we filed a 510(k) submission for 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 medical device reports, or MDRs, 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 MDRs 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 that 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.

26

---

***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 operating results and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. We plan to make further modifications to the design of Pantheris to enhance cutting efficiency and access smaller vessels. Future versions of Pantheris incorporating these enhancements may require additional regulatory clearances or approvals.

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

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

We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDHS. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDHS to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. BSI, our European Notified Body, inspected our facility in 2014 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. BSI conducted a recertification audit (for EU) in 2016 followed by surveillance audits in 2017 & 2018, and found no major non-conformances. BSI also audited us for QSR compliance under MDSAP (Medical Device Single Audit Program) for FDA in July 2016, and found no major non-conformances. Additionally, BSI conducted a Technical File Audit in 2018 that resulted in one major non-conformance and three minor non-conformances. All non-conformances identified in aforementioned audits have been, or are being addressed via Avinger's CAPA system.

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 major compliance problems, we may have to shut down our facility and cease manufacturing until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a shutdown or delay at our manufacturing facility we may be unable to produce our Lumivascular platform products, which would harm our business.

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

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

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

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

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

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

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

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

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

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

HIPAA, as amended by the HITECH Act, which protects the security and privacy of protected health information;  
and

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

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

fraudulent claim for purposes of the False Claims Act.

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

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

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

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

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

#### **Risks Related to Our Common Stock and Preferred Stock**

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

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

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

market acceptance of our Lumivasular platform and products, including Pantheris;

the results of our clinical trials;

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

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

actual or anticipated fluctuations in our financial condition and operating results;

quarterly variations in our or our competitors' results of operations;

general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;

changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;

the loss of key personnel, including changes in our board of directors and management;

legislation or regulation of our business;

lawsuits threatened or filed against us;

the announcement of new products or product enhancements by us or our competitors;

announcements related to patents issued to us or our competitors and to litigation; and

developments in our industry.

From time to time, our affiliates may sell stock for reasons due to their personal financial circumstances. These sales may be interpreted by other stockholders as an indication of our performance and result in subsequent sales of our stock that have the effect of creating downward pressure on the market price of our common stock. In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies.

Our stock price has decreased significantly over the course of the past year. As a result of the decrease in our stock price, the options held by our employees are less valuable which make it more likely that certain of our employees may leave our company. The loss of key employees could have an adverse effect on our business.

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. 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.

***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 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 (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 (“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 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. 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. 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 only able to issue a limited number of shares using the Shelf Registration Statement at this time. Accordingly, it was necessary to register the shares sold pursuant to our various financing activities.. 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, 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 prohibit us from entering into certain transactions involving the issuance of securities for a variable 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 until February 17, 2021. 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 2018 financial statements contain disclosure that there is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.***

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors' report on our 2018 financial statements, included in our Annual Report on Form 10-K filed with the Commission on March 6, 2019 and incorporated herein by reference, a "going concern" opinion, meaning that we have recurring losses from operations and negative cash flows from operations that raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our 2018 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, with the exception that all borrowings are classified as current on the condensed balance sheets.

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance

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

We will incur additional compensation costs in the event that we decide to pay our executive officers cash compensation closer to that of executive officers of other public medical device companies, which would increase our general and administrative expense and could harm our profitability. Any future equity awards will also increase our compensation expense. We also expect that being a public company and compliance with applicable rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain 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 prospectus and in other filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

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

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

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 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 December 4, 2018, we received a letter from Nasdaq's Listing Qualifications Department notifying us that the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price for the Company's listed securities was less than \$1 for the previous 30 consecutive business days. The Company has a period of 180 calendar days, or until June 3, 2019, to regain compliance with the rule referred to in this paragraph. To regain compliance, during the 180 day period, the bid price of the Company's common stock must close at \$1 or more for a minimum of ten consecutive business days. The notice has no present impact on the listing of the Company's securities on Nasdaq.

In the event that the Company does not regain compliance with the Nasdaq Listing Rules prior to the expiration of the compliance period, it will receive written notification that its securities are subject to delisting. At that time, the Company may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. The Company intends to actively monitor its bid price and will consider available options to resolve the deficiency and regain compliance with the Nasdaq Listing Rules, including conducting a reverse stock split.

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, operating results and financial condition.

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

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future, 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 and our Series B 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 titled “*Dividend Policy*” below.

***CRG 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, our governing documents, as amended, have 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 of our outstanding warrants) and Series B 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, plus any unpaid dividends from any such transaction before any amount is paid to the holders of our Series B preferred stock, Series C 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.

## CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein 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,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” or other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

the outcome of and expectations regarding our clinical studies, including our INSIGHT trial and plans to conduct further clinical studies;

our plans to modify our current products, or develop new products, to address additional indications;

our ability to obtain additional financing through future equity or debt financings;

the expected timing of 510(k) clearances by FDA, for enhanced versions of Pantheris;

the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for additional versions of Pantheris designed for use in smaller vessels;

the expected growth in our business and our organization;

our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;

our ability to continue as a going concern;

our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;

our ability to obtain and maintain intellectual property protection for our products;

our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;

our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;

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

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

our financial performance;

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

developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this 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 and our other filings with the SEC incorporated herein by reference. 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. Except as required by law, 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 the documents incorporated by reference in this prospectus 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, including the documents incorporated by reference herein, contains estimates and information concerning our industry, including market size and growth rates of the markets in which we participate, that are based on industry publications and reports. We relied on industry, market and similar data from Millennium Research Group, the Sage Group, peer reviewed journals, formal presentations at medical society meetings and other sources. We also rely on our own research and estimates in this prospectus. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and reports. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

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

## USE OF PROCEEDS

We will not receive any additional proceeds from any future conversions of the Series B Preferred Stock. Upon the exercise of our outstanding Series 1 warrants and Series 2 warrants, if at all, we may receive up to a total of \$35.4 million in additional net proceeds. However, we cannot predict the timing or the number of Series 1 warrants or Series 2 warrants that may be exercised, if any. We expect to use any net proceeds that we may receive in this offering for general corporate purposes and working capital.

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.

## **PLAN OF DISTRIBUTION**

The (i) shares of common stock underlying the Series B convertible preferred stock, (ii) shares of common stock underlying the Series 1 warrants and (iii) shares of common stock underlying the Series 2 warrants that may be issued pursuant to this prospectus may be offered directly by the Company, without an underwriter. The holders of such outstanding shares of Series B convertible preferred stock, Series 1 warrants and Series 2 warrants may acquire the shares of common stock directly from the Company by converting their shares of Series B convertible preferred stock or exercising their warrants as described in the section entitled "Description of Capital Stock."

We previously entered into an underwriting agreement dated February 14, 2018 with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters (the "representative"). A copy of the underwriting agreement is filed as an exhibit to the registration statement of which this prospectus is part.

No action has been taken by us or the underwriters that would permit a public offering of the shares of preferred stock and warrants, or the shares of common stock underlying the preferred stock and warrants to purchase common stock, 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 underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### **Determination of Offering Price**

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "AVGR." On March 13, 2019 the closing price of our common stock was \$0.649 per share. We do not intend to apply for listing of the Series B Preferred Stock or warrants on any securities exchange or other trading system.

The conversion price of the Series B convertible preferred stock is \$0.40 per share, and the exercise price per share of the warrants is \$2.00. The conversion price and other terms of this offering were negotiated between us and the underwriters.

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

The underwriters 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 underwriters 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 underwriters 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 underwriters 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 underwriters make any representations that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

### **Indemnification**

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

## **DESCRIPTION OF CAPITAL STOCK**

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

### **General**

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

### **Common Stock**

#### *Outstanding Shares*

On March 7, 2019, there were 48,129,047 shares of common stock outstanding, held of record by 170 stockholders. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

As of March 7, 2019, there were 42,601,088 shares of common stock subject to outstanding warrants, and 77,592 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 2/3% of our then outstanding voting securities. Additionally, our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a plurality of the votes cast at a meeting of stockholders will be able to elect all of the directors then standing for election.

*Right to Receive Liquidation Distributions*

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

### *Rights and Preferences*

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

### *Fully Paid and Nonassessable*

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

### **Preferred Stock**

Under our amended and 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 of preferred stock, par value \$0.001 per share, in one or more series. As of December 31, 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 8,586 shares of preferred stock were designated Series C preferred stock. As of March 7, 2019, 41,800 shares of Series A preferred stock were issued and outstanding, 615 shares of Series B preferred stock were issued and outstanding and no shares of Series C preferred stock were issued and outstanding.

Pursuant to our amended and 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 Convertible Preferred Stock**

The preferences and rights of the Series A preferred stock are as set forth in a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible 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, as well as the Certificate of Amendment to the Series A Certificate of Designation, filed as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on November 6, 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, Series C 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 and have utilized this option in the past.

*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.

CRG Partner III L.P. and certain of its affiliated funds, collectively referred to as CRG, are the majority holder of the Series A preferred stock and has agreed to suspend the conversion of its Series A 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. The Company has agreed to call a meeting of the Company's stockholders on or before June 30, 2019, and to use its 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 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.* 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 and Series C 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 and Series C 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.

*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 Convertible Preferred Stock**

The preferences and rights of the Series B preferred stock are as set forth in a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible 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 \$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 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, materially alter or change adversely the powers, preferences or rights given to the Series B preferred stock, materially 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.

## **Warrants**

As of December 31, 2018, we had outstanding warrants to purchase common stock as follows:

<b>Total</b>	<b>Exercise price</b>	<b>Expiration Date</b>
<b>Outstanding</b>	<b>per Share</b>	

**and**

	<b>Exercisable</b>		
Warrants issued in November 2018 financing	28,750,000	\$ 0.40	November 2023
Warrants issued in July 2018 financing	1,083,091	\$ 1.58	July 2021
Series 1 Warrants issued in February 2018 financing	8,979,000	\$ 2.00	February 2025
Series 2 Warrants issued in February 2018 financing	8,709,500	\$ 2.00	February 2025
Series E Warrants	53,803	\$ 504.00	September 2019

### November 2018 Warrants

The material terms and provisions of the warrants issued in our November 2018 financing (the “November 2018 Warrants”) are summarized below. This summary of some provisions of the November 2018 Warrants is not complete. For the complete terms of the November 2018 Warrants, you should refer to the form of November 2018 Warrant filed as Exhibit 4.7 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 November 2018 Warrants were issued in book-entry form and were initially 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.

*Exercise.* The November 2018 Warrants have an exercise price equal to \$0.40 per share. The November 2018 Warrants are governed by the terms of a global warrant held in book-entry form. The holder of an November 2018 Warrant is not deemed a holder of our underlying common stock until the November 2018 Warrant is exercised. Subject to certain limitations as described below the November 2018 Warrants expire on November 1, 2023. The holders must pay the exercise price in cash upon exercise of the November 2018 Warrants, unless such holders are utilizing the cashless exercise provision of the November 2018 Warrants. On the expiration date, unexercised November 2018 Warrants will automatically be exercised via the “cashless” exercise provision. Upon the holder’s exercise of an November 2018 Warrant, we will issue the shares of common stock issuable upon exercise of the November 2018 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 November 2018 Warrants to purchase common stock, holders of the November 2018 Warrants do 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.

*Beneficial Ownership Limitation.* Subject to limited exceptions, a holder of November 2018 Warrants does not have the right to exercise any portion of its November 2018 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.

*Stock Dividends and Stock Splits.* The exercise price and the number of shares issuable upon exercise of the November 2018 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.

*Fundamental Transaction.* 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 November 2018 Warrants will be entitled to receive upon exercise of such November 2018 Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their November 2018 Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the November 2018 Warrants. Additionally, as more fully described in the November 2018 Warrants, in the event of certain fundamental transactions, the holders of the November 2018 Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the November 2018 Warrants on the date of consummation of such transaction.

The November 2018 Warrants are not listed on any securities exchange, and we do not intend to apply for listing of the November 2018 Warrants on any securities exchange or other trading system.

## **July 2018 Warrants**

On July 12, 2018, the Company entered into a securities purchase agreement (the "July 2018 Purchase Agreement") with the purchasers of the certain shares of common stock. The July 2018 Purchase Agreement provided for a concurrent private placement of warrants to purchase common stock (the "July 2018 Warrants"). The material terms and provisions of the July 2018 Warrants are summarized below. This summary of some provisions of the July 2018 Warrants is not complete. For the complete terms of the July 2018 Warrants, you should refer to the form of July 2018 Warrant filed as Exhibit 4.6 to the registration statement of which this prospectus forms a part.

*Exercise.* The July 2018 Warrants are exercisable for an aggregate of 1,083,090 shares of common stock. The July 2018 Warrants have an exercise price of \$1.58 per share and expire on July 12, 2021. The holder of a July 2018

Warrant is not deemed a holder of our underlying common stock until the July 2018 Warrant is exercised. Subject to certain limitations as described below, the July 2018 Warrants expire on July 12, 2021. The holders must pay the exercise price in cash upon exercise of the July 2018 Warrants, unless such holders are utilizing the cashless exercise provision of the July 2018 Warrants. On the expiration date, unexercised July 2018 Warrants will automatically be exercised via the “cashless” exercise provision. Upon the holder’s exercise of a July 2018 Warrant, we will issue the shares of common stock issuable upon exercise of the July 2018 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 July 2018 Warrants to purchase common stock, holders of the July 2018 Warrants do 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.

*Beneficial Ownership Limitation.* Subject to limited exceptions, a holder of a July 2018 Warrant does not have the right to exercise any portion of its July 2018 Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99%, or 9.99% at a holder's election, of the number of shares of Common Stock outstanding immediately after giving effect to such exercise; provided, however, that upon prior notice to the Company, the holder may increase or decrease the beneficial ownership limitation, provided further that in no event shall the beneficial ownership limitation exceed 9.99% and any increase in the beneficial ownership limitation will not be effective until 61 days following notice to the Company.

*Stock Dividends and Stock Splits.* The exercise price and the number of shares issuable upon exercise of the July 2018 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.

*Fundamental Transaction.* 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 July 2018 Warrants will be entitled to receive upon exercise of such July 2018 Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their July 2018 Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the July 2018 Warrants. Additionally, as more fully described in the July 2018 Warrants, in the event of certain fundamental transactions, the holders of the July 2018 Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the July 2018 Warrants on the date of consummation of such transaction.

*Call Right.* The July 2018 Warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the July 2018 Warrants are outstanding, if (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 \$3.95 (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 \$100,000 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 July 2018 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 July 2018 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 July 2018 Warrants shall be exercised ratably among the holders based on the then outstanding July 2018 Warrants.

The July 2018 Warrants are not listed on any securities exchange, and we do not intend to apply for listing of the July 2018 Warrants on any securities exchange or other trading system.



## **Series 1 and Series 2 Warrants**

The material terms and provisions of the Series 1 and Series 2 Warrants are summarized below. This summary of some provisions of the Series 1 and Series 2 Warrants is not complete and is qualified in its entirety by the form of warrant filed as Exhibit 4.5 to the registration statement of which this prospectus is a part. Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, the warrants were issued in book-entry form and were initially 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.

*Exercise.* The Series 1 Warrants are immediately exercisable and expire on the seventh anniversary of the date of issuance. The Series 2 Warrants are immediately exercisable and expire on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60<sup>th</sup> calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name); provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven-year anniversary of the initial exercise date. Each whole Series 1 or Series 2 Warrant is exercisable to purchase one share of our common stock at an exercise price of \$2.00 per share at any time prior to expiration. The Series 1 and Series 2 Warrants are each governed by the terms of a global warrant certificate deposited with DTC. The holder of a Series 1 or Series 2 Warrant will not be deemed a holder of our underlying common stock until such warrant is exercised, except as set forth in such warrant. The holders Series 1 and Series 2 Warrants must pay the exercise price in cash upon exercise of the Series 1 and Series 2 Warrants, unless such holders are utilizing the cashless exercise provision of the Series 1 and Series 2 Warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement.

*Beneficial Ownership Limitation.* Subject to limited exceptions, a holder of Series 1 or Series 2 Warrants will not have the right to exercise any portion of its Series 1 or Series 2 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 holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise; provided, however, that upon notice to the Company, the holder may increase or decrease the beneficial ownership limitation, provided that in no event shall the beneficial ownership limitation exceed 9.99% and any increase in the beneficial ownership limitation will not be effective until 61 days following notice of such increase from the holder to us.

*Stock Dividends and Stock Splits.* The exercise price and the number of shares issuable upon exercise of the Series 1 and Series 2 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.

*Fundamental Transaction.* 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 Series 1 and Series 2 Warrants will be entitled to receive upon exercise of the Series 1 and Series 2 Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the Series 1 and Series 2 Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series 1 and Series 2 Warrants. Further, as more fully described in the Series 1 and Series 2 Warrants, in the event of certain fundamental transactions, the holders of the Series 1 and Series 2 Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Series 1 or Series 2 Warrants on the date of consummation of such transaction.

Upon the holder's exercise of a Series 1 or Series 2 Warrant, we will issue the shares of common stock issuable upon exercise of the Series 1 or Series 2 Warrant within the earlier of two trading days following our receipt of a notice of exercise or the standard settlement period for the market on which the common stock is then listed, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any Series 1 or Series 2 Warrants, holders of the Series 1 or Series 2 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.

The Series 1 and Series 2 Warrants are not listed on any securities exchange, and we do not intend to apply for listing of the Series 1 and Series 2 Warrants on any securities exchange or other trading system.

### **Series E Warrants**

In connection with the issuance of the Company's Series E Convertible preferred stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible preferred stock, warrants (the "Series E Warrants") to purchase up to the number of shares of common stock equal to 50% of the number of shares of the Company's Series E Convertible preferred stock purchased. The Series E Warrants are immediately exercisable, at an exercise price per share of \$504.00, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company.

### **Equity Awards**

As of December 31, 2018, there were 3,020,207 shares of our common stock issuable upon exercise of outstanding awards under our 2015 Equity Incentive Plan.

### **Officers' and Directors' Purchase Plan**

As of December 31, 2018, there were 44,012 shares of our common stock issued under our Officer and Director Share Purchase Plan.

### **Exclusive Jurisdiction**

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

any derivative action or proceeding brought on behalf of us;

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

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

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

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

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

The holders of an aggregate of up to 71,877 shares of our common stock, as of December 31, 2018, including shares of common stock issuable upon the exercise of outstanding options and warrants, or their permitted transferees, are entitled to rights with respect to the registration of such shares under the Securities Act. We refer to these shares as "registrable securities." These rights are provided under the terms of our amended and restated investors' rights agreement between us and the holders of registrable securities, and include demand registration rights, "piggyback" registration rights and Form S-3 registration rights.

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

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

### ***Demand Registration Rights***

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

### ***Piggyback Registration Rights***

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

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

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

### ***CRG Registration Rights***

In September 2015, we entered into a Securities Purchase Agreement with CRG, pursuant to which we sold 8,705 shares of our common stock to CRG for a purchase price of \$559.64 per share. Under the Purchase Agreement, CRG is entitled to certain rights with respect to the registration of such shares under the Securities Act as described below.

Within 30 business days of our becoming eligible to use Form S-3, we were required to file a registration statement covering the resale of the shares sold to CRG under the Purchase Agreement, which we did on February 3, 2016 and have also done through the registration statement of which this prospectus forms a part. Our failure to maintain the effectiveness of the registration statement would be considered a registration default and would result in penalty payments payable by us to CRG equal to 1% of the aggregate purchase price paid by CRG under the Purchase Agreement for each 30-day period (or portion thereof) in which there is a registration default. During the time that Avinger must maintain the effectiveness of the registration statement, we must comply with other affirmative covenants.

In February 2018, we entered into a Registration Rights Agreement with CRG (the “2018 Registration Rights Agreement”), pursuant to which we agreed to, upon request of the majority holders of the Series A Preferred Stock, effect the registration of all shares of the Series A Preferred Stock. Additionally, the 2018 Registration Rights Agreement provides that the holders of Series A Preferred Stock will be entitled to have their stock included on any Company initiated registration statements, subject to limitations including a reduction in the number of shares included in registration statements based on the discretion of any underwriters. The Company will bear the costs of any registration statement effected pursuant to the 2018 Registration Rights Agreement, and will provide customary indemnification and reimburse legal fees to participating Purchasers. The foregoing description does not purport to be complete and is qualified in its entirety by reference to the 2018 Registration Rights Agreement, a copy of which is filed to Exhibit 4.4 to the registration statement of which this prospectus forms a part.

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

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is 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."



**CAPITALIZATION**

The following table sets forth our capitalization as of December 31, 2018:

on an actual basis; and

on an as adjusted basis to give effect to the issuance and sale of (i) 850,500 shares of our common stock issuable upon the conversion of outstanding shares of our Series B preferred stock, (ii) 8,979,000 shares of our common stock issuable upon the exercise of Series 1 warrants and (iii) 8,709,500 shares of our common stock issuable upon the exercise of Series 2 warrants in this offering, and the application of the net proceeds of this offering.

You should read this table together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus. The capitalization information discussed below is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing.

	<b>Actual</b>	<b>Pro Forma As Adjusted</b>
Borrowings	\$7,486	\$7,486
Stockholders' equity (deficit):		
Convertible preferred stock issuable in series, par value of \$0.001		
Shares authorized: 5,000,000		
Shares issued and outstanding: 45,671; aggregate liquidation preference related to Series A convertible preferred stock of \$44,718	—	—
Common stock, par value of \$0.001		
Shares authorized: 100,000,000		
Shares issued and outstanding: 34,921,999, 53,460,999 pro forma	34	53
Additional paid-in capital	338,311	373,635
Accumulated deficit	(328,885)	(328,885)
Total stockholders' equity (deficit)	9,460	44,803
Total capitalization	\$16,946	\$52,289

The number of shares of common stock that will be outstanding after this offering is based on 34,921,999 shares outstanding as of December 31, 2018, and excludes:

Edgar Filing: Avinger Inc - Form POS AM

79,545 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2018 with a weighted average exercise price of \$170.73 per share;

29,886,894 shares of common stock issuable upon exercise of outstanding warrants, other than the Series 1 warrants and the Series 2 warrants;

2,940,662 unvested restricted stock units;

126,686 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;

155,988 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 Capital Fund, LLC, other than the 23,584 shares we issued to Lincoln Park Capital Fund, LLC as a commitment fee in November 2017 and 65,000 shares we have sold to date under the Purchase Agreement;

• shares of common stock issuable upon conversion of the Series A 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 a 1-for- 40 reverse stock split of our common stock, which became effective as of January 30, 2018.

**DILUTION**

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of December 31, 2018, our historical net tangible book value was \$9.5 million, or \$0.27 per share of common stock, based on 34,921,999 shares of our common stock outstanding at December 31, 2018. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2018.

After giving effect to our issuance and sale of 850,500 shares of our common stock issuable upon the conversion of outstanding shares of our Series B preferred stock, our net tangible book value as of December 31, 2018 would have been \$9.5 million, or \$0.26 per share of our common stock. This amount represents an immediate dilution of \$0.14 per share to holders of shares of Series B preferred stock.

After giving effect to our issuance and sale of 8,979,000 shares of our common stock issuable upon the exercise of Series 1 warrants, our net tangible book value as of December 31, 2018 would have been \$27.4 million, or \$0.62 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$0.35 per share and an immediate dilution of \$1.38 per share to the holders of Series 1 warrants.

After giving effect to our issuance and sale of 8,709,500 shares of our common stock issuable upon the exercise of Series 2 warrants, our net tangible book value as of December 31, 2018 would have been \$26.9 million, or \$0.62 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$0.35 per share and an immediate dilution of \$1.38 per share to the holders of Series 2 warrants.

This dilution information is illustrative only and will change based on the actual public offering price. The following table illustrates the dilution described above:

Conversion price per share of Series B convertible preferred stock	\$0.40
Actual net tangible book value per share as of December 31, 2018	\$0.27
Increase in net tangible book value per share attributable to conversion of shares of Series B convertible preferred stock	\$(0.01)
Pro forma net tangible book value per share after conversion of shares of Series B convertible preferred stock	\$0.26
Dilution in pro forma net tangible book value per share to holders of shares of Series B convertible preferred stock	\$0.14

Edgar Filing: Avinger Inc - Form POS AM

Exercise price per Series 1 warrant	\$2.00
Actual net tangible book value per share as of December 31, 2018	\$0.27
Increase in net tangible book value per share attributable to exercise of Series 1 warrants	\$0.35
Pro forma net tangible book value per share after exercise of Series 1 warrants	\$0.62
Dilution in pro forma net tangible book value per share to holders of shares of Series 1 warrants	\$1.38
Exercise price per Series 2 warrant	\$2.00
Actual net tangible book value per share as of December 31, 2018	\$0.27
Increase in net tangible book value per share attributable to exercise of Series 2 warrants	\$0.35
Pro forma net tangible book value per share after exercise of Series 2 warrants	\$0.62
Dilution in pro forma net tangible book value per share to holders of shares of Series 2 warrants	\$1.38



The above discussion and table are based on 34,921,999 shares outstanding as of December 31, 2018, and exclude:

79,545 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2018 with a weighted average exercise price of \$170.73 per share;

29,886,894 shares of common stock issuable upon exercise of outstanding warrants, other than the Series 1 warrants and the Series 2 warrants;

2,940,662 unvested restricted stock units;

126,686 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;

155,988 shares of common stock reserved for future issuance under our Officer and Director Share Purchase Plan, or ODPP;

23,584 shares of common stock issuable under the Purchase Agreement with Lincoln Park Capital Fund, LLC, other than the 23,584 shares we issued to Lincoln Park Capital Fund, LLC as a commitment fee in November 2017 and 65,000 shares we have sold to date under the Purchase Agreement;

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

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

To the extent that outstanding options or warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. In the event that additional capital is raised through the sale of equity, our stockholders will be further diluted.

## **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, Series B Preferred Stock or warrants. This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (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 (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, Series B Preferred Stock or warrants as capital assets 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, Series B Preferred Stock or warrants, 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, Series B Preferred Stock or warrants 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, Series B Preferred Stock or warrants 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, Series B Preferred Stock or warrants 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, Series B Preferred Stock or warrants.**

## **U.S. Holders**

### *Exercise of Warrants*

Subject to the discussion in the following paragraph, a U.S. holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of shares of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. holder's initial tax basis in the shares of our common stock received upon the exercise of a warrant will be equal to the sum of (a) such U.S. holder's tax basis in such warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such warrant. A U.S. holder's holding period for the shares of our common stock received upon the exercise of a warrant will begin on the day after the date that the warrant is exercised (or possibly the date of exercise).

In certain circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into shares of common stock is unclear. A cashless exercise may be tax-free, either because the exercise is not a gain recognition event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a U.S. holder's basis in the common stock received would equal the holder's basis in the warrant. If the cashless exercise were treated as not being a gain recognition event, a U.S. holder's holding period in the common stock would be treated as commencing on the date following the date of exercise (or possibly the date of exercise) of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the warrant.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered warrants equal to the number of common shares having a value equal to the exercise price for the total number of warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the common stock represented by the warrants deemed surrendered and the U.S. holder's tax basis in the warrants deemed surrendered. In this case, a U.S. holder's tax basis in the common stock received would equal the sum of the fair market value of the common stock represented by the warrants deemed surrendered and the U.S. holder's tax basis in

the warrants exercised. A U.S. holder's holding period for the common stock would commence on the date following the date of exercise (or possibly the date of exercise) of the warrant. Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

*Certain Adjustments to the Warrants or Series B Preferred Stock*

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant or conversion of a share of Series B Preferred Stock, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants or conversion price of Series B Preferred Stock made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading "Distributions on Common Stock or Series B Preferred Stock" below.

***Expiration of the Warrants without Exercise***

Upon the lapse or expiration of a warrant, a U.S. holder generally will recognize a loss in an amount equal to such U.S. holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrant is held for more than one year. Deductions for capital losses are subject to significant limitations.

***Conversion of Series B Preferred Stock***

A U.S. holder generally will not recognize gain or loss upon the conversion of a share of Series B Preferred Stock into common stock. A U.S. holder's initial tax basis in the shares of our common stock received upon the conversion of a share of Series B Preferred Stock will be equal to such U.S. holder's tax basis in the share of Series B Preferred Stock. A U.S. holder's holding period for the shares of our common stock received upon the conversion of a share of Series B Preferred Stock will include the U.S. holder's holding period in such share of Series B Preferred Stock.

***Distributions on Common Stock or Series B Preferred Stock***

If we pay distributions of cash or property with respect to our common stock or Series B Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series B Preferred 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 or Series B Preferred 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, Series B Preferred Stock or warrants, 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, Series B Preferred Stock or warrants 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, Series B Preferred Stock or warrants 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 or Series B Preferred Stock***

If we pay distributions of cash or property with respect to our common stock or Series B Preferred Stock (including constructive distributions as described above under the heading “Certain Adjustments to the Warrants or Series B Preferred 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 or Series B Preferred 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, Series B Preferred Stock or warrants 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
- our common stock, Series B Preferred Stock or warrants, as applicable, constitute “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, however, 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 (including by reason of holding Series B Preferred Stock or warrants) 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. Non-U.S. holders of Series B Preferred Stock or warrants should consult their tax advisors regarding whether such Series B Preferred Stock of warrants would constitute U.S. real property interests in the event that we have been, are or become a U.S. real property holding corporation.

## **Information Reporting and Backup Withholding**

Distributions on, and the payment of the proceeds of a disposition of, our common stock, Series B Preferred Stock or warrants 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**

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Dorsey & Whitney, LLP, Salt Lake City, Utah.

## **EXPERTS**

The financial statements of Avinger, Inc. as of December 31, 2018 and 2017 and for the years 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 financial statements have been so incorporated in reliance upon the report of such firm (which report expresses an unqualified opinion and includes explanatory paragraphs regarding a going concern emphasis and the adoption of Accounting Standards Codification Topic No. 606, Revenue Recognition) given upon 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>. 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 under the Securities Act of 1933 relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above. The registration statement and the documents referred to below under "Information Incorporated by Reference" are also available on our Internet website, [www.avinger.com](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**

## Edgar Filing: Avinger Inc - Form POS AM

The SEC allows us to incorporate by reference into this prospectus certain information we file with it, which means that we can disclose important information by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement. 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 fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019;

our Current Reports on Form 8-K filed with the SEC on February 15, 2019 and March 11, 2019; and

the description of our common stock contained in our Registration Statement on Form 8-A as filed with the SEC on January 27, 2015 pursuant to Section 12(b) of the Exchange Act.

We also incorporate by reference into this prospectus all documents that we 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. Notwithstanding the foregoing, we are not incorporating by reference information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits, nor in any documents or other information that is deemed to have been "furnished" to and not "filed" with the SEC.

Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

This prospectus may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus. You should rely only on the information incorporated by reference or provided in this prospectus. Neither we nor the selling stockholders have 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

Phone: (650) 241-7900

E-mail: [stockadmin@avinger.com](mailto:stockadmin@avinger.com)

[mweinswig@avinger.com](mailto:mweinswig@avinger.com)

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.

**850,500 Shares of Common Stock Underlying the Series B Preferred Stock**  
**8,979,000 Shares of Common Stock Issuable Upon Exercise of**  
**Series 1 Warrants**

**8,709,500 Shares of Common Stock Issuable Upon Exercise of**  
**Series 2 Warrants**

**PROSPECTUS**

**Ladenburg Thalmann**

**, 2019**

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth all expenses to be paid by the registrant, other than estimated underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the registration fee, the FINRA filing fee and the Nasdaq Stock Market listing fee.

	<b>Amount to be Paid</b>
SEC registration fee	\$5,596*
FINRA filing fee	5,670*
Printing and engraving	10,000
Legal fees and expenses	25,000
Accounting fees and expenses	10,000
Transfer agent and registrar fees	5,000
Miscellaneous	10,000
Total	\$71,266

\* Paid previously.

**Item 14. Indemnification of Officers and Directors**

Section 145 of the Delaware General Corporation Law, or DGCL, provides, in effect, that any person made a party to any action by reason of the fact that he is or was a director, officer, employee or agent of ours may, and in certain cases must, be indemnified by us against, in the case of a non-derivative action, judgments, fines, amounts paid in settlement, and reasonable expenses (including attorneys' fees) incurred by him as a result of such action, and in the case of a derivative action, against expenses (including attorneys' fees), if in either type of action he acted in good faith and in a manner he reasonably believed to be in or not opposed to our best interests. This indemnification does not apply, (i) in a derivative action, to matters as to which it is adjudged that the director, officer, employee or agent is liable to us, unless upon court order it is determined that, despite such adjudication of liability, but in view of all the circumstances of the case, he is fairly and reasonably entitled to indemnity for expenses, and, (ii) in a non-derivative action, to any criminal proceeding in which such person had no reasonable cause to believe his conduct was unlawful.

Article VIII of our current amended and restated certificate of incorporation and Article VIII of the amended and restated certificate of incorporation that our board of directors has approved and we expect our stockholders to approve in connection with this offering will provide for the indemnification of directors to the fullest extent permissible under Delaware law.

Article V of our current bylaws, as amended, and Article VIII of the amended and restated bylaws that our board of directors has approved and we expect our stockholders to approve in connection with this offering will provide for the indemnification of officers, directors and third parties acting on our behalf if such person acted in good faith and in a manner reasonably believed to be in and not opposed to our best interest and, with respect to any criminal action or proceeding, the indemnified party had no reason to believe his or her conduct was unlawful.

We have entered into indemnification agreements with certain of our directors, executive officers and others, in addition to indemnification provided for in our bylaws. Prior to the completion of this offering, we expect to enter into new indemnification agreements with each of our directors, executive officers and certain other officers, which will contain similar provisions.

II-1

---



We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions. Such insurance also provides coverage to our directors and officers against loss arising from claims relating to, among other things, public securities matters.

See also the undertakings set out in response to Item 17 herein.

### **Item 15. Recent Sales of Unregistered Securities**

We have issued and sold the following securities from March 14, 2016 to March 14, 2019.

1. On November 3, 2017, we issued to Lincoln Park 23,584 shares of common stock at a value of \$12.76 per share as a commitment fee for making the commitment to purchase our common stock under the purchase agreement dated November 3, 2017 entered into with Lincoln Park. Subsequently, on November 17, 2017, the SEC declared effective the registration statement filed in connection with the Lincoln Park transaction.

2. On February 14, 2018, we issued to CRG Partners III L.P. and certain of its affiliated funds (the "Lenders") 41,800 shares of Series A convertible preferred stock upon the conversion by the Lenders of \$38.0 million of the outstanding principal amount of their senior secured term loan (plus the back-end fee and prepayment premium applicable thereto), totaling approximately \$41.8 million. Each share of Series A convertible preferred stock is convertible into that number of shares of our common stock determined by dividing \$1,000 by the conversion price of \$2.00. The issuance of the Series A convertible preferred stock to the Lenders was made pursuant to Rule 506(b) of Regulation D promulgated under the Securities Act of 1933.

3. On July 12, 2018, we issued warrants to purchase an aggregate of 1,083,091 shares of common stock beginning on the six-month anniversary of their issuance. The warrants have an exercise price of \$1.58 per share and will expire on the third anniversary of their issuance. The warrants were issued in a private placement to the purchasers of our common stock in a registered offering on the same date. The Company relied on the exemption from registration available under Section 4(a)(2) and Rule 506 of Regulation D of the Securities Act of 1933, as amended, in connection with the private placement.

4. On February 11, 2019, our Board of Directors declared a preferred dividend on the outstanding shares of our Series A convertible preferred stock and issued 2,945 shares of Series A convertible preferred stock to pay such dividend to the holders of the Series A convertible preferred stock. Each share of Series A convertible preferred stock is convertible into that number of shares of our common stock determined by dividing \$1,000 by the conversion price of \$2.00, subject to certain anti-dilution protections and beneficial ownership limitations. The Company relied on the exemption from registration available under Section 4(a)(2) and Rule 506 of Regulation D of the Securities Act of 1933, as amended, in connection with the distribution.

5. From January 1, 2019 through March 14, 2019, we issued 2,715,000 shares of our common stock upon the conversion of outstanding shares of Series B convertible preferred stock pursuant to Section 3(a)(9) of the Securities Act of 1933.



**Item 16. Exhibits and Financial Statement Schedules**

The following exhibits are filed as part of this registration statement.

<b>Exhibit Number</b>	<b>Exhibit Title</b>
3.1 <sup>(1)</sup>	<u>Amended and Restated Certificate of Incorporation of the registrant.</u>
3.2 <sup>(1)</sup>	<u>Bylaws of the registrant.</u>
3.3 <sup>(2)</sup>	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation.</u>
3.4 <sup>(3)</sup>	<u>Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock</u>
3.5 <sup>(4)</sup>	<u>Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock</u>
3.6 <sup>(5)</sup>	<u>Avinger, Inc. Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock</u>
3.7 <sup>(5)</sup>	<u>Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock</u>
4.1 <sup>(6)</sup>	<u>Specimen Common Stock certificate of the registrant.</u>
4.2 <sup>(10)</sup>	<u>Amended and Restated Investors' Rights Agreement dated September 2, 2014 by and among the registrant and certain of its affiliated funds, as purchasers</u>
4.3 <sup>(12)</sup>	<u>Securities Purchase Agreement, dated as of September 22, 2015, by and among Avinger, Inc., and CRG Partners III L.P. and certain of its affiliated funds, as purchasers</u>
4.4 <sup>(3)</sup>	<u>Registration Rights Agreement, dated as of February 16, 2018, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers</u>
4.5 <sup>(4)</sup>	<u>Specimen Series 1/2 warrant of the registrant.</u>
4.6 <sup>(7)</sup>	<u>Form of July 2018 Warrant</u>
4.7 <sup>(8)</sup>	<u>Form of November 2018 Warrant</u>
5.1	<u>Opinion of Dorsey &amp; Whitney LLP</u>
10.1 <sup>(9)</sup>	<u>Form of Indemnification Agreement for directors and executive officers.</u>
10.2 <sup>(10)</sup>	<u>2009 Stock Plan and Form of Option Agreement thereunder.</u>
10.3 <sup>(10)</sup>	<u>2014 Preferred Stock Plan.</u>
10.4 <sup>(11)</sup>	<u>2015 Equity Incentive Plan, as amended</u>
10.5 <sup>(9)</sup>	<u>Form of Restricted Stock Unit Award Agreement.</u>
10.6 <sup>(9)</sup>	<u>Form of Stock Option Agreement.</u>
10.7 <sup>(9)</sup>	<u>2015 Employee Stock Purchase Plan.</u>
10.8 <sup>(9)</sup>	<u>Executive Incentive Compensation Plan.</u>
10.9 <sup>(10)</sup>	<u>Amended and Restated Investors' Rights Agreement dated September 2, 2014 by and among the registrant and certain of its affiliated funds, as purchasers</u>
10.10 <sup>(10)</sup>	<u>Lease Agreement, dated July 30, 2010, by and between the registrant and HCP LS Redwood City, LLC for office space located at 400 and 600 Chesapeake Drive, Redwood City, California.</u>
10.11 <sup>(10)</sup>	<u>First Amendment to Lease Agreement dated September 30, 2011 by and between registrant and HCP LS Redwood City, LLC</u>
10.12 <sup>(13)</sup>	<u>Second Amendment to Lease Agreement dated March 4, 2016 by and between the registrant and HCP LS Redwood City, LLC</u>
10.13 <sup>(10)</sup>	<u>Employment Letter dated December 29, 2010 by and between the registrant and Matthew B. Ferguson.</u>
10.14 <sup>(10)</sup>	<u>Employment Letter dated December 17, 2014 by and between the registrant and Jeffrey M. Soinski.</u>
10.15 <sup>(10)</sup>	<u>Change of Control and Severance Agreement dated March 1, 2012 by and between the registrant and Matthew B. Ferguson.</u>
10.16 <sup>(14)</sup>	<u>Change of Control and Severance Agreement dated March 29, 2018 by and between the registrant and Jeffrey M. Soinski.</u>



- 10.17 (3) Registration Rights Agreement, dated as of February , 2018, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers.
- 10.18 (10) Note and Warrant Purchase Agreement dated October 29, 2013 by and between the registrant and holders of convertible promissory notes.
- 10.19 (10) Amendment No. 1 to the Note and Warrant Purchase Agreement dated May 6, 2014 by and between the registrant and holders of convertible promissory notes.
- 10.20 (12) Term Loan Agreement, dated as of September 22, 2015, by and among the registrant, certain of its subsidiaries from time to time party thereto as guarantors and CRG Partners III L.P. and certain of its affiliated funds, as lenders.
- 10.21 (12) Securities Purchase Agreement, dated as of September 22, 2015, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers.
- 10.23 (15) Purchase Agreement, dated as of November 3, 2017, by and between the registrant and Lincoln Park Capital Fund, LLC.
- 10.24 (15) Registration Rights Agreement, dated as of November 3, 2017, by and between the registrant and Lincoln Park Capital Fund, LLC.
- 10.26 (16) Waiver and Consent, dated as of December 14, 2017, by and among the registrant and the lenders party thereto.
- 10.27 (17) Waiver and Consent, dated as of January 24, 2018, by and among the registrant and the lenders party thereto.
- 10.28 (3) Amendment No. 2 to Term Loan Agreement, dated as of February 14, 2018, by and among the registrant and the lenders party thereto.
- 10.29 (3) Series A Preferred Stock Purchase Agreement, dated as of February 14, 2018, by and among the registrant, CRG Partners III L.P. and certain of its affiliated funds, as purchasers.
- 10.30 (18) Securities Purchase Agreement, dated as of July 12, 2018, by and among the registrant and the purchasers identified on the signature pages thereto.
- 10.31 (19) Separation Agreement and Release, dated as of August 1, 2018, between the registrant and Matt Ferguson.
- 10.32 (19) Master Consulting Agreement, dated as of August 1, 2018, between the registrant and Matt Ferguson.
- 10.33 (19) Employment Offer Letter, dated as of June 11, 2018, between the registrant and Mark Weinswig.
- 10.34 (19) Change of Control and Severance Agreement, dated as of June 25, 2018, between the registrant and Mark Weinswig.
- 10.35 (20) Officer and Director Share Purchase Plan.
- 10.36 (21) Change of Control and Severance Agreement, dated as of October 10, 2013, between the registrant and Himanshu Patel
- 23.1 Consent of Independent Registered Public Accounting Firm.
- 23.2 Consent of Dorsey & Whitney LLP (included in Exhibit 5.1)
- 24.1(22) Power of Attorney

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

(2) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2018.

(3) Previously filed as an Exhibit to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File No. 333-222517) filed with the Securities and Exchange Commission on February 12, 2018, and incorporated by

reference herein.

Previously filed as an Exhibit to Amendment No. 3 to the registrant's Registration Statement on Form S-1 (File (4)No. 333-222517) filed with the Securities and Exchange Commission on February 13, 2018, and incorporated by reference herein.

(5) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 6, 2018, and incorporated by reference herein.

Previously filed as an Exhibit to Amendment No. 2 to the registrant's Registration Statement on Form S-1 (File (6)No. 333-201322) filed with the Securities and Exchange Commission on January 28, 2015, and incorporated by reference herein.

- (7) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 13, 2018, and incorporated by reference herein.  
Previously filed as an Exhibit to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-227689) filed with the Securities and Exchange Commission on October 19, 2018, and incorporated by reference herein.
- (8) Previously filed as an Exhibit to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 20, 2015, and incorporated by reference herein.
- (9) Previously filed as an Exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-201322), filed with the Securities and Exchange Commission on December 30, 2014, and incorporated by reference herein.
- (10) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2018, and incorporated by reference herein.
- (11) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 12, 2015, and incorporated by reference herein.
- (12) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2016, and incorporated by reference herein.
- (13) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2018, and incorporated by reference herein.
- (14) Previously filed as an Exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-221368), filed with the Securities and Exchange Commission on November 6, 2017, and incorporated by reference herein.
- (15) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2017, and incorporated by reference herein.
- (16) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2018, and incorporated by reference herein.
- (17) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 13, 2018, and incorporated by reference herein.
- (18) Previously filed as an Exhibit to the registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 13, 2018, and incorporated by reference herein.
- (19) Previously filed as an Exhibit to the registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 24, 2018, and incorporated by reference herein.
- (20) Previously filed as an Exhibit to the registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 6, 2019, and incorporated by reference herein.
- (21) Previously included on the signature page to the registrant's Registration Statement on Form S-1 (File No. 333-222517) filed with the Securities and Exchange Commission on January 12, 2018, and incorporated by reference herein.
- (22)

**Item 17. Undertakings**

The Registrant hereby undertakes:

(a) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933, as amended (the “Act”);

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective Registration Statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

*provided, however,* that paragraphs (a)(i), (a)(ii) and (a)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

(b) That, for the purpose of determining any liability under the Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(c) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;



(d) That, for the purpose of determining liability under the Act to any purchaser each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A (§ 230.430A of this chapter), shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use;

(e) That, for the purpose of determining any liability under the Act to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter);
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(f) That, for purposes of determining any liability under the Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(g) That, insofar as indemnification for liabilities arising under the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**Signatures**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Post-Effective Amendment No. 1 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Redwood City, California, on the 14th day of March, 2019.

By: /s/ Jeffrey M. Soinski  
 Jeffrey M. Soinski  
 Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933 this Post-Effective Amendment No. 1 to Registration Statement on Form S-1 has been signed below by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Jeffrey M. Soinski	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2019
Jeffrey M. Soinski		
/s/ Mark Weinswig	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2019
Mark Weinswig		
* Donald A. Lucas	Director	March 14, 2019
* James B. McElwee	Director	March 14, 2019

\*

Director      March 14, 2019

James G. Cullen

\*By:      /s/ Jeffrey M.  
             Soinski  
             Jeffrey M.  
             Soinski  
             *Attorney-in-Fact*