Avinger Inc
Form S-1
January 12, 2018
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As filed with the Securities and Exchange Commission on January 12, 2018

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

Under

The Securities Act of 1933

AVINGER, INC.

(Exact name of Registrant as specified in its charter)

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

400 Chesapeake Drive

Redwood City, California 94063

(650) 241-7900

(Address, including zip code, and telephone number, including

area code, of Registrant s principal executive offices)

Jeffrey M. Soinski

Chief Executive Officer

Avinger, Inc.

400 Chesapeake Drive

Redwood City, CA 94063

(650) 241-7900

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

Copies to:

Philip H. Oettinger
Wilson Sonsini Goodrich & Rosati
Professional Corporation
650 Page Mill Road
Palo Alto, California 94304
(650) 493-9300

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

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

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

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

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

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer (Do not check if a smaller reporting company)	o	Smaller reporting company	x
		Emerging growth company	x

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(1)	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
[redacted]		

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the Securities Act).

(2) Includes the price of additional shares of common stock and warrants to purchase shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.

(3) No separate fee is required pursuant to Rule 457(i) under the Securities Act.

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

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

Subject to Completion, dated January 12, 2018

Avinger, Inc.

Class A Units consisting of common stock and warrants and

Class B Units consisting of shares of Series A Preferred Stock and warrants

(and the shares of common stock underlying shares of Series A Preferred Stock and warrants)

We are offering Class A Units, with each Class A Unit consisting of one share of common stock, par value $0.001 per share (the common stock) and a warrant to purchase shares of our common stock (together with the shares of common stock underlying such warrants, the Class A Units) at a public offering price of $ per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase shares of common stock at an initial exercise price per share of $, subject to adjustment in certain events as set forth in this prospectus.

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%), Class B Units. Each Class B Unit will consist of one share of Series A Preferred Stock, par value $0.001 per share (the Series A Preferred Stock), initially convertible into shares of common stock, subject to adjustment in certain events as set forth in this prospectus, and warrants to purchase shares of our common stock (together with the shares of common stock underlying such shares of Series A Preferred Stock and such warrants, the Class B Units, and together with the Class A Units, the units) at a public offering price of $ per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase shares of common stock at an initial exercise price per share of $, subject to adjustment in certain events as set forth in this prospectus.

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 A Preferred Stock and warrants comprising such units are immediately separable and will be issued separately in this offering. The underwriters have the option to purchase up to additional shares of common stock and/or warrants to purchase shares of

common stock to cover over-allotments, if any, at the price to the public less the underwriting discounts and commissions. The over-allotment option is exercisable for 45 days from the date of this prospectus.

Our common stock is listed on The NASDAQ Global Market under the symbol AVGR. On January 10, 2018, the last reported sales price of our common stock was $0.20 per share. We do not intend to apply for listing of the warrants offered hereby or the shares of Series A Preferred Stock on any securities exchange or trading system.

We are an emerging growth company as defined under the federal securities laws. Investing in the units involves a high degree of risk. Please see the section entitled Risk Factors starting on page 10 of this prospectus to read about risks you should consider carefully before making any investment in these securities.

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

	Per Class A Unit	Per Class B Unit	Total
Public Offering Price(1)			
Underwriting Discount(2)(3)			
Proceeds, before expenses, to Avinger, Inc.			

(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 $ and (ii) a public offering price per share underlying the warrants of $ and (y) in respect of the Class B Units (i) a public offering price per share of Series A Preferred Stock of $ and (ii) a public offering price per share underlying the warrants of $.

(2) We have also agreed to reimburse for certain expenses. See Underwriting.

(3) We have granted the underwriters a 45-day option to purchase up to an additional shares of common stock and/or warrants to purchase 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 A Preferred Stock) and warrants sold in the primary offering) to cover over-allotments, if any.

Ladenburg Thalmann

The date of this prospectus is , 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. Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the 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, neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, 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.

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PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference herein and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read the entire prospectus, including Risk Factors beginning on page 10, as well as the other information in this prospectus and other information incorporated by reference herein. As used in this prospectus, references to we, our, us and Avinger refer to Avinger, Inc. unless the context requires otherwise. This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners.

Company Overview

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

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

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

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During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. Although the original VISION study protocol was not designed to follow patients beyond six months, we have worked with 18 of the 20 VISION sites to re-solicit consent from previous clinical trial patients in order to evaluate patient outcomes through 12 and 24 months following initial treatment. Data collection for the patients from participating sites was completed in May 2017, and we released the final 12 and 24-month results for a total of 89 patients in July 2017. We commenced commercialization of Pantheris as part of our 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.

Name	Clinical Indication	Regulatory Status	Original Clearance Date
NEXT GENERATION PRODUCTS			
Pantheris 3.0	Atherectomy	FDA 510(k) submitted	
Pantheris BTK	Atherectomy	FDA 510(k) planned	
PRODUCTS			
Lightbox(1)	OCT Imaging	FDA Cleared CE Mark	November 2012 September 2011
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 two next-generation versions of our Pantheris atherectomy device, Pantheris 3.0 and a lower profile Pantheris, that we believe represent significant improvements over our existing product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe will improve usability and reliability, while the lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels and below-the-knee applications. We filed a 510(k) submission for Pantheris 3.0 in the fourth quarter of 2017, and we plan to make a 510(k) submission for Pantheris BTK in the second quarter of 2018. On January 3, 2017, we announced the successful treatment of the first seven patients to be treated with Pantheris 3.0 by a vascular surgeon in Münster, Germany. The Pantheris 3.0 is available in limited supply for commercial sale in the EU; it is not available commercially in the United States at this time.

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We have assembled a team with extensive medical device development and commercialization capabilities. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $11.2 million in 2014, $10.7 million in 2015, $19.2 million in 2016, and $8.0 million for the nine months ended September 30, 2017.

Recent Developments

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 , 2018, we effected a one-for- reverse stock split of our shares of common stock (the 2018 Reverse Stock Split) at the direction of our board of directors. As a result of the 2018 Reverse Stock Split, every ( ) shares of our common stock outstanding was automatically changed and reclassified into one (1) new share of common stock. Fractional shares of common stock otherwise issuable pursuant to the 2018 Reverse Stock Split were rounded up to the nearest whole share and no cash was paid out in lieu of the 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 registration statement (this Registration Statement) have been retroactively adjusted to reflect the 2018 Reverse Stock Split for all periods presented. The financial statements incorporated by reference herein have not been adjusted to reflect the 2018 Reverse Stock Split.

After the completion of this offering, we expect that our board of directors will approve and recommend to our stockholders an increase to the number of shares of common stock reserved for issuance under our 2015 Stock Incentive Plan, or the creation of a new stock incentive plan with additional shares. Shares reserved for issuance under any such plans, if approved by stockholders to the extent required by applicable laws and regulations, may be issued by the board of directors, or a committee of the board of directors, to employees, consultants and directors of the Company, including our current officers and directors. The amount of such increase has not been determined, but could equal up to 20% or more of our total number of shares outstanding or issuable after this offering, including shares issuable upon the exercise of options and warrants or conversion of preferred stock into common stock. The final determination of the amount of such increase will be made by the board of directors or a committee thereof and will be subject to stockholder approval to the extent required by applicable laws or regulations. Any issuance of such shares could dilute the ownership of our other stockholders.

Lincoln Park Purchase Agreement

We entered into a purchase agreement (the Purchase Agreement) with Lincoln Park Capital Fund, L.P. (Lincoln Park) on November 3, 2017, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over the thirty-month term of the Purchase Agreement. At the time we signed the Purchase Agreement, we issued 943,396 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 , 2018. The Purchase Agreement may be terminated by the Company at any time at its discretion without any cost to the Company. As of the date of this prospectus, we have sold an aggregate of 1,350,000 shares of our common stock under the Purchase Agreement for approximately $272,175 of gross proceeds. As of December 31, 2017, the Company had cash and cash equivalents of $5.4 million.

Nasdaq Compliance

On April 20, 2017, we received a letter from the Listing Qualifications Department of the NASDAQ Stock Market (Nasdaq) notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) as the market value of the Company s listed securities, or MVLS, was below the minimum $50 million for the previous 30 consecutive business days. This letter also informed us that we were not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), as we did not have total assets and total revenue of at least $50 million each for the most recently completed fiscal year. We did not regain compliance with these rules in the 180-day period ended October 17, 2017.

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

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On October 24, 2017, we received another letter from Nasdaq indicating that, based upon non-compliance with the MVLS requirement, ours securities would be subject to delisting from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel, or the Panel. We requested a hearing before the Panel and were granted a hearing date in January 2018, which stayed any delisting action by Nasdaq at least pending the ultimate outcome of the hearing and any extension granted by the Panel.

On January 11, 2018, management presented to the Panel regarding the actions the Company has taken and plans to take to regain compliance, including raising additional equity capital through this Registration Statement and the implementation of the 2018 Reverse Stock Split. In the interim, our securities will continue to trade on The NASDAQ Global Market. To regain compliance, the MVLS of our common stock must reach at least $50 million for a minimum of ten consecutive business days.

Pending the receipt of a written decision from the Panel regarding whether the Company will be afforded additional time to regain compliance with the Nasdaq Listing Rules, our securities will continue to trade on The NASDAQ Global Market. We expect to publicly announce any such decision as promptly as practicable.

There can be no guarantee that we will be able to regain compliance with the stockholders equity requirement or minimum bid requirement prior to being delisted, or at all. Any failure to maintain the Nasdaq listing of our common stock could have a material adverse effect on our ability to complete this offering on the terms set forth in this prospectus and on the secondary trading of shares of our common stock.

Risks Associated with Our Business

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

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

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

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

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

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

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

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

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

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

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

- Management will have broad discretion as to the use of proceeds from this offering and we may use the net proceeds in ways with which you may disagree;

- The offering price will be set by our board of directors and does not necessarily indicate the actual or market value of our common stock;

- The Series A Preferred Stock and the warrants are unlisted securities and there is no public market for these securities; and

- The warrants may not have any value.

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Company Information

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

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

Implications of Being an Emerging Growth Company

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

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

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

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

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

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.

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THE OFFERING

Class A Units offered by us	We are offering Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase shares of our common stock (together with the shares of common stock underlying such warrants).
Offering price per Class A Unit	$.
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, Class B Units. Each Class B Unit will consist of one share of Series A Preferred Stock, par value $0.001 per share, convertible into a number of shares of common stock equal to , subject to adjustment in certain events as set forth in this prospectus, and a warrant to purchase shares of our common stock (together with the shares of our common stock underlying such shares of Series A Preferred Stock and warrants).
Offering price per Class B Unit	$.
Overallotment option	The underwriters have the option to purchase up to additional shares of common stock, and/or warrants to purchase shares of common stock to cover over-allotments, if any, at the price to the public less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriters, 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 A Preferred Stock) and warrants sold in the primary offering. The over-allotment 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 , 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 A Preferred Stock	Each share of Series A Preferred Stock is convertible at any time at the holder s option into shares of common stock, subject to adjustment in certain events as set forth in this prospectus and for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions after the date of the first issuance. Notwithstanding the foregoing, we shall not effect any conversion of Series A Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series A 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, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see Description of Securities We Are Offering Preferred Stock on page 66 of this prospectus.

Shares of common stock outstanding before this offering	31,539,117 shares as of September 30, 2017.

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Shares of Series A Preferred Stock outstanding before this offering	None.
Shares of common stock outstanding after this offering	shares.
Shares of Series A Preferred Stock outstanding after this offering	shares.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for working capital and general corporate purposes, which may include development of our Lumivascular platform products, expansion of our sales and marketing organizations, intellectual property protection and enforcement, capital expenditures, investments, in-licenses and acquisitions of complementary products, technologies or businesses. See Use of Proceeds on page 39 of this prospectus.
Risk Factors	You should carefully read and consider the information set forth under Risk Factors on page 10 of this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.
NASDAQ Global Market symbol	AVGR .
No listing of Series A Preferred Stock or warrants	We do not intend to apply for listing of the shares of the Series A Preferred Stock or warrants on any securities exchange or trading system.

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The number of shares of common stock that will be outstanding after this offering is based on 31,539,117 shares outstanding as of September 30, 2017, and excludes:

- 3,683,323 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of $6.42 per share;

- 2,152,117 shares of common stock issuable upon exercise of outstanding warrants;

- 2,248,543 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;

- 801,138 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;

- shares of common stock issuable under the Purchase Agreement with Lincoln Park, including the 943,396 Shares we issued to Lincoln Park in November 2017;

- shares of common stock to be issued pursuant to the Class A Units and Class B Units in this offering, including any shares issuable upon conversion or exercise, as the case may be, of the Series A Preferred Stock and warrants;

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

- a 1-for- reverse stock split of our common stock, which became effective as of ;

- no additional issuances of common stock to Lincoln Park under the Purchase Agreement;

- no exercise of options or warrants outstanding as of the date of this prospectus; and

- no exercise of by the underwriters of their overallotment option.

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RISK FACTORS

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

Risks Related to Our Business

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

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

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

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

- the availability of reimbursement for our Lumivascular platform products;

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

- results of our clinical trials;

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

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

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

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

- the regulatory environment;

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

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

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

- our ability to obtain additional financing; and

- advances and trends in new technologies and industry standards.

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

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $32.0 million in 2014, $47.3 million in 2015, $56.1 million in 2016, and $38.6 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of approximately $291.2 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, net proceeds from the sale of our common stock to Lincoln Park Capital Fund, LLC (Lincoln Park) pursuant to the Purchase Agreement entered into on November 3, 2017, together with our cash and cash equivalents at September 30, 2017, and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations for at least the next nine months. Even if we are able to issue and sell up to $15.0 million in our common stock under the Purchase Agreement and are able to issue and sell up to $ in Class A Units and Class B Units in this offering, we will need to raise additional funds through future equity or debt financings within the next nine months to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next nine months could cause substantial dilution to our existing stockholders.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our at-the-market program, our initial public offering, or IPO, and our follow-on public offering. On November 3, 2017, we entered into the 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. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, and any next-generation versions of such products;

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

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

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

- 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;

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

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

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

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

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

As of September 30, 2017, we had $43.1 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds (collectively CRG). Our significant amount of debt may:

- 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;

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- 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 covenants of the Loan Agreement, as amended, include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents, and we had to achieve minimum revenue of $7.0 million in 2015 and $18.0 million in 2016, and will have to achieve minimum revenue of $40.0 million in 2017, $50.0 million in 2018, $60.0 million in 2019 and $70.0 million in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. On December 14, 2017, we entered into a waiver agreement with CRG waiving compliance with the minimum required revenue financial covenant for calendar year 2017. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended.

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

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

We are also subject to standard event of default provisions under the Loan Agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. We used the initial net proceeds under the Loan Agreement to repay and terminate our credit facility with PDL Biopharma, Inc., or PDL, however, our obligation to continue to make royalty payments to PDL out of our quarterly revenues through April 18, 2018 remain in effect. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The existing collateral pledged under the Loan Agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. If we default under any of these debt covenants, we would need relief from default, which may involve waivers or amendments to the applicable debt agreement, if we were unable

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to cure the default within the relevant cure period. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

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

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

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

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

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful

commercialization and continued development of Pantheris and we expect that sales of Pantheris and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA approval to market an enhanced version of Pantheris in March 2016, and Pantheris became commercially available in the United States and select international markets promptly thereafter. As such acceptance among physicians of these products may not increase or may decline.

Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Sales of Pantheris and our other Lumivascular

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platform products may decline as a result of the reduced sales and marketing personnel headcount after our organizational realignment in April 2017 and the implementation of our cost reduction plan in September 2017. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivascular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

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

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

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

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

In addition, in April 2017, we undertook an organizational realignment, which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016, and reducing our field sales personnel by nearly 50%. In September 2017, we effected a cost reduction plan, which also included a company-wide reduction in force, lowering our total headcount by 24 employees. As of December 31, 2017 our field sales personnel headcount was reduced to 19, compared to 60 as of December 31, 2016. Other employees may leave voluntarily as a result of the reduction in force that we implemented. Given the significant reduction in our sales force, there can be no assurance that our remaining field sales personnel will be adequate to successfully commercialize our products. Further reductions in sales staff may have additional adverse impacts on our business.

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

Our gross margin decreased to -58% and -40% for the three and nine months ended September 30, 2017, respectively, compared to 30% and 26% for the three and nine months ended September 30, 2016, respectively. Gross margin for the three and nine months ended September 30, 2017 was negatively impacted primarily by an increase of $1.4 million and $4.5 million in charges predominantly related to excess and obsolete Lightbox and Pantheris inventories, respectively.

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

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

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

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

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,

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leading to a heart attack, or blocking an artery to the brain, leading to a stroke. If our Lumivascular platform products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management s attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

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

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

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

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

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

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

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

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

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

- procedural safety and efficacy;
- acute and long-term outcomes;
- ease of use and procedure time;
- price;
- size and effectiveness of sales force;
- radiation exposure for physicians, hospital staff and patients; and
- third-party reimbursement.

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

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

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more and failure of the trial can occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not 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;

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

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

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

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

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

- trouble in managing multiple clinical sites;

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

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

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

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

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

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

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

The results of short-term clinical experience of our Lumivascular platform products, including Pantheris, do not necessarily predict long-term clinical benefit. Restenosis rates typically increase over time. We believe that physicians will compare the rates of long-term restenosis and reintervention for procedures using our Lumivascular platform products against alternative procedures, such as angioplasty, stenting, bypass surgery and other atherectomy procedures. If the long-term rates of restenosis and reintervention do not meet physicians expectations, our Lumivascular platform products may not become

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widely adopted and physicians may recommend alternative treatments for their patients. Another significant factor that physicians will consider is acute safety data on complications that occur during the use of our Lumivascular platform products. If the results obtained from any post-market studies that we conduct or post-clearance surveillance indicate that the use of our Lumivascular platform products are not as safe or effective as other treatment options or as current short-term data would suggest, adoption of our product may suffer and our business would be harmed. Even if we believe the data collected from clinical studies or clinical experience indicate positive results, each physician s actual experience with our products will vary. Physicians who are technically proficient participate in our clinical trials and are high-volume users of our Lumivascular platform products. Consequently, the results of our clinical trials and their experiences using our products may lead to better patient outcomes than those of physicians that are less proficient, perform fewer procedures or who use our products infrequently.

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

Our current products are cleared in the United States only for crossing sub-total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These clearances prohibit our ability to market or advertise our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off-label uses of medical devices are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. We are not allowed to actively promote or advertise our products for off-label uses. In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot or Pantheris in the United States for use in other applications for which we do not currently have clearance, such as the coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 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.

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

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

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

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

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

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. For example, in December 2017, Dr. John B. Simpson resigned from our board of directors and as an employee of our company. This departure has had and may continue to have a disruptive effect on 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.

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

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

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

As of December 31, 2016, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $219.1 million and $161.8 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2017 for state purposes. Generally, 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 pursuant to the Purchase Agreement and the sale of the Class A Units and Class B Units pursuant to this 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.

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

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

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

results, business and financial condition may suffer.

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

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Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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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 September 30, 2017, we held 15 issued U.S. patents and had 21 U.S. utility patent applications and 7 PCT applications pending. As of September 30, 2017, we also had 25 issued patents outside of the United States. As of September 30, 2017, we had 40 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business. We use certain open source software in Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re- engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and operating results.

Risks Related to Government Regulation

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

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

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

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

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;

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- record keeping;

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

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

Before a new medical device, or a new intended use for, an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval from FDA, unless an exemption applies. Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained 510(k) clearance to market Pantheris, our image-guided atherectomy device, and our Ocelot family of catheters for crossing sub and total occlusions in the peripheral vasculature, our clearance can be revoked if safety or efficacy problems develop. We plan to apply for 510(k) clearance for improvements to our Pantheris device in the fourth quarter of 2017, and we intend to file for FDA clearance of a lower-profile device for below-the-knee peripheral vascular applications in the first quarter of 2018. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

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

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

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including Warning Letters, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

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

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

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

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

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

- criminal prosecution.

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

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

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

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

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

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

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

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

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

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

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Although previously suspended, this tax is expected to apply to sales of our products in 2018.. 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;

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

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

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

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

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

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

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

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

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

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

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the SEC promulgated final rules regarding disclosure of the use of certain minerals, known as conflict minerals, that are mined from the Democratic Republic of the Congo and adjoining countries, as well as procedures regarding a manufacturer s efforts to prevent the sourcing

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of such minerals and metals produced from those minerals. These disclosure requirements require ongoing due diligence efforts and disclosure obligations. We have incurred and expect to incur additional costs to comply with these disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in our products. Additional costs could include the cost of remediation and other changes to products, processes, or sources of supply as a consequence of such verification activities. In addition, our implementation of these rules could adversely affect the sourcing, supply, and pricing of materials used in our products. We may face reputational harm if we determine that certain of our components contain minerals not determined to be conflict free or if we are unable to alter our processes or sources of supply to avoid using such materials. Reputational harm could adversely affect our business, financial condition or results of operations.

Risks Related to Our Common Stock

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

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

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

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

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

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

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

- legislation or regulation of our business;

- lawsuits threatened or filed against us;

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

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

- developments in our industry.

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

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. Two analysts who previously published research reports on our stock have discontinued coverage. If one or more of the remaining analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

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

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

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

substantial dilution to our existing stockholders.

On February 3, 2016, we filed a universal shelf registration statement (the Shelf Registration Statement) to offer up to $150.0 million of our securities and entered into an at-the-market program pursuant to a Sales Agreement with Cowen, through which we issued and sold approximately 8.7 million shares of common stock having an aggregate offering value of approximately $8.7 million between the Shelf Registration Statement s effectiveness on March 8, 2016 and September 2017. In addition, in August 2016, we issued and sold 9,857,800 shares of our common stock in our follow-on public offering at a public offering price of $3.50 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. We have established, and may in the future establish, at-the-market programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under our at-the-market program with Cowen at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $0.2 million in commissions and fees to Cowen. During the nine months ended September 30, 2017, we sold 7,587,593 shares of common stock through the at-the-market program at an average price of $0.44 and raised net proceeds of $3.2 million, after payment of $0.1 million in commissions and fees to Cowen. Due to the SEC s baby shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such

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company s public float in a twelve-month period, we are unable to issue more shares in our at-the-market program at this time. Accordingly, it has been necessary to register the shares sold pursuant to the Purchase Agreement and this offering 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 348,262 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 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. 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 directors, officers and their affiliates have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2017, our directors, officers and their affiliates collectively beneficially own approximately 4.6% of our outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors report on our 2016 financial statements, included in our Annual Report on Form 10-K, as filed with the SEC on March 14, 2017, a going concern opinion, meaning that we have recurring losses from operations and negative cash flows from operations that raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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

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

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

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

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

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

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

Our common stock is currently listed on Nasdaq, which has qualitative and quantitative listing criteria. On April 20, 2017 we received a letter from the Listing Qualifications Department of Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) as the market value of the Company s listed securities, or MVLS, was below the minimum $50 million for the previous 30 consecutive business days. This letter also informed us that we were not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), as we did not have total assets and total revenue of at least $50 million each for the most recently completed fiscal year. We did not regain compliance with these rules in the 180-day period ended October 17, 2017, and, on October 24, 2017, we received another letter from Nasdaq indicating that, based upon non-compliance with the MVLS requirement, our securities would be subject to delisting from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel, or the Panel. We requested a hearing before the Panel and were granted a hearing

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date in January 2018. At the hearing we will present our plan to evidence compliance with all applicable requirements for continued listing on Nasdaq. We are considering a number of options in its efforts to regain compliance with the Nasdaq listing criteria, including raising additional equity capital and the implementation of a reverse stock split. Our request for a hearing will stay any delisting action by Nasdaq at least pending the ultimate outcome of the hearing and any extension granted by the Panel. In the interim, our securities will continue to trade on The NASDAQ Global Market. To regain compliance, the MVLS of our common stock must reach at least $50 million for a minimum of 10 consecutive business days.

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

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

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

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

- a classified board of directors;

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

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

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

- allowing stockholders to remove directors only for cause;

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

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

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

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

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

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

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

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

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

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. In addition, our Loan Agreement with CRG prohibits us from, among other things, paying any dividends or making any other distribution or payment on account of our common stock. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates.

Risks Related to This Offering

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways with which you may not agree. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested or otherwise used in a way that does not yield a favorable, or any, return for our company.

The Series A 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 A Preferred Stock or warrants, and we do not expect a market to develop. In addition, the Series A Preferred Stock and warrants are not listed, and we do not intend to apply for listing of the Series A Preferred Stock and warrants on any securities exchange or trading system. Without an active market, the liquidity of the Series A Preferred Stock and warrants will be limited, and investors may be unable to liquidate their investments in the Series A Preferred Stock and warrants.

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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 $. 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.

The warrants are subject to an issuer call.

If, after the date that is 180 days after the closing date, (i) the volume weighted average price for each of 30 consecutive trading days (the Measurement Period), which Measurement Period commences after the date that is 180 days after the closing date, exceeds 300% of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like after the initial exercise date), (ii) the average daily volume for such Measurement Period exceeds $500,000 per trading day and, (iii) the warrant holder is not in possession of any material non-public information which was provided by the Company, then the Company may, within 1 trading day of the end of such Measurement Period, call for cancellation of all or any portion of the warrants for which an exercise notice has not yet been delivered for consideration equal to $0.001 per warrant share. The Company s right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants. You may be unable to reinvest your proceeds from the call in an investment with a return that is as high as the return on the warrants would have been if they had not been called.

A warrant does not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your warrants, the warrants will not provide you any rights as a common stockholder. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock included in the units or issuable upon exercise of the warrants or conversion of the preferred stock in this offering.

Since the effective price per share of common stock included in the units or issuable upon exercise of the warrants or conversion of the Series A Preferred Stock being offered is substantially higher than the net tangible book deficit per share of our common stock outstanding prior to this offering, you will suffer immediate and substantial dilution in the net tangible book value of the common stock included in the units or issuable upon the exercise of the warrants or the conversion of the Series A Preferred Stock issued in this offering. See the section titled, Dilution below for a more detailed discussion of the dilution you will incur if you purchase units in this offering.

As a result of the dilution to investors purchasing units in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

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

- the outcome of and expectations regarding our current clinical studies and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through future equity or debt financings;
- the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to continue as a going concern;
- our ability to remain in compliance with the listing requirements of the Nasdaq Global 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, or ability to obtain, additional financing;

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

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

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

- our financial performance;

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

- our expectations regarding a proposed increase in the shares reserved for issuance pursuant to our 2015 Stock Incentive Plan;

- our intention to vigorously defend against pending securities lawsuits; and

- developments and projections relating to our competitors or our industry.

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

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MARKET, INDUSTRY AND OTHER DATA

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

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

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately $ 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 A 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.

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PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY

Our common stock began trading on The NASDAQ Global Market on January 30, 2015 and trades under the symbol AVGR. Prior to January 30, 2015, there was no public market for our common stock. In our IPO, our common stock priced at $13.00 per share on January 29, 2015. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market:

	Low	High
Fiscal Year ending December 31, 2015		
First Quarter (beginning January 30, 2015)	$ 10.00	$ 13.32
Second Quarter	$ 10.50	$ 13.15
Third Quarter	$ 12.52	$ 16.45
Fourth Quarter	$ 14.67	$ 24.75
Fiscal Year ending December 31, 2016		
First Quarter	$ 8.51	$ 20.46
Second Quarter	$ 9.92	$ 13.72
Third Quarter	$ 3.66	$ 11.99
Fourth Quarter	$ 3.50	$ 5.05
Fiscal Year ending December 31, 2017		
First Quarter	$ 1.60	$ 3.66
Second Quarter	$ 0.36	$ 1.68
Third Quarter	$ 0.22	$ 0.96
Fourth Quarter	$ 0.17	$ 0.41

As of January 10, 2018, the last reported sale price of our common stock on the NASDAQ Global Market was $0.20.

As of December 31, 2017, there were 33,339,998 shares of our common stock held by 182 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.

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CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2017:

- on an actual basis; and

- on an as adjusted basis to give effect to the sale of Class A Units and Class B Units in this offering, the application of the net proceeds of this offering and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with 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 September 30, 2017, which is incorporated by reference into this prospectus.

	As of September 30, 2017	
	Actual	Pro Forma As Adjusted
	(unaudited) (in thousands, except share data)	
Cash and cash equivalents	$ 10,170	
Borrowings	43,112	
Total	53,282	
Stockholders equity (deficit):		
Preferred stock, $0.001 par value; no shares authorized, issued and outstanding, actual; no shares issued and outstanding, pro forma as adjusted		
Common stock, $0.001 par value; 100,000,000 shares actual and pro forma as adjusted, 31,539,117 shares issued and outstanding, actual; and shares issued and outstanding, pro forma as adjusted	32	
Additional paid-in capital	264,434	
Accumulated deficit	(291,177)	
Total stockholders equity (deficit)	(26,711)	
Total capitalization	$ 26,571	

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The number of shares of common stock that will be outstanding after this offering is based on 31,539,117 shares outstanding as of September 30, 2017, and excludes:

- 3,683,323 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of $6.42 per share;

- 2,152,117 shares of common stock issuable upon exercise of outstanding warrants;

- 2,248,543 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;

- 801,138 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;

- shares of common stock issuable under the Purchase Agreement with Lincoln Park, including the 943,396 Shares we issued to Lincoln Park in November 2017; and

- shares of common stock to be issued pursuant to the Class A Units and Class B Units in this offering, including any shares issuable upon conversion or exercise, as the case may be, of the Series A Preferred Stock and warrants.

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DILUTION

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of September 30, 2017, our historical net tangible book value was $(26.7) million, or $(0.85) per share of common stock, based on 31,539,117 shares of our common stock outstanding at September 30, 2017. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of September 30, 2017.

After giving effect to our sale in this offering of shares of common stock, inclusive of the shares of common stock that the Series A Preferred Stock to be issued is convertible into, at a public offering price of $ per unit and after excluding shares that may be issued upon exercise of the underwriter s overallotment option and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2017 would have been $ million, or $ per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of $ per share and an immediate dilution of $ per share to the new investors purchasing securities in this offering. The following table illustrates this dilution:

Public offering price per share	$	
Net tangible book value per share as of September 30, 2017	$	(0.85)
Increase in net tangible book value per share attributable to new investors in this offering	$	
Pro forma net tangible book value per share after the offering	$	
Dilution per share to investors in this offering	$	

The above discussion and table are based on 31,539,117 shares outstanding as of September 30, 2017, and excludes:

- 3,683,323 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of $6.42 per share;

- 2,152,117 shares of common stock issuable upon exercise of outstanding warrants;

- 2,248,543 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;

- 801,138 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;

- shares of common stock issuable under the Purchase Agreement with Lincoln Park, other than the 943,396 Shares we issued to Lincoln Park in November 2017; and

- shares of common stock to be issued pursuant to the Class A Units and Class B Units in this offering, including any shares issuable upon conversion or exercise, as the case may be, of the Series A Preferred Stock and warrants.

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

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BUSINESS

Overview

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

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

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

In March 2015, we completed enrollment of 134 patients in VISION, a clinical trial designed to support our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and effectiveness endpoints. We believe the data from VISION allows us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the EEL, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. We commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select international markets in March 2016 after obtaining the required marketing authorizations.

We are developing two next-generation versions of our Pantheris atherectomy device, Pantheris 3.0 and a lower profile Pantheris, that we believe represent significant improvements over our existing product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe will improve usability and reliability, while the lower profile Pantheris has a smaller

diameter and longer length that we believe will optimize it for use in smaller vessels and below-the-knee applications. We filed a 510(k) submission for Pantheris 3.0 in the fourth quarter of 2017, and we plan to file a 510(k) submission for Pantheris BTK in the second quarter of 2018.

We have assembled a team with extensive medical device development and commercialization capabilities. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $11.2 million in 2014, $10.7 million in 2015, $19.2 million in 2016 and $8.0 million for the nine months ended September 30, 2017.

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Our Products

Our current products include our Lightbox imaging console and our various catheters used in PAD treatment. All of our revenues are currently derived from sales of our Lightbox imaging console and our various PAD catheters and related services in the United States and select international markets. Each of our current products is, and our future products will be, designed to address significant unmet clinical needs in the treatment of vascular disease.

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LUMIVASCULAR PRODUCTS

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

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

(2) The Ocelot system is intended to facilitate the intra-luminal placement of conventional guidewires beyond stenotic lesions including subtotal and chronic total occlusions in the peripheral vasculature prior to further percutaneous interventions using OCT-assisted orientation and imaging. The system is an adjunct to fluoroscopy and provides images of vessel lumen, plaques and wall structures. The Ocelot system is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.

NON-IMAGING PRODUCTS

Name	Indication	Size (Length, Diameter)	Regulatory Status	Original Clearance Date
Wildcat(1)	Guidewire Support CTO Crossing	110cm, 6F 110cm, 6F	FDA Cleared FDA Cleared CE Mark	February 2009(3) August 2011 May 2011
Kittycat 2(2)	CTO Crossing	150cm, 5F	FDA Cleared CE Mark	October 2011 September 2011

(1) The Wildcat catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including subtotal and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Wildcat catheter is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature. The Wildcat catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast.

(2) The Kittycat 2 catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including subtotal and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat 2 catheter is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.

(3) This original clearance date is for the 7F version of Wildcat. The commercially available version of Wildcat is listed and was cleared in August 2010.

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Lumivascular Platform Overview

Our Lumivascular platform integrates OCT visualization with interventional catheters and is the industry s only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. Our Lumivascular platform consists of a capital component, Lightbox, and a variety of disposable catheter products, including Ocelot, Ocelot PIXL, Ocelot MVRX and Pantheris.

Lightbox

Lightbox is our proprietary imaging console, which enables the use of Lumivascular catheters during PAD procedures. The console contains an optical transceiver that transmits light into the artery through an optical fiber and displays a cross-sectional image of the vessel to the physician on a high definition monitor during the procedure. Lightbox is configured with two monitors, one for the physicians, and one for the Lightbox technician.

Lightbox displays a cross-sectional view of the vessel, which provides physicians with detailed information about the orientation of the catheter and the surrounding artery and plaque. Layered structures represent relatively healthy portions of the artery and non-layered structures represent the plaque that is blocking blood flow in the artery. Navigational markers allow the physician to orient the catheter toward the treatment area, helping to avoid damage to the healthy arterial structures during a procedure. Lightbox received FDA 510(k) clearance in November 2012 and CE Mark in Europe in September 2011.

Pantheris

We believe Pantheris is the first atherectomy catheter to incorporate real-time OCT intravascular imaging. Pantheris may be used alone or following a CTO crossing procedure using Ocelot or other products. Pantheris is a single-use product and provides physicians with the ability to see a cross-sectional view of the artery throughout the procedure. The device restores blood flow by shaving thin strips of plaque using a high-speed directional cutting mechanism that enables physicians to specifically target the portion of the artery where the plaque resides while minimizing disruption to healthy arterial structures. The excised plaque is deposited in the nosecone of the device and removed from the artery within the device.

In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We made modifications to Pantheris after the completion of the VISION trial and commenced sales in the United States and select international markets following receipt of FDA approval for this version of Pantheris in March 2016. We first received CE Mark for Pantheris in June 2015.

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

quarter of 2018.

Ocelot, Ocelot PIXL and Ocelot MVRX

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

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

Other Products

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

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Clinical Development

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

CONNECT (Wildcat)

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

CONNECT II (Ocelot)

Our clinical trial for Ocelot, known as CONNECT II, was a prospective, multi-center, non-randomized trial that evaluated the safety and efficacy of Ocelot in crossing CTOs in arteries of the upper leg using OCT intravascular imaging. The CONNECT II trial enrolled 100 patients with CTOs at 14 centers in the United States and two centers in Europe. Patients were followed for 30 days post-procedure and an independent group of physicians verified the results to confirm the primary efficacy and safety endpoints. Results from the CONNECT II trial demonstrated that Ocelot surpassed its primary efficacy endpoint by successfully crossing the CTO in 97% of the cases following unsuccessful attempts to cross with standard guidewire techniques. Ocelot achieved these rates with 98% freedom from MAEs.

VISION (Pantheris)

VISION was our pivotal, non-randomized, prospective, single-arm trial to evaluate the safety and effectiveness of Pantheris across 20 sites within the United States and Europe. The objective of the clinical trial was to demonstrate that Pantheris can be used to effectively remove plaque from diseased lower extremity arteries while using on-board visualization as an adjunct to fluoroscopy. Two groups of patients were treated in VISION: (1) optional roll-ins, which are typically the first two procedures at a site, and (2) the primary cohort, which are the analyzable group of patients. The data for these two groups were reported separately in our 510(k) submission to the FDA. Based on final enrollment, the primary cohort included 130 patients. In March 2015, we completed enrollment of patients in the VISION clinical trial and we submitted for 510(k) clearance from the FDA in August 2015. In October 2015, we received 510(k) clearance from the FDA for commercialization of Pantheris. We have made modifications to Pantheris subsequent to the completion of VISION and received 510(k) clearance on the enhanced version of Pantheris in March 2016.

VISON s primary efficacy endpoint required that at least 87% of lesions treated by physicians using Pantheris have a residual stenosis of less than 50%, as verified by an independent core laboratory. The primary safety endpoint required that less than 43% of patients experience an MAE through six-month follow-up as adjudicated by an independent Clinical Events Committee, or CEC. MAEs as defined in VISION included cardiovascular-related death, unplanned major index limb amputation, clinically driven target lesion revascularization, or TLR, heart attack, clinically significant perforation, dissection, embolus, and pseudoaneurysm. Results from the VISION trial demonstrated that Pantheris surpassed its primary efficacy and safety endpoints; residual restenosis of less than 50% was achieved in 96.3% of lesions treated in the primary cohort, while MAEs were experienced in 17.6% of patients.

Although not mandated by the FDA to support the market clearance of Pantheris, the protocol for the VISION trial allowed for routine histopathological analysis of the tissue extracted by Pantheris to be conducted. This process allowed us to determine the amount of adventitia present in the tissue, which in turn indicated the extent to which the external elastic lamina had been disrupted during Pantheris procedures. We completed histopathological analysis on tissue from 129 patients in the primary cohort, representing 162 lesions and determined that the average percent area of adventitia was only 1.0% of the total excised tissue. We believe the low level of EEL disruption will correlate to lower restenosis rates and improved long-term outcomes for patients treated with Pantheris, but we do not intend to make any promotional claims to that effect based on the data from this study. We published the results of the histopathological analysis in conjunction with the primary safety and efficacy endpoint data from the VISION trial.

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Final VISION trial data are summarized in the table below.

	Roll-In Cohort	Primary Cohort	Total
Patients Treated	28	130	158
Lesions treated	34	164	198
Primary Efficacy Endpoint			
Lesions analyzed by core lab	34	164	198
Lesions meeting primary efficacy endpoint criterion of residual restenosis of less than 50% by core lab	100%	96.3%	97%
	(34/34)	(158/164)	(192/198)
Primary Safety Endpoint (MAEs through 6 months)			
Total MAEs Reported	3	22	25
Reported MAEs as a percentage of patients enrolled	11.5%	17.6%	16.6%
	(3/26)	(22/125)	(25/151)
Histopathology Results (Non-Endpoint Data)			
Lesions with histopathology results	34	162	196
Average percent area of adventitia in all lesions with histopathology results	0.56%	1.02%	0.94%

Although the original VISION study protocol was not designed to follow patients beyond six months, in 2016 we began working with 18 of the VISION sites to re-consent patients in order for them to be evaluated for patient outcomes through 12 and 24 months following initial treatment. Data collection for patients from participating sites was completed in May 2017, and we released the final 12- and 24-month results for a total of 73 patients and 89 lesions in July 2017. The key metrics reported for this group were freedom from target lesion revascularization, or TLR, at 12 months and 24 months, which were 82% and 74% by patient and 83% and 76% by lesion, respectively, based on Kaplan-Meier curve assessments.

INSIGHT (Pantheris)

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

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

Sales and Marketing

We focus our sales and marketing efforts primarily on the approximately 10,000 interventional cardiologists, vascular surgeons and interventional radiologists in the United States that are potential users of our Lumivascular platform products. Our marketing efforts are focused on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders based on their knowledge of our products, clinical expertise and reputation. We also use continuing medical education programs and other opportunities to train interventional cardiologists, vascular surgeons, and interventional radiologists in the use of our Lumivascular platform products and educate them as to the benefits of our products as compared to alternative procedures such as angioplasty, stenting, bypass surgery or other atherectomy procedures. In addition, we work with physicians to help them develop their practices and with hospitals to market themselves as centers of excellence in PAD treatment by making our products available to physicians for treating patients.

Our sales team currently consists of a Vice President, Regional and Territory Sales Managers, Clinical Specialists, and one Director of International Sales. Territory Sales managers are responsible for all product sales, which include disposable catheters and sale and service of our Lightbox console, while Clinical Specialists are primarily responsible for case coverage and account support. We have an extensive hands-on sales training program, focused on our technologies, Lumivascular image interpretation, case management, sales processes, sales tools and implementing our sales and marketing

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programs and compliance with applicable federal and state laws and regulations. Our sales team is supported by our marketing team, which focuses primarily on clinical training and education, marketing communications and product management. We have partnered with a third party field service firm for the installation, service and maintenance of our Lightbox consoles.

As of December 31, 2017, we had 23 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 2014, 2015, 2016 and for the nine months ended September 30, 2017 were $18.5 million, $29.2 million, $40.0 million and $20.4 million, respectively. No single customer accounted for more than 10% of our revenues during 2014, 2015, 2016 or for the nine months ended September 30, 2017.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions, results of clinical research, corporate combinations and other factors relating to our industry. Because of the market opportunity and the high growth potential of the PAD treatment market, competitors and potential competitors have historically dedicated, and will continue to dedicate, significant resources to aggressively develop and commercialize their products.

Our products compete with a variety of products or devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon market segments include Abbott Laboratories, Becton Dickinson, Boston Scientific, Cardinal Health, Cook Medical, Medtronic and Philips. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic and Philips. Some competitors have attempted to combine intravascular imaging with atherectomy and although we are not aware of any active initiatives in this area, these and other companies may attempt to incorporate on-board visualization into their products in the future or may have ongoing programs of which we are not aware. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our solution.

Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels and broader product offerings, and have established stronger and deeper relationships with target customers.

To compete effectively, we have to demonstrate that our products are attractive alternatives to other devices and treatments on the basis of:

- procedural safety and efficacy;
- acute and long-term outcomes;

- ease of use and procedure time;
- price;
- size and effectiveness of sales force;
- radiation exposure for physicians, hospital staff and patients; and
- third-party reimbursement.

Intellectual property

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights.

It is our policy to require our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from using the proprietary rights of third parties in their work for us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

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As of December 31, 2017, we held 15 issued U.S. patents and had 22 U.S. utility patent applications and 7 PCT applications pending. As of December 31, 2017, we also had 24 issued patents from outside of the United States. As of December 31, 2017, we had 48 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. As we continue to research and develop our products and technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our devices. Our issued patents expire between the years 2028 and 2035.

Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

As of December 31, 2017, we held four registered U.S. trademarks and one pending U.S. trademark application. In Europe, we hold three registered trademarks. In addition, we held one International Registration under the Madrid Protocol with granted extensions to China, Europe, Japan, and Korea.

Research and Development

Our ongoing research and development activities are primarily focused on improving and enhancing our Lumivascular platform, specifically our core competency of integrating OCT intravascular imaging onto therapeutic catheters. Our research objectives target areas of unmet clinical need, increase the utility of the Lumivascular platform and adoption of our products by healthcare providers.

- ***Product line improvements and extensions.*** We are developing improvements to our Lumivascular platform, including additional catheters for use in different clinical applications. For example, we are developing versions of Pantheris designed to treat smaller vessels, and we are also developing next-generation CTO crossing devices to target both the peripheral and coronary CTO markets.

- ***Additional treatment indications.*** We intend to seek additional regulatory clearances from FDA to expand the indications for which our products can be marketed within PAD, as well as in other areas of the body. This includes both expanding the marketed indications for our current products, as well as development of new products.

- ***Next-generation console.*** We are focusing our console development efforts on miniaturization, equipment integration and increased processing power in anticipation of future catheter products. We may also develop a version of our Lumivascular platform that integrates OCT imaging into existing catheterization lab and operating room imaging systems.

- ***Improved software and user interface.*** We intend to further develop our software to provide more information and control to our end users during a procedure. We use physician and staff feedback to improve the features and user functionality of our Lumivascular platform.

As of December 31, 2017, we had 13 employees focused on research and development. In addition to our internal team, we retain third-party contractors from time to time to provide us with assistance on specialized projects. We also work closely with experts in the medical community to supplement our internal research and development resources. Research and development expenses for the years ended December 31, 2014, 2015, 2016 and the nine months ended September 30, 2017 were $11.2 million, $15.7 million, $15.5 million and $9.3 million, respectively.

Manufacturing

Prior to the introduction of our Lumivascular platform, our non-imaging catheter products were manufactured by a third-party. All of our products are now manufactured in-house using components and sub-assemblies manufactured both in-house at our facility in Redwood City, California and by outside vendors. We assemble all of our products at our manufacturing facility but certain critical processes such as coating and sterilization are done by outside vendors. We expect our current manufacturing facility will be sufficient through at least 2019.

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Our manufacturing operations are subject to regulatory requirements of 21 CFR part 820 of the Federal Food, Drug and Cosmetic Act, or FFDCA; the Quality System Regulation, or QSR, for medical devices sold in the United States, which is enforced by FDA; the Medical Devices Directive 93/42/EEC, which is required for doing business in the European Union; and applicable requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances, and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. We cannot ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims by or injury to employees or the public.

Order quantities and lead times for components purchased from outside suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. To date, we have not experienced significant delays in obtaining any of our components or subassemblies.

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply for them. Identifying and qualifying additional or replacement suppliers for any of the components used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

Other than current accepted purchase orders, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations.

We have registered with FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Public Health, or CDPH. We and our component suppliers are required to manufacture our products in compliance with FDA s QSR in 21 CFR part 820 of the FFDCA. The QSR regulates extensively the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. FDA enforces the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. Our Quality System has undergone 20 external audits by third-parties and regulatory authorities since 2009, the latest of which was a surveillance audit conducted in January 2017 by BSI, our European Notified Body, under the Medical Device Single Audit Program, or MDSAP. The audit resulted in zero observations of non-conformances.

Our failure or the failure of our component suppliers to maintain compliance with the QSR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. Our Redwood City facilities meet the requirements set forth by ISO 13485:2003 Medical devices Quality management systems Requirements for regulatory purposes and MDD 93/42/EEC European Union Council Medical Device Directive.

Government Regulation

In general, medical device companies must navigate a challenging regulatory environment. In the United States the FDA regulates the medical device market to ensure the safety and efficacy of these products. The FDA allows for two primary pathways for a medical device to gain approval for commercialization: a successful pre-market approval, or PMA application or 510(k) premarket notification submission. A completely novel product must go through the more rigorous premarket approval, or PMA, if it cannot receive authorization through a 510(k). The FDA has established three different classes of medical devices that indicate the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy. Class I and Class II devices are considered lower risk and often can gain

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approval for commercial distribution by submitting an application to the FDA, generally known as the 510(k) process. The devices regarded as the highest risk by the FDA are designated Class III status and generally require the submission of a PMA application for approval to commercialize a product. These generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA.

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

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

A PMA application must include reasonable scientific and clinical data that demonstrates the device is safe and effective for the intended uses and indications being sought. The application must also include preclinical testing, technical, manufacturing and labeling information. If the FDA determines the application can undergo substantive review, it has 180 days to review the submission, but it can typically take longer (up to several years) as this regulatory body can request additional information or clarifications. The FDA may also impose additional regulatory hurdles for a PMA, including the institution of an advisory panel of experts to assess the application or provide recommendations as to whether to approve the device. Although the FDA in the end approves or disapproves the device, in nearly all cases the FDA follows the recommendation from the advisory panel. As part of this process, the FDA will usually inspect the manufacturing facilities and operations prior to approval to verify compliance with quality control regulations. Significant changes in the manufacturing of a device, or changes in the intended use, indications and labeling or design of a product require new PMA applications or PMA supplements for a product originally approved under a PMA. This creates substantial regulatory risk for devices undergoing the PMA route.

Pervasive and Continuing Regulation

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

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

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

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

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

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

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

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We have registered with the FDA as a medical device manufacturer and have obtained a manufacturing license from the CDPH. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of CDPH to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers. Our current facility has been inspected by the FDA in 2009, 2011 and 2013, and two, three and zero observations, respectively, were noted during those inspections. In the latest FDA audit in 2013, there were no observations that involved a material violation of regulatory requirements, and no non-conformances were noted. Our responses to the observations noted in 2009 and 2011 were accepted by the FDA, and we believe that we are in substantial compliance with the QSR. BSI, our European Notified Body, inspected our facility several times between 2010 and 2015 and found zero non-conformances. BSI conducted four external audits in 2016 and zero non-conformances were found in all except for one audit, for which four minor non-conformances were found. The BSI audit performed in January 2017 resulted in zero non-conformances.

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

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

Regulatory System for Medical Devices in Europe

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

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

Federal, State and Foreign Fraud and Abuse Laws

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

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

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

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

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

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

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

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 and $11,000 for each separate instance of false claim. As part of any settlement, the

government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

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

The Sunshine Act. The Physician Payment Sunshine Act, or the Sunshine Act, which was enacted as part of the Affordable Care Act, requires all entities that operate in the United States and manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children s Health Insurance Program to report annually to the Secretary of HHS: (i) payments or other transfers of value made by that entity, or by a third-party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician

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ownership and investment interests in the entity. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. We are subject to the Sunshine Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

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

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

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

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The Act contains a number of provisions that impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in federal healthcare programs and reimbursement changes.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payors. Furthermore, the current presidential administration and Congress may again attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. But, any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect any future legislation or regulation in the United States may have on our business.

Third-Party Reimbursement

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

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

- Type of procedure performed angioplasty, stent or atherectomy;
- Patient-specific complexities and comorbidities;
- Type of facility hospital, teaching hospital or office-based lab;
- Inpatient or outpatient status; and
- Geographic region.

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

Medicare reimbursement levels for inpatient PAD procedures for fiscal year 2018 went into effect as of October 1, 2017 and range between $10,928 and $19,492. Medicare reimbursement for outpatient PAD procedures for 2018 go into effect on January 1, 2018 and are expected to range between $6,835 and $14,856. These amounts include the cost of disposable catheters such as Ocelot and Pantheris. While reimbursement varies based on the type of procedure performed (i.e., angioplasty, stent or atherectomy), additional device-specific reimbursement is not available. The amount of reimbursement can vary substantially by geographical region and by facility. Payment rates of other third-party payors may follow Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. Because of the wide variability, it is not possible to identify an average rate for third-party payors other than Medicare.

Employees

As of December 31, 2017, we had 65 employees, including 13 in manufacturing and operations, 23 in sales and marketing, 13 in research and development and clinical and regulatory affairs, 7 in quality assurance and 9 in finance, general administrative and executive administration. All 65 employees are full time employees. None of our employees are represented by a labor union or are parties to a collective bargaining

agreement and we believe that our employee relations are good.

Legal Proceedings

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

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

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On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted the motions to remand the Olberding and Gonzalez actions to the State Court. On August 9, 2017, the State Court consolidated the Olberding and Gonzalez actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284 (State Action). On September 22, 2017, an amended complaint was filed in the State Action. On October 31, 2017, the parties in the State Action stipulated to a stay of proceedings until judgment is entered in the federal Grotewiel action (Federal Action).

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Federal Action. An amended complaint was filed in the Federal Action on November 21, 2017. In order to allow the parties to pursue mandatory alternative dispute resolution, the parties have stipulated and the Federal Court ordered that defendants motion to dismiss the Federal Action will be due on January 17, 2018, with a hearing set for May 1, 2018.

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

Corporate and other Information

We were incorporated in Delaware on March 8, 2007. Our principal executive offices are located at 400 Chesapeake Drive, Redwood City, California 94063, and our telephone number is (650) 241-7900. Our website address is *www.avinger.com*. References to our website address do not constitute incorporation by reference of the information contained on the website, and the information contained on the website is not part of this document.

We make available, free of charge on our corporate website, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC s on-line database, which is located at *www.sec.gov*. Our common stock is traded on the NASDAQ Global Market under the symbol AVGR .

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.0 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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EXECUTIVE COMPENSATION

Processes and Procedures for Compensation Decisions

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

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

Fiscal 2017 Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was earned by our Chief Executive Officer and our two other most highly compensated executive officers in our fiscal year ended December 31, 2017. The individuals listed in the table below are our named executive officers for our fiscal year ended December 31, 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
John B. Simpson, Ph.D., M.D.(2)	2017	363,500		61,500	67,161		232,500	724,661
Executive Chairman	2016	390,000		342,511	334,360	91,134		1,158,005
Jeffrey M. Soinski(3)	2017	390,000		61,500	67,161		3,000	521,661
President and Chief Executive Officer	2016	390,000		342,511	334,360	91,134	105,891	1,263,896
Matthew B. Ferguson(4)	2017	300,000		51,250	55,967		3,000	410,217
Chief Financial Officer and Chief Business Officer	2016	300,000		143,043	139,286	56,083	3,000	641,412

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officer in 2016 and 2017, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in the section of our Annual Report on Form 10-K

titled Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-Based Compensation.

(2) In 2014, the amounts reported in All Other Compensation for Dr. Simpson include a cash severance payment of $195,000 and reimbursement for accrued paid time off of $37,500. Dr. Simpson resigned as a director and Executive Chairman from our board of directors and as an employee in December 2017.

(3) The amounts reported for Mr. Soinski represent reimbursed relocation expenses, of $102,891 for 2016, pursuant to his employment offer letter and funds contributed to his health savings account of $3,000 for each of 2016 and 2017.

(4) The amount reported for Mr. Ferguson represents funds contributed to his health savings account of $3,000 for each of 2016 and 2017.

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Executive Employment Letters

John B. Simpson

We entered into an employment offer letter in November 2014 with John B. Simpson. The letter had no specific term and provides for at-will employment. The letter did not provide for any bonus. Effective January 1, 2016, Dr. Simpson s annual base salary was $390,000. Dr. Simpson resigned as director and Executive Chairman in December 2017.

Jeffrey M. Soinski

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

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

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

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

Matthew B. Ferguson

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

401(k) Plan

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

Pension Benefits and Nonqualified Deferred Compensation

We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2017.

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Outstanding Equity Awards at Fiscal Year-End

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

		Option Awards				Stock Awards	
Name	**Grant Date**	**Number of Securities Underlying Unexercised Options (#) Exercisable (3)**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)(4)**	**Option Expiration Date**	**Number of Shares or Units of Stock That Have Not Vested (#)**	**Market Value of Shares or Units of Stock That Have Not Vested ($)(5)**
John B. Simpson	5/1/2013(1)(6)	28,888		22.50	5/1/2018		
	12/31/2014(1)(7)	611,223		4.95	12/31/2024		
	3/7/2016(2)(7)	26,250		12.96	3/7/2026		
Jeffrey M. Soinski	12/31/2014(1)(7)	619,385		4.50	12/31/2024		
	3/7/2016(2)(7)	26,250	33,750	12.96	3/7/2026		
	3/7/2016(2)(8)					22,500	4,050
	3/13/2017(2)(7)		60,000	2.05	3/13/2027		
	3/13/2017(2)(8)					30,000	5,400
Matthew B. Ferguson	7/29/2011(1)(9)	33,965		12.60	7/29/2021		
	5/1/2013(1)(6)	6,816		20.25	5/1/2023		
	9/2/2014(1)	9,653		12.60	9/2/2019		
	12/31/2014(1)(7)	95,482		4.50	12/31/2024		
	3/3/2016(2)(7)	10,937	14,063	12.99	3/3/2026		
	3/3/2016(2)(8)					9,375	1,688
	3/13/2017(2)(7)		50,000	2.05	3/13/2027		
	3/13/2017(2)(8)					25,000	4,500

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

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

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

(4) This column represents the fair value of a share of our common stock on the date of grant which, prior to our initial public offering in January 2015, was determined by our board of directors. Subsequently, the fair value of our common stock is determined based on the closing price of our common stock, as reported on the Nasdaq Global Market.

(5) This column represents the market value of the unvested shares of our common stock underlying the RSUs as of December 29, 2017, based on the closing price of our common stock, as reported on the Nasdaq Global Select Market, of $0.18 per share.

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

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

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

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

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Potential Payments upon Termination or Change of Control

In March 2012, we entered into change of control and severance agreements with each of John B. Simpson and Matt Ferguson that superseded all previous severance and change of control arrangements we had entered into with these employees. Under each of these agreements, if, within the 18 month period following a change of control, we terminate the employment of the applicable employee other than for cause, death or disability, or the employee resigns for good reason (as such terms are defined in the employee s employment agreement) and, within 60 days following the employee s termination, the employee executes an irrevocable separation agreement and release of claims, the employee is entitled to receive (i) continuing payments of severance pay at a rate equal to the employee s base salary and target bonus, as then in effect, for 12 months, (ii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to COBRA for employee and employee s dependents for up to 12 months, (iii) accelerated vesting as to 100% of the employee s outstanding unvested stock options and/or restricted stock, and (iv) the extension of the post-termination exercise period of any options held by the employee for a period of 1 year. Additionally, if we experience a change in control, 50% of the employee s outstanding unvested stock options and/or restricted stock will vest. Dr. Simpson resigned as director and Executive Chairman in December 2017 and is no longer eligible for any change of control payments.

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

Executive Incentive Compensation Plan

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

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

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

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

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Equity Compensation Plan Information

All of our equity compensation plans have been approved by our stockholders. The following table provides information as of December 31, 2017, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (2)	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by stockholders (1)	5,426,107	$ 8.97	3,721,385

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

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

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our capital stock as of December 31, 2017 for:

- each of our named executive officers;
- each of our directors and nominees for director; and
- all of our current executive officers and directors as a group.

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

Applicable percentage ownership is based on 33,339,998 shares of our common stock outstanding as of December 31, 2017. In computing the number of shares of capital stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of our capital stock subject to options held by the person that are currently exercisable or exercisable within 60 days of December 31, 2017. However, we did not deem such shares of our capital stock outstanding for the purpose of computing the percentage ownership of any other person.

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

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares**	**Percentage**
Named Executive Officers and Directors		
Jeffrey M. Soinski(1)	721,179	2.1%
Matthew Ferguson(2)	189,447	*
James G. Cullen(3)	173,010	*
Donald A. Lucas(4)	77,879	*
James B. McElwee(5)	64,499	*
All executive officers and directors as a group (6 individuals)(6)	1,549,035	4.6%

* Represents ownership of less than 1%

(1) Consists of (i) 73,044 shares of common stock held of record by Mr. Soinski and (ii) 648,135 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(2) Consists of (i) 31,552 shares of common stock held of record by Mr. Ferguson, (ii) warrants to purchase 9,653 shares of common stock and (iii) 148,242 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(3) Consists of (i) 73,835 shares of common stock held by Gilbert Investments, LLC, (ii) warrants to purchase 24,862 shares of common stock held by Gilbert Investments, LLC, (iii) 13,101 shares of common stock held by 2000 James Cullen Generation Skipping Family Trust and (iv) 61,212 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2017. Mr. Cullen has sole voting and dispositive power with respect to shares held by Gilbert Investments, LLC and James Cullen Generation Skipping Family Trust. Mr. Cullen does not have a pecuniary interest in the James Cullen Generation Skipping Family Trust and disclaims beneficial ownership in Gilbert Investments, LLC except to the extent of his pecuniary interest therein.

(4) Consists of (i) 23,229 shares of common stock held of record by Lucas Venture Group III, LP and (ii) 54,620 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(5) Consists of (i) 15,090 shares of common stock held of record by Mr. McElwee, (ii) warrants to purchase 5,521 shares of common stock and (iii) 43,888 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(6) Consists of (i) 326,766 shares of common stock outstanding, (ii) warrants to purchase 58,357 shares of common stock (iii) 1,163,912 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

Description of Units

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

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, 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%), Class B Units. Each Class B Unit will consist of one share of Series A Preferred Stock, par value $0.001 per share (the Series A Preferred Stock), initially convertible into shares of common stock, subject to adjustment in certain events as set forth in this prospectus, and warrants to purchase shares of our common stock (together with the shares of common stock underlying such shares of Series A Preferred Stock and such warrants, the Class B Units, and together with the Class A Units, the units) at a public offering price of $ per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase shares of common stock at an initial exercise price per share of $, subject to adjustment in certain events as set forth in this prospectus.

Description of Capital Stock

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

General

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

Common Stock

Outstanding Shares

On December 31, 2017, there were 33,339,998 shares of common stock outstanding, held of record by 182 stockholders. Our board of directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

As of December 31, 2017, there were 2,152,117 shares of common stock subject to outstanding warrants, and 3,069,611 shares of common stock subject to outstanding options.

Dividend Rights

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

Voting Rights

There are 100,000,000 shares of common stock authorized for issuance. Pursuant to our amended and restated certificate of incorporation, each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of stockholders; provided, however, that, except as otherwise required by law, holders of our common stock, as such, shall not be entitled to vote on any amendment to our amended and restated certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either

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separately or together with the holders of one or more other such series, to vote thereon pursuant to our amended and restated certificate of incorporation. Pursuant to our amended and restated certificate of incorporation and amended and restated bylaws, corporate actions can generally be taken by a majority of our board and/or stockholders holding a majority of our outstanding shares, except as otherwise indicated in the section entitled Anti-takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws, where certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws require the vote of at least 662/3% of our then outstanding voting securities. Additionally, our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a plurality of the votes cast at a meeting of stockholders will be able to elect all of the directors then standing for election.

Right to Receive Liquidation Distributions

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

Rights and Preferences

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

Fully Paid and Nonassessable

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

Description of Series A Preferred Stock Included in the Units

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

Our board of directors has designated shares of our preferred stock as Series A Preferred Stock, none of which are currently issued and outstanding. The preferences and rights of the Series A Preferred Stock will be as set forth in a Certificate of Designation (the Series A Certificate of Designation) filed as an exhibit to the registration statement of which this prospectus is a part.

In the event of a liquidation, the holders of Series A Preferred Stock are entitled to participate on an as-converted-to-Common Stock basis with holders of the Common Stock in any distribution of assets of the Company to the holders of the Common Stock. The Series A Certificate of Designation provides, among other things, that we shall not pay any dividends on shares of Common Stock (other than dividends in the form of Common Stock) unless and until such time as we pay dividends on each Series A Preferred Share on an as-converted basis. Other than as set forth in the previous sentence, the Series A Certificate of Designation provides that no other dividends shall be paid on Series A Preferred Stock and that we shall pay no dividends (other than dividends in the form of common stock) on shares of Common Stock unless we simultaneously comply with the previous sentence. The Series A Certificate of Designation does not provide for any restriction on the repurchase of Series A Preferred Stock by us while there is any arrearage in the payment of dividends on the Series A Preferred Stock. There are no sinking fund provisions applicable to the Series A Preferred Stock.

With certain exceptions, as described in the Series A Certificate of Designation, the Series A Preferred Stock has no voting rights. However, as long as any shares of Series A Preferred Stock remain outstanding, the Series A Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding Series A

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Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Series A Certificate of Designation, (b) increase the number of authorized shares of Series A Preferred Stock or (c) effect a stock split or reverse stock split of the Series A Preferred Stock or any like event.

Each share of Series A Preferred Stock is convertible at any time at the holder s option into a number of shares of common stock equal to $1,000 divided by the Series A Conversion Price. The Series A Conversion Price is initially $ and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series A Certificate of Designation further provides that we shall not effect any conversion of Series A Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series A 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 Common Stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise (the Preferred Stock Beneficial Ownership Limitation); provided, however, that upon notice to the Company, the holder may increase or decrease the Preferred Stock Beneficial Ownership Limitation, provided that in no event shall the Preferred Stock Beneficial Ownership Limitation exceed 9.99% and any increase in the Preferred Stock Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

No fractional shares of common stock will be issued upon conversion of Series A Preferred Stock. Rather, we shall, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the conversion price or round up to the next whole share.

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

Description of Warrants Included in the Units

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

Each Class A Unit includes a warrant to purchase shares of our common stock and each Class B Unit issued in this offering includes a warrant to purchase shares of our common stock at a price equal to $ per share at any time for up to five (5) years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised.

Subject to certain limitations as described below the warrants are immediately exercisable upon issuance on the closing date and expire on the five (5) year anniversary of the closing date. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder s affiliates, and any persons acting as a group together with such holder or any of such holder s affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise.

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

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Upon the holder s exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised through the cashless exercise provision). In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants.

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

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

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

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

We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

Exclusive Jurisdiction

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

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

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

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

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

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

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

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

Delaware Law

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

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

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

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

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

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

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

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

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

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

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

Transfer Agent and Registrar

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

Market Listing

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

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UNDERWRITING

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

Underwriters	Class A Units	Class B Units
Ladenburg Thalmann & Co. Inc.		
Total		

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the units directly to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may sell Class A Units or Class B Units separately to purchasers or may sell a combination of Class A Units and Class B Units to purchasers in any proportion. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $ per Class A Unit. The underwriters may allow and these selected dealers may re-allow a concession of not more than $ per Class A Unit to other brokers and dealers.

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

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

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

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

	Per Class A Unit(1)	Per Class B Unit(1)	Total
Public offering price			
Underwriting discount to be paid to the underwriters by us(2)			
Proceeds to us (before expenses)			

(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 $ and (ii) a public offering price per warrant of $ and (y) in respect of the Class B Units (i) a public offering price per share of Series A Preferred Stock of $ and (ii) a public offering price per warrant of $.

(2) We have granted a 45 day option to the underwriter to purchase up to additional shares of common stock and/or warrants to purchase 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 A Preferred Stock) and the number of shares of common stock underlying the warrants sold in the primary offering) at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions, solely to cover over-allotments, if any.

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We estimate the total expenses payable by us for this offering to be approximately $ which amount includes (i) the underwriting discount of $ ($ if the underwriters over-allotment option is exercised in full) and (ii) reimbursement of the accountable expenses of the representative equal to $ including the legal fees of the representative being paid by us and (iii) other estimated company expenses of approximately $ which includes legal accounting printing costs and various fees associated with the registration and listing of our shares.

Over-allotment Option

We have granted the representative an option, which is exercisable not later than 45 days after the date of this prospectus, to purchase a number of additional shares of common stock in an amount that is up to 15% of the number of shares of common stock sold in the primary offering (which number includes the number of shares of common stock issuable upon conversion of shares of the Series A Preferred Stock, but excludes any shares of common stock underlying the warrants issued in this offering, and any shares of common stock issued upon any exercise of the over-allotment option). These shares would be sold to the representative at the public offering price per share of common stock sold in the primary offering, less the underwriting discounts and commissions. Further, the option we have granted to the representative is also exercisable not later than 45 days after the date of this prospectus to purchase a number of additional warrants in an amount that is up to 15% of the warrants sold in the primary offering at the public offering price per warrant set forth on the cover page hereto, less the underwriting discounts and commissions. The representative may exercise the option to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased from us under this over-allotment option, the representative will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Our common stock is currently traded on The NASDAQ Global Market under the symbol AVGR. On January 10, 2018 the closing price of our common stock was $0.20 per share. We do not intend to apply for listing of the Series A Preferred Stock or warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the units were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;

- the previous experience of our executive officers; and

- the general condition of the securities markets at the time of this offering.

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

Lock-up Agreements

Our officers, directors and each of their respective affiliates and associated persons have agreed with the representative to be subject to a lock-up period of days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

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Other Relationships

Upon completion of this offering, we have granted the representative a right of first refusal to act as lead bookrunner, lead placement agent or financial advisor in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering;

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum; and

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker s bid that bid must then be

lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

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

Indemnification

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

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CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

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

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

- insurance companies;
- tax-exempt organizations;
- banks or other financial institutions;
- brokers or dealers in securities;
- regulated investment companies or mutual funds;
- pension plans;
- controlled foreign corporations;

- passive foreign investment companies;
- persons that own (directly, indirectly or constructively) more than 5% of our common stock;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- certain former citizens or long-term residents of the United States;
- persons that have a functional currency other than the U.S. dollar;
- persons that acquire our stock or warrants as compensation for services;
- owners that hold our stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes.

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

For purposes of this discussion, the term U.S. holder means a beneficial owner of our common stock, Series A Preferred Stock or warrants that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;

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

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

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

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

General

For U.S. federal income tax purposes, the purchase of a Class A Unit will be treated as the purchase of two components: a component consisting of shares of our common stock and a component consisting of a warrant to purchase shares of our common stock. The purchase of a Class B Unit will be treated as the purchase of two components: a component consisting of one share of our Series A Preferred Stock and a component consisting of warrants to purchase shares of our common stock. The purchase price for each Unit will be allocated between its components in proportion to the relative fair market value of each at the time the Unit is purchased by the holder. This allocation of the purchase price for each Unit will establish a holder s initial tax basis for U.S. federal income tax purposes in the shares and warrants that comprise each Unit.

U.S. Holders

Exercise of Warrants

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

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

commencing on the date following the date of exercise (or possibly the date of exercise) of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the warrant.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered warrants equal to the number of common shares having a value equal to the exercise price for the total number of warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the common stock represented by the warrants deemed surrendered and the U.S. holder s tax basis in the warrants deemed surrendered. In this case, a U.S. holder s tax basis in the common stock received would equal the sum of the fair market value of the common stock represented by the warrants deemed surrendered and the U.S. holder s tax basis in the warrants exercised. A U.S. holder s holding period for the common stock would commence on the date following the date of exercise (or possibly the date of exercise) of the warrant. Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

Certain Adjustments to the Warrants or Series A Preferred Stock

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant or conversion of a share of Series A Preferred Stock, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such

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adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants or conversion price of Series A Preferred Stock made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading Distributions on Common Stock or Series A Preferred Stock below.

Expiration of the Warrants without Exercise

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

Conversion of Series A Preferred Stock

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

Distributions on Common Stock or Series A Preferred Stock

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

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

Gain on Sale, Exchange or Other Taxable Disposition

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

Non-U.S. Holders

Distributions on Common Stock or Series A Preferred Stock

If we pay distributions of cash or property with respect to our common stock or Series A Preferred Stock (including constructive distributions as described above under the heading Certain Adjustments to the Warrants or Series A Preferred Stock), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder s investment, up to such holder s tax basis in its shares of our common stock or Series A Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading Gain on Sale, Exchange or Other Taxable Disposition. Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal

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income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder s country of residence. In the case of any constructive distribution, it is possible that this tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

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

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

Gain on Sale, Exchange or Other Taxable Disposition

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

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

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

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

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warrants should consult their tax advisors regarding whether such Series A Preferred Stock of warrants would constitute U.S. real property interests in the event that we have been, are or become a U.S. real property holding corporation.

Information Reporting and Backup Withholding

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

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

Foreign Account Tax Compliance Act

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

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

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LEGAL MATTERS

Certain legal matters relating to the issuance of the securities offered by this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati,