

Avinger Inc

Form 424B4

October 30, 2018

Filed Pursuant to Rule 424(b)(4)

Registration No. 333-227689

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

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

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

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

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

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

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

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

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

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

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

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

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

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

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

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is October 30, 2018

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You should rely only on the information contained in this prospectus or contained in any free writing prospectus prepared by or on behalf of us. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of securities.

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

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

PROSPECTUS SUMMARY

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

Company Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select international markets. Our current products include our Lightbox imaging console, the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris, and we received additional 510(k) clearances for enhanced versions of Pantheris in March 2016 and May 2018, and commenced sales of Pantheris in the United States and select European countries promptly thereafter. We also offer the Wildcat and Kittykat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

Current treatments for PAD, including bypass surgery, can be costly and may result in complications, high levels of post-surgery pain, and lengthy hospital stays and recovery times. Minimally invasive, or endovascular, treatments for PAD include stenting, angioplasty, and atherectomy, which is the use of a catheter-based device for the removal of plaque. These treatments all have limitations in their safety or efficacy profiles and frequently result in recurrence of the disease, also known as restenosis. We believe one of the main contributing factors to high restenosis rates for PAD patients treated with endovascular technologies is the amount of vascular injury that occurs during an intervention. Specifically, these treatments often disrupt the membrane between the outermost layers of the artery, which is referred to as the external elastic lamina, or EEL.

Our Lumivasular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment through the use of optical coherence tomography, or OCT, a high resolution, light-based, radiation-free imaging technology. Our Lumivasular platform provides physicians with real-time OCT images from the inside of an artery, and we believe Ocelot and Pantheris are the first products to offer intravascular visualization during CTO crossing and atherectomy, respectively. We believe this approach will significantly improve patient outcomes by providing physicians with a clearer picture of the artery using radiation-free image guidance during treatment, enabling them to better differentiate between plaque and healthy arterial structures. Our Lumivasular platform is designed to improve patient safety by enabling physicians to direct treatment towards the plaque, while avoiding damage to healthy portions of the artery.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the EEL reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. Although the original VISION study protocol was not designed to follow patients beyond six months, we have worked with 18 of the 20 VISION sites to re-solicit consent from previous clinical trial patients in order to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the patients from participating sites was completed in May 2017, and we released the final 12 and 24-month results for a total of 89 patients in July 2017. We commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select international markets in March 2016, after obtaining the required marketing authorizations. During the fourth quarter of 2017, we began enrolling patients in INSIGHT, a clinical trial designed to support a filing with the FDA to expand the indication for our Pantheris atherectomy device to include in-stent restenosis.

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

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

We have assembled a team with extensive medical device development and commercialization capabilities. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-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 \$3.9 million for the six months ended June 30, 2018.

Recent Developments

Common Stock Offering

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

Series B Preferred Stock Financing

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

CRG Debt Conversion

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

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

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

Reverse Stock Split

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

Lincoln Park Purchase Agreement

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

Nasdaq Compliance

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

Resale S-1 Registration Statement for July 2018 Warrants

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

Preliminary September 30, 2018 Financial Results

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

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

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

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

Risks Associated with Our Business

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

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

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

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

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

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

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

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

We rely heavily on our sales professionals to market and sell our products. If we are unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, our business will be harmed, which would impair our future revenue and profitability.

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

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

We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration, increasing our revenues or becoming profitable.

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

We have limited long-term data regarding the safety and efficacy of our Lumivasular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivasular platform may not be positive or consistent with our short-term data, which would harm our ability to obtain clearance to market and sell our products.

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

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

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

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

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

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

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

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

• We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our Lumivasular platform products.

• We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivasular platform products.

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

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

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

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

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

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

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Our 2017 financial statements contained disclosure that there is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

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

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

The warrants may not have any value.

Company Information

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

“Avinger,” “Pantheris” and “Lumivascular” are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this prospectus supplement and accompanying prospectus are our property. Other trade names, trademarks and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus and accompanying prospectus appear without the TM symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Implications of Being an Emerging Growth Company

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

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

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

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

We may use these provisions until the last day of our fiscal year following the fifth anniversary of our initial public offering, or December 31, 2020. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We may choose to take advantage of some but not all of these reduced burdens. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than

you might obtain from other public companies in which you hold equity interests.

Available Information

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

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

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

THE OFFERING

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

Offering price per Class A Unit \$0.40

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

Offering price per Class B Unit \$1,000

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

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

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

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

Shares of common stock outstanding before this offering	11,554,149 shares
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Shares of common stock
outstanding after this offering 15,089,149 shares

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

Use of proceeds We estimate that the net proceeds to us from this offering will be approximately \$8.7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use net proceeds from this offering for working capital, payment of interest on our debt and general corporate purposes, which may include research and development of our Lumivasular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses or to repay principal on our debt; however, we currently have no agreements or commitments to complete any such transactions or to make any such principal repayments and are not involved in negotiations to do so. See the section entitled “Use of Proceeds” on page 39 of this prospectus.

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

Nasdaq Capital Market
common stock symbol AVGR

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

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

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

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

8,306 unvested restricted stock units;

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

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

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

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

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

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

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including the financial statements and the related notes incorporated by reference in this prospectus, before deciding whether to invest in shares of our common stock. If any of the following risks or other risks actually occur, our business, financial condition, results of operations and future prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. Please also see the section entitled “Cautionary Notes Regarding Forward-Looking Statements.”

Risks Related to Our Business

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

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

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

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

the availability of reimbursement for our Lumivascular platform products;

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

• results of our clinical trials;

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

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

• changes in our pricing policies or those of our competitors;

• general economic, political, industry and market conditions, including economic and political uncertainty caused by the recent U.S. presidential election;

• the regulatory environment;

• the hiring, training and retention of key employees, including our sales team;

• the cost and potential outcomes of existing and future litigation;

• our ability to obtain additional financing; and

• advances and trends in new technologies and industry standards.

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

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of \$16.1 million for the six months ended June 30, 2018, \$48.7 million in 2017, \$56.1 million in 2016 and \$47.3 million in 2015. As of June 30, 2018, we had an accumulated deficit of approximately \$317.4 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

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

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

We believe that the net proceeds from this offering, together with the recently completed offerings of our Series B preferred stock and common stock, our cash and cash equivalents at June 30, 2018 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations for at least the next twelve months. Even though we sold \$18.0 million in Series B preferred stock and warrants in our February 2018 offering, and \$3.5 million of common stock and warrants in our July 2018 offering, we will need to raise additional funds through future equity or debt financings within the next twelve months to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next twelve months could cause substantial dilution to our existing stockholders.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our “at-the-market” program, our initial public offering, or IPO, and our follow-on public offerings. The warrants issued pursuant to the Series B Purchase Agreement entered into in connection with the Series B preferred stock follow-on in February 2018, or the Series B Offering, prohibit us from entering into certain transactions involving the issuance of securities for a price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case for a period of three years from the closing date of the Series B Offering (and excluding purchases pursuant to the Series B Purchase Agreement, which may be made on the 120 day anniversary of the closing date of the offering). This

prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivasular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

- the degree of success we experience in commercializing our Lumivasular platform products, particularly Pantheris 3.0 and Pantheris SV, and any future versions of such products;

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

- the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations;

- the costs and timing of developing variations of our Lumivasular platform products, especially Pantheris and, if necessary, obtaining FDA clearance of such variations;

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

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

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

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

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

We may raise additional funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and/or if we convert all or a portion of our existing debt to equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations, or we may become insolvent. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

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

As of June 30, 2018, we had \$7.8 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively the CRG. This amount reflects the completion of the Series B Offering and CRG's conversion of \$38 million in outstanding principal and interest into Series A preferred stock, or the CRG Conversion. Our significant amount of debt may:

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

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

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

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

• restrict us from exploiting business opportunities;

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

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

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

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

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

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

• incur or assume liens;

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

• issue redeemable stock and preferred stock;

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

• make loans, investments or acquisitions;

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

• enter into certain transactions with affiliates;

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

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

In particular, the Loan Agreement, as amended, includes a covenant that we maintain a minimum of \$3.5 million of cash and certain cash equivalents, and we will have to achieve minimum revenue of \$15.0 million in 2020, \$20.0 million in 2021 and \$25.0 million in 2022. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended.

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

- finance our operations;
- make needed capital expenditures;
- make strategic acquisitions or investments or enter into alliances;
- withstand a future downturn in our business or the economy in general;
- refinance our outstanding indebtedness prior to maturity;
- engage in business activities, including future opportunities, that may be in our interest; and
- plan for or react to market conditions or otherwise execute our business strategies.

We are also subject to standard event of default provisions, including in the event of a material adverse change, under the Loan Agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. The existing collateral pledged under the Loan Agreement may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. If we default under any of these debt covenants and are unable to cure the default within the relevant cure period, we would need relief from default or else our creditors could exercise their remedies. There can be no assurance that our debtholders would accord any relief from default. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

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

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

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

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

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

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

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

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

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

We were incorporated in 2007, began commercializing our initial non-Lumivascular platform products in 2009 and introduced our first Lumivascular platform products in the United States in late 2012. We received 510(k) clearance from the FDA, for commercialization of Pantheris in October 2015, an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select international markets promptly thereafter. Our current version of Pantheris, Pantheris 3.0, received FDA clearance in May 2018. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries. These risks and uncertainties include the risks inherent in clinical trials, market acceptance of our products, and increasing and unforeseen expenses as we continue to attempt to grow our business.

In addition, we have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have attempted to address certain of these concerns with Pantheris 3.0. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our reputation could suffer, which could lead to decreased sales of our products. Our revenue has been and continues to be adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, and to replace products in accordance with our warranty policy. This additional expense, and any future expense that we may incur as a result of future product performance issues, will negatively impact our financial performance and results of operations. If we are unable to improve the performance of our products to meet the concerns of physicians our revenue may decline further or fail to increase.

Our short commercialization experience and limited number of approved products also make it difficult for us to forecast our future financial performance and such forecasts are limited and subject to a number of uncertainties, including our ability to obtain FDA clearance for new versions of Pantheris and other Lumivasular platform products we intend to commercialize in the United States. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivasular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of the next-generation versions of Pantheris and our other current and future Lumivasular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivasular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA approval to market enhanced versions of Pantheris in March 2016 and May 2018, and those versions of Pantheris became commercially available in the United States and select international markets promptly thereafter. As such acceptance among physicians of these products may not increase or may decline.

Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivasular platform

products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivasular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivasular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivasular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivasular platform products. Any studies we may conduct comparing our Lumivasular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivasular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivasular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

We are also aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption. For example, in procedures using the current model of Pantheris, some physicians may prefer to have a technician or second physician assisting with the operation of the catheter as well as a separate technician to operate the Lightbox, potentially making it less financially attractive for physicians and their hospitals and medical facilities. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications, or obtain any additional and necessary regulatory clearances for such modifications. Although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our Lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye, particularly with Pantheris. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it will require training for technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. These or other characteristics and features of our Lumivascular platform may cause our products not to be widely adopted and harm our business, financial condition and results of operation.

We rely heavily on our sales professionals to market and sell our products. If we are unable to hire, effectively train, manage, improve the productivity of, and retain our sales professionals, our business will be harmed, which would impair our future revenue and profitability.

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

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

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

have a material adverse effect on our stock price.

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

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

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

In order to generate sales, we must be able to clearly demonstrate that our Lumivascular platform is both a more effective treatment system and more cost-effective than the alternatives offered by our competitors. If we are unable to convince physicians that our Lumivascular platform leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse events during treatment than those using competing technologies, our business will suffer. In order to use Pantheris or our Ocelot family of catheters, hospitals must make an investment in our Lightbox. Accordingly, we must convince hospitals and physicians that our Lumivascular platform results in significantly better patient outcomes at a competitive overall cost. For example, we may need to demonstrate that the investment hospitals must make when purchasing our Lightbox and the incremental costs of having a technician or a second physician operate Pantheris can be justified based on the benefits to patients, physicians and hospitals. If we are unable to develop robust clinical data to support these claims, we will be unable to convince hospitals and third-party payors of these benefits and our business will suffer.

Our value proposition to physicians and hospitals is largely dependent upon our contention that the rate of arterial damage when physicians are using our products is lower than with competing products. If minimizing arterial damage does not significantly impact patient outcomes, meaning either (i) that restenosis is often triggered without disrupting healthy arterial structures, or (ii) arteries can be damaged during treatment without triggering restenosis, then we may be unable to demonstrate our Lumivascular platform's benefits are any different than competing technologies. Furthermore, physicians may find our imaging system difficult to use, and we may not be able to provide physicians with adequate training to be able to realize the benefits of our Lumivascular platform. If physicians do not value the benefits of on-board imaging and the enhanced visualization enabled by our products during an endovascular intervention as compared to our competitor's products, or do not believe that such benefits improve clinical outcomes, our Lumivascular platform products may not be widely adopted.

The use, misuse or off-label use of the products in our Lumivascular platform may result in injuries that lead to product liability suits, which could be costly to our business.

We require limited training in the use of our Lumivascular platform products because we market primarily to physicians who are experienced in the interventional techniques required to use our device. If demand for our Lumivascular platform continues to grow, less experienced physicians will likely use the devices, potentially leading to more injury and an increased risk of product liability claims. The use or misuse of our Lumivascular platform products has in the past resulted, and may in the future result, in complications, including damage to the treated artery, infection, internal bleeding, and limb loss, potentially leading to product liability claims. Our Lumivascular platform products are contraindicated for use in the carotid, cerebral, coronary, iliac, or renal arteries. Our sales force does not promote the use of our products for off-label indications, and our U.S. instructions for use specify that our Lumivascular platform products are not intended for use in the carotid, cerebral, coronary, iliac or renal arteries. However, we cannot prevent a physician from using our Lumivascular platform products for these off-label applications. The application of our Lumivascular platform products to coronary arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences. For example, if excised plaque were not captured properly in our device, it could be carried by the bloodstream to a more narrow location, blocking a coronary artery, leading to a heart attack, or blocking an artery to the brain, leading to a stroke. If our Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

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

We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any

product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and results of operations.

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

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

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

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

Maintaining adequate research and development personnel and resources to meet the demands of the market is essential. If we are unable to develop products, applications or features due to certain constraints, such as insufficient cash resources, inability to raise sufficient cash in future equity or debt financings, high employee turnover, inability to hire sufficient research and development personnel or a lack of other research and development resources, we may miss market opportunities. Furthermore, many of our competitors expend a considerably greater amount of funds on their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to our competitors' research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

We compete against companies that have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration, increasing our revenues or becoming profitable.

Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, Boston Scientific, Cardinal Health, Cook Medical, CR Bard and Medtronic. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic and Philips. Some competitors have previously attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on-board visualization into their products in the future and may remain competitive with us in marketing traditional technologies. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our products. Many of our competitors have significantly greater financial and other resources than we do and have well-established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

Our ability to compete effectively depends on our ability to distinguish our company and our Lumivasular platform from our competitors and their products, and includes such factors as:

• procedural safety and efficacy;

• acute and long-term outcomes;

• ease of use and procedure time;

• price;

• size and effectiveness of sales force;

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

• third-party reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

trouble in managing multiple clinical sites;

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

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

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

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

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

We have limited long-term data regarding the safety and efficacy of our Lumivasular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivasular platform may not be positive or consistent with our short-term data, which would harm our ability to obtain clearance to market and sell our products.

Our Lumivasular platform is a novel system, and our success depends on its acceptance by the medical community as being safe and effective, and improving clinical outcomes. Important factors upon which the efficacy of our Lumivasular platform products, including Pantheris, will be measured are long-term data on the rate of restenosis following our procedure, and the corresponding duration of patency, or openness of the artery, and publication of that data in peer-reviewed journals. Another important factor that physicians will consider is the rate of reintervention, or retreatment, following the use of our Lumivasular platform products. The long-term clinical benefits of procedures that use our Lumivasular platform products, including Pantheris, are not known.

The results of short-term clinical experience of our Lumivasular platform products, including Pantheris, do not necessarily predict long-term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long-term restenosis and reintervention for procedures using our Lumivasular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long-term rates of restenosis and reintervention do not meet physicians' expectations, our Lumivasular platform products may not become widely adopted and physicians may recommend alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivasular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivasular platform products are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of our product may suffer and our business would be harmed. Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high-volume users of our Lumivasular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

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

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

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

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

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

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

Because we have only limited experience in manufacturing our Lumivasular platform products in commercial quantities, we may encounter production delays or shortfalls. Such production delays or shortfalls may be caused by many factors, including the following:

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

- key components and sub-assemblies of our Lumivasular platform products are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities; and

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

If we are unable to keep up with demand for our Lumivasular platform products, our revenues could be impaired, market acceptance for our Lumivasular platform products could be harmed and our customers might instead purchase our competitors' products. Our inability to successfully manufacture our Lumivasular platform products would materially harm our business.

Our manufacturing facilities and processes and those of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain, or not fully comply with the requirements of, a quality system could result in regulatory authorities initiating enforcement actions against us and our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

If our manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, or our electronic systems are compromised, our ability to manufacture and sell our Lumivasular platform products and to pursue our research and development efforts may be jeopardized.

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

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

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

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

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

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

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

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

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

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

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

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

Our future growth depends on physician adoption of our 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 Lumivasular platform products, they may not refer patients to interventional cardiologists, vascular surgeons and interventional radiologists for treatment using our Lumivasular platform procedure, and those patients may instead be surgically treated or treated with an alternative interventional procedure. In addition, there is a significant correlation between PAD and coronary artery disease, and many physicians do not routinely screen for PAD while screening for coronary artery disease. If we are not successful in educating physicians about screening for PAD and about the capabilities of our Lumivasular platform products, our ability to increase our revenues may be impaired.

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

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

We must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales professionals. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business would be harmed.

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

Marketing our Lumivasular platform outside of the United States would require substantial additional sales and marketing, regulatory and personnel expenses. As part of our product development and regulatory strategy, we plan to expand into select international markets, but we do not currently intend to devote significant additional resources to market our Lumivasular platform internationally in order to focus our resources and efforts on the U.S. market. Our decision to market our products primarily in the United States in the near-term will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share outside of the United States until such time, if ever, that we devote significant additional resources to market our Lumivasular platform products or other products internationally.

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

As of December 31, 2017, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of \$258.4 million and \$191.9 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2018 for state purposes. Generally, subject to certain limitations, NOLs can be used to offset taxable income for U.S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. It is possible that prior transactions with respect to our stock may have caused, and that future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause, an “ownership change.” The sale of our common stock to Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to the Purchase Agreement, dated as of November 3, 2017, between us and Lincoln Park, or the Purchase Agreement, and the sale of Series B preferred stock and warrants pursuant to the Series B Offering may affect our ability to use NOLs. If an “ownership change” occurs, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes, which could harm our profitability. On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Act, was enacted into law with many significant changes to the U.S. tax laws. The Tax Act limits the utilization of NOLs arising in tax years beginning after December 31, 2017 to 80% of taxable income per year. However, existing NOLs that arose in years prior to December 31, 2017 are not affected by these provisions. Our ability to utilize NOLs arising in future tax periods may be limited by the Tax Act.

We may acquire other companies or technologies or be the target of strategic transactions, which could divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our results of operations.

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

To date, our technology and product development efforts have been organic, and we have no experience in acquiring other businesses. In any acquisition, we may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following the acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our results of operations. In addition, if an acquired business fails to meet our expectations, our results of operations, business and financial condition may suffer.

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

Risks Related to Our Intellectual Property

We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell our Lumivasular platform products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include hardware and software components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. They may devote substantial resources towards obtaining claims that cover the design of our atherectomy products to prevent the marketing and selling of competitive products. We may become a party to patent or trademark infringement or trade secret claims and litigation as a result of these and other third-party intellectual property rights being asserted against us. The defense and prosecution of these matters are both costly and time consuming. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our Lumivasular platform products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination, inter partes review, or opposition proceedings, before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our Lumivasular platform products or using product names, which would have a significant adverse impact on our business.

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

We are aware of patents held by third parties that may be asserted against us in litigation that could be costly and could limit our ability to sell our Lumivasular platform products.

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

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

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

Risks Related to Government Regulation

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

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

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

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

• product design, development and manufacture;

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

pre-marketing clearance or approval;

record keeping;

product marketing, promotion and advertising, sales and distribution; and

post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for, an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or pre-marketing approval from FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market Pantheris, our image-guided atherectomy device, and our Ocelot family of catheters for crossing sub and total occlusions in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. We obtained 510(k) clearance for Pantheris 3.0 in May 2018, and we submitted for FDA clearance of Pantheris SV in August 2018. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we are required to timely file various reports with the FDA, including reports required by the MDRs that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor

misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

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

Material modifications to the intended use or technological characteristics of our Lumivascular platform products will require new 510(k) clearances or pre-market approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on published FDA guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a pre-market approval. We may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our Lumivascular platform products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our Lumivascular platform products in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our Lumivascular platform products as modified, which could harm our results of operations and require us to redesign our Lumivascular platform products. In these circumstances, we may be subject to significant enforcement actions. We plan to make further modifications to the design of Pantheris to enhance cutting efficiency and access smaller vessels. Future versions of Pantheris incorporating these enhancements may require additional regulatory clearances or approvals.

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

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

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

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

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

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

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

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Although this tax has been suspended through 2019, it is expected to apply to sales of our products in 2020 and thereafter. The current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may harm:

our ability to set a price that we believe is fair for our products;

our ability to generate revenues and achieve or maintain profitability; and

the availability of capital.

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

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that will affect how we operate include:

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

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

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

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

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

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

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

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

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

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use,

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

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

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

Risks Related to Our Securities

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

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

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

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

• the results of our clinical trials;

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

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

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

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

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

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

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

- legislation or regulation of our business;

lawsuits threatened or filed against us;

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

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

developments in our industry.

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

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

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

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

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

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

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

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

The warrants may not have any value.

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. The analysts who previously published research reports on our stock following our IPO have discontinued coverage. Although one new analyst initiated coverage of our business in March 2018, if additional analysts do not begin regularly publishing reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If our results of operations fail to meet the forecast of analysts, our stock price will likely decline.

Sales of a substantial number of shares of our common stock in the public market, including by our existing stockholders, could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

We will need to raise additional funds through future equity or debt financings within the next twelve months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next nine months could cause substantial dilution to our existing stockholders. On February 3, 2016, we filed a universal shelf registration statement, or the Shelf Registration Statement, to offer up to \$150.0 million of our securities and entered into an “at-the-market” program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through which we issued and sold approximately 200,000 shares of common stock having an aggregate offering value of approximately \$8.7 million between the Shelf Registration Statement’s effectiveness on March 8, 2016 and September 2017. In July 2018, we sold a further 2,166,180 shares of our common stock (excluding the July 2018 Warrants to purchase an additional 1,083,091 shares of our common stock issued in a concurrent private placement) pursuant to the Shelf Registration Statement, for gross proceeds of approximately \$3.5 million. In addition, in August 2016, we issued and sold 200,000 shares of our common stock in our follow-on public offering at a public offering price of \$140.00 per share, for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately \$0.6 million. We have established, and may in the future establish, “at-the-market” programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. During the year ended December 31, 2016, we sold 27,374 shares of common stock under our “at-the-market” program with Cowen at an average price of \$194.74 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the three and six months ended June 30, 2018, we sold no shares of common stock through the “at-the-market” program. Due to the SEC’s “baby shelf rules,” which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company’s public float in a twelve-month period, we are unable to issue more shares using the Shelf Registration Statement at this time. Accordingly, it was necessary to register the shares sold pursuant to the Purchase Agreement, the CRG Conversion and Series B Purchase Agreement on Form S-1. This has increased our transaction expenses and the number of shares required to be sold to finance our operations.

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

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

reduction in the price of our common stock as a result. We have also registered shares of our common stock that we may issue under our employee equity incentive plans. These shares will be able to be sold freely in the public market upon issuance.

Our 2017 financial statements contained disclosure that there is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern.

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has included in its auditors' report on our 2017 financial statements, included in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2018, an explanatory paragraph that substantial doubt exists relating to our ability to continue as a "going concern," meaning that as of the date of the audit report, due to our recurring losses from operations and negative cash flows from operations, substantial doubt regarding our ability to continue as a going concern has not been alleviated. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our 2017 financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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

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

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

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

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

As a result of disclosure of information in this Quarterly Report on Form 10-Q and in filings required of a public company, our business and financial condition will become more visible, which could be advantageous to our competitors and clients and could result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and results of operations.

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

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

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our IPO, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria.

On March 1, 2018, we regained compliance with all applicable Nasdaq listing criteria; however, there can be no assurance that we will continue to be compliant with such listing criteria. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum market value of listed securities and minimum closing bid price requirements or prevent future non-compliance with Nasdaq's listing requirements.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws and Delaware law could discourage a takeover.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;

• advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder's notice;

• a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;

• the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;

• allowing stockholders to remove directors only for cause;

• a requirement that the authorized number of directors may be changed only by resolution of the board of directors;

• allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;

• a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;

• limiting the forum for certain litigation against us to Delaware; and

• limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees to us or to our stockholders, (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law or our certificate of incorporation or bylaws (iv) any action to interpret apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

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

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future, except the cumulative dividend payable on our Series A preferred stock. The payment of all other dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. The terms of our Series A preferred stock, our Series B preferred stock and our Series C preferred stock provide that we may not pay dividends on our common stock without concurrently declaring dividends on each. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates. For more information on restrictions governing our ability to pay dividends, see the section entitled "Dividend Policy" in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2018.

CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

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

- the outcome of and expectations regarding our current clinical studies and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through future equity or debt financings;
- the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to continue as a going concern;
- our ability to remain in compliance with the listing requirements of the Nasdaq Capital Market;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain customers with a reduced salesforce headcount after our April 2017 realignment and the implementation of our September 2017 cost reduction plan;

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

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

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

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

our ability to identify and acquire new products;

our financial performance;

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

developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

You should read this prospectus and any free writing prospectus that we have authorized for use in connection with this offering with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

MARKET, INDUSTRY AND OTHER DATA

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

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

USE OF PROCEEDS

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

We intend to use net proceeds from this offering for working capital, payment of interest on our debt and general corporate purposes, which may include research and development of our Lumivascular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. We have not yet determined the amount of net proceeds to be used specifically for any particular purpose or the timing of these expenditures. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses or to repay principal on our debt; however, we currently have no agreements or commitments to complete any such transactions or to make any such principal repayments and are not involved in negotiations to do so. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities.

PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY

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

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

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

As of June 30, 2018, there were 9,305,872 shares of our common stock held by 175 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. The terms of the Series A preferred stock also limit our ability to pay dividends.

CAPITALIZATION

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

on an actual basis; and

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

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

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

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

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

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

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

8,306 unvested restricted stock units;

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

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

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

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

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

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

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

BUSINESS

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment o