

Avinger Inc  
Form S-1/A  
February 12, 2018

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[INDEX TO FINANCIAL STATEMENTS](#)

[INDEX TO UNAUDITED FINANCIAL STATEMENTS](#)

[Table of Contents](#)

As filed with the Securities and Exchange Commission on February 12, 2018

Registration No. 333-222517

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

AMENDMENT NO. 2  
TO

**FORM S-1**

REGISTRATION STATEMENT

Under

The Securities Act of 1933

---

**AVINGER, INC.**

(Exact name of Registrant as specified in its charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)  
**400 Chesapeake Drive**  
**Redwood City, California 94063**  
**(650) 241-7900**

**20-8873453**  
(I.R.S. Employer  
Identification Number)

(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)

---

# Edgar Filing: Avinger Inc - Form S-1/A

**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.

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.

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.

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

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

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

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

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Series B Convertible Preferred Stock	\$15,000,000	\$1,867.50
Common Stock issuable upon conversion of Series B Convertible Preferred Stock(2)		
Warrants to purchase common stock(2)		
Common stock issuable upon exercise of Series 1 Warrants and Series 2 Warrants	\$29,948,400	\$3,728.58
<b>Total</b>	<b>\$44,948,400</b>	<b>\$5,596.08(3)</b>

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

## Edgar Filing: Avinger Inc - Form S-1/A

(3) The Registrant previously paid \$4,290.48 of the registration fee with the prior filing of this Registration Statement.

---

**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.**

---

Table of Contents

**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 February 12, 2018**

## **Avinger, Inc.**

### **15,000 Shares of Series B Convertible Preferred Stock (and 3,540,000 Shares of Common Stock Underlying the Series B Convertible Preferred Stock) Warrants to Purchase up to 7,080,000 Shares of Common Stock (and 7,080,000 Shares of Common Stock Issuable Upon Exercise of Warrants)**

---

We are offering 15,000 shares of Series B convertible preferred stock, and 7,080,000 warrants each exercisable for one share of our common stock, which number of warrants equals 200% of the number of shares of our common stock issuable upon conversion of the shares of Series B convertible preferred stock at the conversion price, at an exercise price per share equal to \$ . This prospectus also covers up to 3,540,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock and up to 7,080,000 shares of common stock issuable upon exercise of the warrants.

Each share of Series B convertible preferred stock will be sold with one warrant that expires on the seventh anniversary of the date of issuance to purchase up to 236 shares of common stock (referred to as "Series 1 warrants") and one warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee ("BTK") device (or the same or similar product with a different name) to purchase up to 236 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date (referred to as "Series 2 warrants"), and collectively will be sold, at the public offering price of \$1,000 per share of Series B convertible preferred stock. The shares of Series B convertible preferred stock and related warrants are immediately separable and will be issued separately. Subject to certain ownership limitations, the Series B convertible preferred stock is convertible at any time at the option of the holder into shares of our common stock at an initial assumed conversion price per share equal to \$4.23. Subject to certain ownership limitations, the warrants are immediately exercisable.

For a more detailed description of the Series B convertible preferred stock, see the section entitled "Description of Securities We Are Offering Preferred Stock" beginning on page 104. For a more detailed description of the warrants, see the section entitled "Description of Securities We Are Offering Series 1 and Series 2 Warrants Being Offered" beginning on page 106 of this prospectus. For a more detailed description of our common stock, see the section entitled "Description of Securities We Are Offering Common Stock" beginning on page 103 of this prospectus. We refer to the Series B convertible preferred stock issued hereunder, the warrants to purchase common stock issued hereunder and the shares of common stock issuable upon conversion of the Series B convertible preferred stock and upon exercise of the warrants issued hereunder, collectively, as the securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol "AVGR." On February 7, 2018, the last reported sales price of our common stock was \$4.23 per share. We do not intend to apply for listing of the warrants offered hereby or the shares of Series B Preferred Stock on any securities exchange or trading system. All share amounts in this prospectus are based on an assumed conversion price of \$4.23 per share of common stock, the last reported sales of our common stock on February 7, 2018.

---

**We are an "emerging growth company" as defined under the federal securities laws. Investing in our securities involves a high degree of risk. Please see the section entitled "Risk Factors" starting on page 13 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.

---

<b>Per Share of Series B Convertible Preferred Stock and Accompanying Warrants</b>	<b>Total</b>
--	--------------

Public Offering Price(1)

Underwriting Discount(2)

Proceeds, before expenses, to Avinger, Inc.

(1) The public offering price and underwriting discount corresponds to a public offering price per share of Series B Preferred Stock of \$ , a public offering price per Series 1 warrant of \$ (or \$ for Series 1 warrants to purchase 236 shares of common stock), and a public offering price per Series 2 warrant of \$ (or \$ for Series 2 warrants to purchase 236 shares of common stock).

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

---

**Ladenburg Thalmann**

The date of this prospectus is , 2018

---

Table of Contents

## TABLE OF CONTENTS

Section	Page
<u>Prospectus Summary</u>	<u>1</u>
<u>Risk Factors</u>	<u>13</u>
<u>Cautionary Notes Regarding Forward-Looking Statements</u>	<u>48</u>
<u>Market, Industry and Other Data</u>	<u>50</u>
<u>Use of Proceeds</u>	<u>50</u>
<u>Price Range of Our Common Stock and Dividend Policy</u>	<u>51</u>
<u>Capitalization</u>	<u>52</u>
<u>Dilution</u>	<u>54</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>56</u>
<u>Business</u>	<u>67</u>
<u>Management</u>	<u>85</u>
<u>Executive Compensation</u>	<u>95</u>
<u>Security Ownership of Certain Beneficial Owners and Management</u>	<u>101</u>
<u>Description of Securities We Are Offering</u>	<u>103</u>
<u>Underwriting</u>	<u>111</u>
<u>Certain Material U.S. Federal Income Tax Considerations</u>	<u>114</u>
<u>Legal Matters</u>	<u>120</u>
<u>Experts</u>	<u>120</u>
<u>Where You Can Find More Information</u>	<u>120</u>

---

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.

Table of Contents

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

Table of Contents

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
<b>NEXT GENERATION PRODUCTS</b>			
<b>Pantheris 3.0</b>	Atherectomy	FDA 510(k) submitted	
<b>Pantheris BTK</b>	Atherectomy	FDA 510(k) planned	
<b>PRODUCTS</b>			
<b>Lightbox(1)</b>	OCT Imaging	FDA Cleared CE Mark	November 2012 September 2011
<b>Pantheris 8F</b>	Atherectomy	FDA Cleared CE Mark	October 2015 June 2015
<b>Pantheris 7F</b>	Atherectomy	FDA Cleared CE Mark	March 2016 June 2015
<b>Ocelot(2)</b>	CTO Crossing	FDA Cleared CE Mark	November 2012 September 2011
<b>Ocelot MVRX(2)</b>	CTO Crossing	FDA Cleared	December 2012
<b>Ocelot PIXL(2)</b>	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



Table of Contents

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 ("BTK") applications. We filed a 510(k) submission for Pantheris 3.0 in December 2017, and we plan to make a 510(k) submission for Pantheris BTK in mid-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.

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**

**CRG Debt Conversion**

Concurrently with the pricing of this offering, we expect to enter into an agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG") pursuant to which CRG will agree to convert \$38.0 million of the outstanding principal amount of the senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock (the "Series A preferred stock"), which would be convertible into our common stock at a price per share equal to the lower of (a) the closing price of our common stock on date of the entry into the underwriting agreement for this offering and (b) the initial Series B preferred stock conversion price. Such conversion of debt (the "CRG Conversion") would be contingent upon the closing of this offering with at least \$12 million in gross equity proceeds (the "Offering").

Under the terms of such agreement, the holders of the Series A preferred stock would be entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at our option. The shares of Series A preferred stock would have no voting rights and would rank senior to all other classes and series of our equity in terms of repayment and certain other rights. The Series A preferred stock and any of our common stock issued upon conversion of the Series A preferred stock would be subject to a lockup agreement for one year following the date of the underwriting agreement for this offering. We may be required to file a resale registration statement for the shares of common stock issuable upon the conversion of the Series A preferred stock (the "Conversion Shares") at the request of CRG at any time after 90 days of the CRG Conversion. In

Table of Contents

addition, the issuance of Conversion Shares would be subject to shareholder approval if and to the extent they exceed 19.99% of our pre-transaction outstanding common stock. The summary of terms of the Series A preferred stock above is qualified in its entirety by the Certificate of Designation of Series A preferred stock (the "Series A Certificate of Designation") and the related registration rights agreement. Please refer to the Series A Certificate of Designation and the related registration rights agreement for more information on the preferences, rights and limitations of Series A preferred stock, which certificate and agreement are filed as exhibits to the registration statement of which this prospectus forms a part.

In connection with the CRG Conversion, we expect that certain terms in the Term Loan Agreement we had entered into with CRG on September 22, 2015 (the "Loan Agreement") will be amended. The cash payments for interest due on the remaining amount of CRG debt under the Loan Agreement for an additional two year period could be deferred, and we could instead pay the 12.5% interest in the form of payment in kind ("PIK") loans. The interest-only period under the Loan Agreement would be extended to June 30, 2021, and the maturity date of the debt under the Loan Agreement would be extended to June 30, 2023.

**2017 Financial Information**

The preliminary 2017 financial information included in this prospectus supplement reflects management's estimates based solely upon information available to us as of the date of this submission and is the responsibility of management. The preliminary financial results presented below are not a comprehensive statement of our financial results for fiscal year 2017. In addition, the preliminary financial results presented above have not been audited, reviewed, or compiled by our independent registered public accountant. Based on our preliminary, unaudited results, we estimate that (i) our total revenue will be within a range of \$9.8 million to \$9.9 million for the year ended December 31, 2017, as compared to \$19.2 million for the year ended December 31, 2016, (ii) our cash and cash equivalents as of December 31, 2017 were \$5.4 million, as compared to \$36.1 million at December 31, 2016 and \$10.2 million as of September 30, 2017.

**Reverse Stock Split**

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

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 Equity 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 our employees, consultants and directors, including our current officers and directors. The amount of such increase has not been determined, but could equal up to

Table of Contents

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

**Nasdaq Compliance**

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.

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 requested 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 we have 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. On January 17, 2018, we received formal notification from Nasdaq that the Panel had determined to grant the Company's request for the transfer of its listing from the Nasdaq Global Market to the Nasdaq Capital Market, pursuant to an

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

extension through March 31, 2018 to evidence compliance with all applicable requirements for continued listing on Nasdaq. We are taking definitive steps to timely evidence compliance with the terms of the Panel's decision.

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 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;

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;

## Edgar Filing: Avinger Inc - Form S-1/A

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;

Table of Contents

The Series B 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.

**Company Information**

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

"Avinger," "Pantheris" and "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 \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We may choose to take advantage of some but not all of these reduced burdens. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

**Available Information**

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

The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

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

Table of Contents

**THE OFFERING**

Securities offered by us	We are offering 15,000 shares of Series B convertible preferred stock. Each share will be accompanied by (a) Series 1 warrants to purchase a number of shares of common stock equal to 100% of the shares of common stock initially issuable upon conversion of the Series B convertible preferred stock, as described below, and (b) Series 2 warrants to purchase a number of shares of common stock equal to 100% of the shares of common stock initially issuable upon conversion of the Series B convertible preferred stock, as described below. This prospectus also relates to the offering of the shares of common stock issuable upon conversion of the Series B convertible preferred stock and exercise of the Series 1 warrants and Series 2 warrants.
Description of Series B preferred stock	The Series B preferred stock has a liquidation preference of \$0.001 per share, full ratchet price based anti-dilution protection, and is subject to certain ownership limitations. See the section entitled "Description of Securities We Are Offering Preferred Stock" beginning on page 104. This prospectus also relates to the offering of shares of common stock issuable upon conversion of the Series B preferred stock at its initial conversion price.
Conversion of Series B preferred stock	\$4.23 per share (subject to adjustment as described in this prospectus). Until the volume weighted average price of our common stock exceeds 300% of the conversion price of the Series B preferred stock for any 30 consecutive trading days and the daily dollar trading volume for each trading day during such period exceeds \$500,000 per trading day, the Series B preferred stock has full ratchet price based antidilution protection, subject to customary carve-outs, in the event of a down-round financing below the Series B conversion price.
Shares of common stock underlying the Series B preferred stock	3,540,000 (Based on an assumed Series B preferred stock conversion price of \$4.23 per share, which was the closing price of our common stock on the Nasdaq Capital Market on February 7, 2018.)



Table of Contents

<p>Limitations on beneficial ownership</p>	<p>Notwithstanding anything herein to the contrary, no holder will be permitted to convert its Series B preferred stock or exercise its warrants if, after such conversion or exercise, such holder would beneficially own more than 4.99% of the shares of common stock then outstanding or, upon election by a holder prior to the issuance of any shares of Series B preferred stock, 9.99%; provided, however, that upon notice to the Company, a holder may increase or decrease its beneficial ownership limitation, provided that in no event shall the beneficial ownership limitation exceed 9.99% and any increase in the beneficial ownership limitation will not be effective until 61 days following notice of such increase from the holder to us.</p>
<p>Series 1 warrants</p>	<p>The Series 1 warrants will be exercisable beginning on the date of issuance and expire on the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to _____, 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.</p>
<p>Series 2 warrants</p>	<p>The Series 2 warrants will be exercisable beginning on the date of issuance and expire on the earlier of (1) the 60th calendar day following the receipt and announcement of FDA clearance to market our Pantheris BTK device (or the same or similar product with a different name), and (2) the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to _____, 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.</p>
<p>Shares of common stock underlying the warrants</p>	<p>The Series 1 warrants and the Series 2 warrants are collectively referred to as the "warrants." The forms of warrant are filed as an exhibit to the registration statement of which this prospectus forms a part.</p>
<p>Shares of common stock outstanding before this offering</p>	<p>7,080,000 shares.</p>
<p>Shares of common stock outstanding after this offering</p>	<p>788,575 shares as of September 30, 2017.</p>
<p>Shares of Series B Preferred Stock outstanding before this offering</p>	<p>788,575 shares (4,328,575 shares on an as-converted basis, assuming the conversion of the Series B Preferred Stock).</p>
<p>Shares of Series B Preferred Stock outstanding after this offering</p>	<p>None.</p>
	<p>15,000 shares.</p>

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

#### Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately \$13.3 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. We may also use a portion of the net proceeds from this offering in order to resolve legal proceedings that are more fully described in the section of this prospectus titled "Business Legal Proceedings," in an amount not to exceed \$1.6 million. See "Use of Proceeds" on page 50 of this prospectus.

#### Risk Factors

You should carefully read and consider the information set forth under "Risk Factors" on page 13 of this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.

#### NASDAQ Capital Market symbol

"AVGR".

#### No listing of Series B Preferred Stock or warrants

We do not intend to apply for listing of the shares of the Series B preferred stock or warrants on any securities exchange or trading system.

The number of shares of common stock that will be outstanding after this offering is based on 788,575 shares outstanding as of September 30, 2017, and excludes:

91,939 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of \$303.76 per share;

53,715 shares of common stock issuable upon exercise of outstanding warrants;

43,041 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;

19,095 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 23,584 Shares we issued as a commitment fee to Lincoln Park in November 2017 and 65,000 Shares we have sold to date under the Purchase Agreement;

shares of common stock issuable upon conversion or exercise, as the case may be, of the Series B Preferred Stock and warrants in this offering; and

shares of Series A Preferred Stock and the common stock issuable upon conversion of the Series A Preferred Stock issued to CRG in connection with the CRG Conversion.

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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

a 1-for- 40 reverse stock split of our common stock, which became effective as of January 30, 2018;

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

no exercise of options or warrants outstanding as of the date of this prospectus.

Table of Contents

**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;

## Edgar Filing: Avinger Inc - Form S-1/A

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 2017 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*

Table of Contents

*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.

***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 Lumivasular platform and acquire customers.

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

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

We believe that the net proceeds from this offering, together with 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 Series B preferred stock and warrants in this offering, we will need to raise additional funds through future equity or debt financings in approximately 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 Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park is obligated to purchase, at our request, up to \$15.0 million of our common stock over a 30-month period, subject to certain limitations set forth in the Purchase Agreement. The underwriting agreement we will enter into with the underwriters in connection with this offering prohibits entering into variable rate transactions for a period of one year from the closing date of this offering, which would prohibit any additional purchases under the Purchase Agreement during that time. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivasular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

(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;

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;



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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

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

restrict us from exploiting business opportunities;

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

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

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

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

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

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

incur or assume liens;

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

issue redeemable stock and preferred stock;

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

make loans, investments or acquisitions;

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

enter into certain transactions with affiliates;

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

## Edgar Filing: Avinger Inc - Form S-1/A

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

In particular, the Loan Agreement, as amended, includes a covenant that we maintain a minimum of \$3.5 million of cash and certain cash equivalents, and we 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 \$15.0 million in 2020, \$20.0 million in 2021 and \$25.0 million in 2022. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. 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. On January 24, 2018, we entered into another waiver

Table of Contents

agreement (the "Waiver") with CRG and certain of its affiliated funds, as lenders for the waiver of the \$5.0 million minimum liquidity financial covenant and reduced it to \$2.5 million for the period beginning January 1, 2018 through February 28, 2018, and waived any event of default resulting from non-compliance with the \$5.0 million minimum liquidity financial covenant. 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 remains in effect. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The existing collateral pledged under the Loan Agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. If we default under any of these debt covenants, we would need relief from default, which may involve waivers or amendments to the applicable debt agreement, if we were unable to cure the default within the relevant cure period. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

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

On February 1, 2018, we entered into an agreement with CRG to convert a total of \$38 million of the outstanding principal amount of our debt into shares of our to-be-designated Series A convertible preferred stock, par value \$0.001 per share ("Series A preferred stock"), with such conversion being contingent upon completion of this offering ("CRG Conversion"). After the CRG Conversion, we will have approximately \$6.6 million in outstanding debt under the Loan Agreement. Borrowings under our credit facility are secured by substantially all of our personal property, including our intellectual property. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected

Table of Contents

financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated. If we fail to comply with our obligations under the Loan Agreement, the lender would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets securing our obligations under the Loan Agreement. In addition, certain events of default have already occurred with CRG in 2017 and we cannot assure you similar future events of default will not occur under the Loan Agreement.

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

Upon completion of CRG Conversion, entities affiliated with CRG will beneficially own approximately 4.99% of our outstanding common stock, including shares of our to-be-designated Series A preferred stock, which are convertible into common stock, but excluding any shares of common stock that they may purchase in this offering. Even though Series A preferred stock is non-voting stock, and has beneficial ownership restrictions, the Series A Certificate of Designations has protective provisions that will require CRG consent to perform certain significant company events. For example, CRG's consent would be necessary to create additional shares of Series A Preferred Stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock. CRG may have interests different than yours. For example, CRG may want us to pursue strategies that deviate from the interests of other stockholders.

***The Series A preferred stock that will be issued upon completion of the CRG Conversion would have a liquidation preference to our common stock and the Series B preferred stock issued in this offering.***

Upon completion of the CRG Conversion, CRG will receive shares of Series A preferred stock. Series A preferred stock has a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of the Series 1 or Series 2 warrants) and Series B preferred stock issued in this offering. As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately \$41,800,000 from any such transaction before any amount is paid to the holders of our Series B preferred stock or common stock or pursuant to the redemption rights in the warrants for fundamental transactions. The payment of the liquidation preferences could result in common stockholders, Series B preferred stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

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

Table of Contents

***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-Lumivasular platform products in 2009 and introduced our first Lumivasular 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 Lumivasular platform products we intend to commercialize in the United States. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivasular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of Pantheris and our other current and future Lumivasular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivasular platform products by the medical community. All of our products have a limited

Table of Contents

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

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

Table of Contents

***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.

***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.

Table of Contents

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

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

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

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

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



Table of Contents

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,

Table of Contents

many of our competitors expend a considerably greater amount of funds on their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to our competitors' research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

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

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

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

procedural safety and efficacy;

acute and long-term outcomes;

ease of use and procedure time;

price;

size and effectiveness of sales force;

radiation exposure for physicians, hospital staff and patients; and

third-party reimbursement.

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

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

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more and failure of the trial can



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

occur at any time. We cannot provide any assurance that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities. Even if we achieve positive early or preliminary results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not indicate success in later trials. Many companies in the medical device industry have suffered significant setbacks in late-stage clinical trials, even after receiving promising results in earlier trials or in the preliminary results from these late-stage clinical trials.

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

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

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

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

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

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

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

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

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

trouble in managing multiple clinical sites;

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

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

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

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

## Edgar Filing: Avinger Inc - Form S-1/A

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

Table of Contents

regulations and standards, commonly referred to as good clinical practices. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances that we need to commercialize our products.

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

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

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

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

Our current products are cleared in the United States only for crossing sub-total and chronic total occlusions and for performing atherectomy in the peripheral vasculature. These clearances prohibit our ability to market or advertise our products for any other indication within the peripheral vasculature, which restricts our ability to sell these products and could affect our growth. Additionally, our products are contraindicated for use in the cerebral, carotid, coronary, iliac, and renal arteries. While off-label

Table of Contents

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

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

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

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

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

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

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

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

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

If we are unable to keep up with demand for our Lumivasular platform products, our revenues could be impaired, market acceptance for our Lumivasular platform products could be harmed and

Table of Contents

our customers might instead purchase our competitors' products. Our inability to successfully manufacture our Lumivasular platform products would materially harm our business.

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

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

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

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

We currently manufacture some of our components and sub-assemblies at our Redwood City facility and rely on third-party vendors for other components and sub-assemblies used in our Lumivasular 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;



Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

As of December 31, 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 Series B preferred stock and warrants 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

Table of Contents

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

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

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

**Risks Related to Our Intellectual Property**

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

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

Table of Contents

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.

***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

Table of Contents

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.

Table of Contents

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

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

product design, development and manufacture;

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

premarketing clearance or approval;

record keeping;

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

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

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

Table of Contents

we may be subject to enforcement actions, including Warning Letters, adverse publicity, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

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

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

operating restrictions, partial suspension or total shutdown of production;

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

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

criminal prosecution.

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

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

Material modifications to the intended use or technological characteristics of our Lumivasular 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 Lumivasular 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 Lumivasular 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 Lumivasular platform products as modified, which could harm our operating results and require us to redesign our Lumivasular 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 Lumivasular 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 Lumivasular 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

Table of Contents

records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenues to decline.

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

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

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

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

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



Table of Contents

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

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

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

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

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

the availability of capital.

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

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

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

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

Table of Contents

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

Table of Contents

regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

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

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

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

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

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

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

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

market acceptance of our 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;

## Edgar Filing: Avinger Inc - Form S-1/A

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;

Table of Contents

legislation or regulation of our business;

lawsuits threatened or filed against us;

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

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

developments in our industry.

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

Our stock price has decreased significantly over the course of the past year and we are currently defending against a 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. The analysts who previously published research reports on our stock have discontinued coverage. If one or more of these analysts do not resume regularly publishing reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

Table of Contents

***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 0.2 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 0.2 million shares of our common stock in our follow-on public offering at a public offering price of \$140.00 per share, for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately \$0.6 million. We have established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Shelf Registration Statement. During the year ended December 31, 2016, we sold 27,374 shares of common stock under our "at-the-market" program with Cowen at an average price of \$194.74 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the nine months ended September 30, 2017, we sold 0.2 million shares of common stock through the "at-the-market" program at an average price of \$17.68 and raised net proceeds of \$3.2 million, after payment of \$0.1 million in commissions and fees to Cowen. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are unable to issue more shares in our "at-the-market" program at this time. 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 8,705 shares of common stock held by CRG, which may be sold freely in the public market. On November 3, 2017, we also entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park is obligated to purchase, at our request, up to \$15.0 million of our common stock over a 30-month period, subject to certain limitations set forth in the Purchase Agreement. The underwriting agreement we will enter into with the underwriters in connection with this offering prohibits entering into variable rate transactions for a period of one year from the closing date of this offering, which would prohibit any additional purchases under the Purchase Agreement during that time. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Sales of newly issued securities under any registration statement will result in dilution of our stockholders and could cause our stock price to fall.

Table of Contents

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

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

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

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

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and

Table of Contents

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 \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

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



Table of Contents

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. 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 did not regain compliance with these rules in the time allotted to us, 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 date in January 2018. At the hearing we presented our plan to evidence compliance with all applicable requirements for continued listing on Nasdaq, requested a transfer of our listing to the Nasdaq Capital Market and requested additional time to regain compliance with all applicable Nasdaq listing criteria. On January 17, 2018, the Nasdaq Hearings Panel granted our request. The terms of this relief require that, by March 31, 2018, we:

achieve a closing bid price of \$1.00 or more for a minimum of ten consecutive trading days;

effect a conversion of part of our debt with CRG into preferred equity;

issue disclosure that our stockholders' equity is above \$2.5 million; and

provide Nasdaq with updated financial projections demonstrating our ability to maintain compliance through the end of fiscal year 2018.

We are diligently working to evidence compliance with all applicable Nasdaq listing criteria; however, there can be no assurance that we will be able to achieve all elements of our compliance plan or that we will be able to satisfy the applicable requirements within the timeframe provided by the Panel. If we do not regain compliance with the Nasdaq listing requirements 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;

Table of Contents

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

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

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

allowing stockholders to remove directors only for cause;

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

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

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

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

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

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

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

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

Table of Contents

***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. The terms of the Series A Preferred will also limit our ability to pay dividends.

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

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

The Series 1 warrants will be exercisable for seven years from the closing date, and the Series 2 warrants will be exercisable until the earlier of (1) the 60th calendar day following the receipt and announcement of FDA clearance to market our Pantheris BTK product candidate (or the same or similar product with a different name) and (2) the seven (7) year anniversary of the date of issuance at an initial exercise price per share 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.

***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.

Table of Contents

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

Since the effective price per share of common stock or issuable upon exercise of the warrants, conversion of the Series B Preferred Stock being offered or conversion of the Series A Preferred Stock being issued to CRG in connection with the CRG Conversion 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 issuable upon the exercise of the warrants, or the conversion of the Series B Preferred Stock issued in this offering or conversion of the Series A Preferred Stock issued to CRG in connection with the CRG Conversion. See the section titled, "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase preferred stock and warrants in this offering. Furthermore, the Series B Preferred Stock issued in this offering has full ratchet price based anti-dilution protection, subject to customary carve outs, in the event of a down-round financing at a price per share below the conversion price of the Series B Preferred Stock. If this anti-dilution protection is triggered, it could result in additional dilution to holders of common stock.

As a result of the dilution to investors purchasing Series B preferred stock and warrants 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.

Table of Contents

**CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS**

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

the outcome of and expectations regarding our current clinical studies and any additional clinical studies we initiate;

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

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

the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;

the expected growth in our business and our organization;

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

our ability to continue as a going concern;

our ability to remain in compliance with the listing requirements of the Nasdaq Capital Market;

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

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

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

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

## Edgar Filing: Avinger Inc - Form S-1/A

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;

Table of Contents

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.

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

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

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

Table of Contents

**MARKET, INDUSTRY AND OTHER DATA**

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

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

**USE OF PROCEEDS**

We estimate that the net proceeds from this offering will be approximately \$13.3 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 B 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 Lumivasular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. We may also use a portion of the net proceeds from this offering in order to resolve legal proceedings that are more fully described in the section of this prospectus titled "Business Legal Proceedings," in an amount not to exceed \$1.6 million. 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.



Table of Contents**PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY**

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

	Low	High
<b>Fiscal Year ending December 31, 2015</b>		
First Quarter (beginning January 30, 2015)	\$ 400.00	\$ 532.80
Second Quarter	\$ 420.00	\$ 526.00
Third Quarter	\$ 500.80	\$ 658.00
Fourth Quarter	\$ 586.80	\$ 990.00
<b>Fiscal Year ending December 31, 2016</b>		
First Quarter	\$ 340.40	\$ 818.40
Second Quarter	\$ 396.80	\$ 548.80
Third Quarter	\$ 146.40	\$ 479.60
Fourth Quarter	\$ 140.00	\$ 202.00
<b>Fiscal Year ending December 31, 2017</b>		
First Quarter	\$ 64.00	\$ 146.40
Second Quarter	\$ 14.40	\$ 67.20
Third Quarter	\$ 8.80	\$ 38.40
Fourth Quarter	\$ 6.80	\$ 16.40

As of February 7, 2018, the last reported sale price of our common stock on the Nasdaq Capital Market was \$4.23.

As of December 31, 2017, there were 833,409 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. The terms of the Series A Preferred Stock will also limit our ability to pay dividends.

Table of Contents**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 Series B preferred stock and warrants in this offering, the application of the net proceeds of this offering, and the conversion of a total of \$38.0 million of the outstanding principal amount of our CRG debt into shares of our to-be-designated Series A convertible preferred stock, 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 this prospectus. The capitalization information discussed below is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing.

	<b>Actual</b>	<b>Pro Forma As Adjusted</b>
Cash and cash equivalents	\$ 10,170	\$ 23,495
Borrowings	\$ 43,112	\$ 5,112
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding, actual; 5,000,000 shares authorized, 56,800 shares issued and outstanding, pro forma as adjusted		
Common stock, \$0.001 par value; 100,000,000 shares authorized, 788,575 shares issued and outstanding, actual and pro forma as adjusted	1	1
Additional paid-in capital	264,465	319,590
Accumulated deficit	(291,177)	(294,977)
Total stockholders' equity (deficit)	(26,711)	24,614
Total capitalization	\$ 16,401	\$ 29,726

The number of shares of common stock that will be outstanding after this offering is based on 788,575 shares outstanding as of September 30, 2017, and excludes:

91,939 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of \$303.76 per share;

53,715 shares of common stock issuable upon exercise of outstanding warrants;

43,041 shares of common stock reserved for future issuance under our 2015 Plan, and any additional shares that become available under our 2015 Plan pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

## Edgar Filing: Avinger Inc - Form S-1/A

19,095 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 23,584 Shares we issued to Lincoln Park as a commitment fee in November 2017 and 65,000 Shares we have sold to date under the Purchase Agreement;

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

shares of common stock issuable upon conversion or exercise, as the case may be, of the Series B Preferred Stock and warrants; and

shares of Series A Preferred Stock and the common stock issuable upon conversion of the Series A Preferred Stock issued to CRG in connection with the CRG Conversion.

Table of Contents**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 \$(33.87) per share of common stock, based on 788,575 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 (i) our sale in this offering of 15,000 shares of Series B preferred stock, including the 10,620,000 shares of common stock that the Series B Preferred Stock and the warrants to be issued in connection therewith will be convertible into, at a public offering price of \$4.23 per share, and (ii) the conversion of \$38.0 million of our outstanding CRG debt and related obligations into an aggregate of 41,800 shares of newly designated Series A Preferred Stock after the closing of this offering, which shares shall be convertible into 40,214,400 shares of common stock, 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 \$24.6 million, or \$0.60 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$34.47 per share and an immediate dilution of \$3.63 per share to the new investors purchasing securities in this offering. The dilution information discussed below is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing. The following table illustrates this dilution:

Assumed public offering price per share		\$ 4.23
Net tangible book value per share as of September 30, 2017	\$ (33.87)	
Increase in net tangible book value per share attributable to new investors in this offering	\$ 34.47	
Pro forma net tangible book value per share after the offering		\$ 0.60
<b>Dilution per share to investors in this offering</b>		<b>\$ 3.63</b>

The above discussion and table are based on 788,575 shares outstanding as of September 30, 2017, and excludes:

91,939 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2017 with a weighted average exercise price of \$303.76 per share;

53,715 shares of common stock issuable upon exercise of outstanding warrants;

43,041 shares of common stock reserved for future issuance under our 2015 Plan, and any additional shares that become available under our 2015 Plan pursuant to provisions thereof that automatically increase the share reserve under the plan each year;

19,095 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 23,584 Shares we issued to Lincoln Park as a commitment fee in November 2017 and 65,000 Shares we have sold to date under the Purchase Agreement; and

shares of common stock issuable upon conversion or exercise, as the case may be, of the Series B Preferred Stock and warrants.



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

shares of Series A Preferred Stock and the common stock issuable upon conversion of the Series A Preferred Stock issued to CRG in connection with the CRG Conversion.

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.

Table of Contents

**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this prospectus entitled "Risk Factors."*

**Overview**

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

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

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians because they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our



Table of Contents

customers, as they typically are responsible for purchasing our products. We are designing future products to be compatible with our Lumivasular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. Pantheris qualifies for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

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

In addition to commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivasular platform products in 2009 and introduced our Lumivasular platform products in the United States in late 2012. We generated revenues of \$8.0 million in the nine months ended September 30, 2017 and \$14.5 million in the nine months ended September 30, 2016. During the nine months ended September 30, 2017 and 2016, our net loss was \$38.6 million and \$42.6 million, respectively. We have not been profitable since inception, and as of September 30, 2017, our accumulated deficit was \$291.2 million. Since inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering, or IPO, of 125,000 shares. As a result of our IPO, which closed in February 2015, we received net proceeds of approximately \$56.9 million, after underwriting discounts and commissions of approximately \$4.5 million and other expenses associated with our IPO of approximately \$3.6 million.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we were able to borrow up to \$50.0 million on or before March 29, 2017, subject to certain terms and conditions. We borrowed \$30.0 million on September 22, 2015 and an additional \$10.0 million on June 15, 2016 under the Loan Agreement. Contingent on achievement of certain revenue milestones, among other conditions, we would have been eligible to borrow an additional \$10.0 million, on or prior to March 29, 2017; however, we did not achieve the level of revenues required to borrow the final \$10.0 million. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 8,705 shares of our common stock on September 22, 2015 at a price of \$559.64 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to \$150.0 million of our securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, we sold 27,374 shares of common stock through the "at-the-market" program at an average price of \$194.74 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the three and nine months ended September 30, 2017, we sold 189,684 shares of common stock through the "at-the-market" program at an average price of \$17.68 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

Table of Contents

shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, at this time we are unable to issue more shares through our "at-the-market" program. In addition, in August 2016 we completed a follow-on public offering of 246,445 shares of our common stock for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately \$0.6 million. The 246,445 shares include the exercise in full by the underwriters of their option to purchase an additional 32,145 shares of our common stock.

On November 3, 2017, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or 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. As a fee for Lincoln Park's commitment to purchase such shares, we issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Purchase Agreement, we filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 17, 2017. To the extent more than 248,750 shares of our common stock are issued to Lincoln Park pursuant to the Purchase Agreement, we are obligated to file additional registration statements for the resale of such shares.

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

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

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant

Table of Contents

and material changes in our critical accounting policies during the three months ended September 30, 2017, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations Critical accounting policies and significant judgments and estimates" in our most recent Annual Report on Form 10-K, as filed with the SEC on March 14, 2017.

**Components of Our Results of Operations**

***Revenues***

All of our revenues are currently derived from sales of our Lightbox console and sales of our various PAD catheters, as well as related services in the United States and select international markets. We expect the continued product performance issues with the current version of Pantheris as well as our strategic decision to reduce the size of our sales force in April 2017 and September 2017 to continue to adversely impact our revenues in the near term. However, we expect our revenues to increase in 2018 as we introduce new Lumivascular platform products including new versions of Pantheris. One and no single customer accounted for more than 10% of our revenues during the three months ended September 30, 2017 and 2016, respectively. No single customer accounted for more than 10% of our revenues during the nine months ended September 30, 2017 and 2016.

Revenues may fluctuate from quarter to quarter due to a variety of factors including capital equipment purchasing patterns that are typically increased towards the end of the calendar year and decreased in the first quarter. In addition, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients.

***Cost of Revenues and Gross Margin***

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases following the commercial launch of our next-generation Pantheris catheters in 2018. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for placed Lightboxes held by customers and certain direct costs such as those incurred for shipping our products.

We calculate gross margin as gross profit divided by revenues. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, manufacturing costs, product yields, headcount, charges for excess and obsolete inventories and cost-reduction strategies. We expect our gross margin to increase over the long term as our production volume increases and as we spread the fixed portion of our manufacturing overhead costs over a larger number of units produced, thereby reducing our per unit manufacturing costs. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. In the future, we may seek to manufacture certain of our products outside the United States to further reduce costs. Our gross margin will likely fluctuate from quarter to quarter as we continue to introduce new products and sales channels, and as we adopt new manufacturing processes and technologies.

Table of Contents**Research and Development Expenses**

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical and regulatory affairs, consulting services, materials, depreciation and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, quality assurance expenses allocated to R&D programs, consulting, related travel expenses and facilities expenses. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of manufacturing products for clinical trials. We expect R&D expenses as a percentage of revenues to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

**Selling, General and Administrative Expenses**

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to remain decreased in the near term compared to recent prior quarters due to our reductions in force in April and September 2017.

**Interest Income (Expense), net**

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our various debt agreements.

**Other Income (Expense), net**

Other income (expense), net primarily consisted of gains and losses resulting from the remeasurement of foreign exchange transactions.

**Results of Operations:**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ 2,071	\$ 5,316	\$ 8,021	\$ 14,535
Cost of revenues	3,274	3,742	11,268	10,747
Gross profit	(1,203)	1,574	(3,247)	3,788
Gross margin	58%	30%	40%	26%
Operating expenses:				
Research and development	2,322	3,591	9,342	11,505
Selling, general and administrative	4,928	9,414	20,435	31,036
Restructuring	416		935	
Total operating expenses	7,666	13,005	30,712	42,541
Loss from operations	(8,869)	(11,431)	(33,959)	(38,753)
Interest income (expense), net	(1,574)	(1,526)	(4,632)	(3,871)
Other income (expense), net		(12)	9	(7)
Net loss and comprehensive loss	\$ (10,443)	\$ (12,969)	\$ (38,582)	\$ (42,631)

Table of Contents

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

*Revenues.* Revenues decreased \$3.2 million, or 61%, to \$2.1 million during the three months ended September 30, 2017, compared to \$5.3 million during the three months ended September 30, 2016. For the three months ended September 30, 2017, revenues related to sales of our disposable catheters decreased by 56% to \$1.7 million while revenues related to our Lightbox imaging consoles decreased by 71% to \$0.4 million. The decreased revenues in the three months ended September 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris and the reduced size of our field sales force, as well as a strategic decision we made at the beginning of the year to realign the focus of our sales force on driving the utilization at our current installed base rather than on building the installed base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

*Cost of Revenues and Gross Margin.* Cost of revenues decreased \$0.4 million, or 13%, to \$3.3 million during the three months ended September 30, 2017, compared to \$3.7 million during the three months ended September 30, 2016. This decrease was primarily attributable to our decreased sales partially offset by a \$1.6 million charge in the three months ended September 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories. Gross margin for the three months ended September 30, 2017 decreased to 58%, compared to 30% in the three months ended September 30, 2016. Gross margin was negatively impacted primarily by an increase of \$1.4 million in the charge for inventory excess and obsolescence in the three months ended September 30, 2017 compared to the prior year period, partially offset by a decrease of \$0.3 million in warranty expenses.

*Research and Development Expenses.* R&D expenses decreased \$1.3 million, or 35%, to \$2.3 million during the three months ended September 30, 2017, compared to \$3.6 million during the three months ended September 30, 2016. This decrease was primarily due to a \$0.9 million decrease in personnel-related expenses, a decrease of \$0.2 million in product development materials and related costs, a decrease of \$0.1 million in outside services and a decrease of \$0.1 million relating to the allocation of facilities expense. Personnel-related expenses included stock-based compensation expense of \$0.5 million compared to \$0.6 million for the three months ended September 30, 2017 and 2016, respectively.

*Selling, General and Administrative Expenses.* SG&A expenses decreased \$4.5 million, or 48%, to \$4.9 million during the three months ended September 30, 2017, compared to \$9.4 million during the three months ended September 30, 2016. This decrease was primarily due to a \$4.1 million decrease in personnel-related expenses, a decrease of \$0.3 million in marketing costs, a decrease of \$0.2 million in outside services, partially offset by an increase of \$0.2 million relating to the allocation of facilities expense. Personnel-related expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. For the three months ended September 30, 2017, our marketing costs decreased as a result of our workforce reduction and efforts to reduce operating expenses. Personnel-related expenses included stock-based compensation expense of \$0.7 million compared to \$0.9 million for the three months ended September 30, 2017 and 2016, respectively.

*Restructuring.* In September 2017, we effected a cost reduction plan, which included a company-wide reduction in force, lowering our total headcount by 24 employees. We recorded a restructuring charge at that time of approximately \$0.4 million, which consisted of severance related costs specific to the termination of 24 employees. As of September 30, 2017, \$55,000 of the total severance related costs had been paid. We expect the remaining \$0.4 million in severance costs to be paid by December 31, 2017.

Table of Contents

*Interest Income (Expense), Net.* Interest expense, net increased \$0.1 million, or 3%, to an expense of \$1.6 million during the three months ended September 30, 2017, compared to an expense of \$1.5 million during the three months ended September 30, 2016.

*Other Income (Expense), Net.* Other income, net was none during the three months ended September 30, 2017, compared to an expense of \$12,000 during the three months ended September 30, 2016. Other income for the three months ended September 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

***Comparison of Nine Months Ended September 30, 2017 and 2016***

*Revenues.* Revenues decreased \$6.5 million, or 45%, to \$8.0 million during the nine months ended September 30, 2017, compared to \$14.5 million during the nine months ended September 30, 2016. For the nine months ended September 30, 2017, revenues related to sales of our disposable catheters decreased by 39% to \$6.6 million while revenues related to our Lightbox imaging consoles decreased by 61% to \$1.4 million. The decreased revenues in the nine months ended September 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris and the reduced size of our field sales force, as well as a strategic decision we made at the beginning of the year to realign the focus of our sales force on driving the utilization at our current installed base rather than on building the installed base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

*Cost of Revenues and Gross Margin.* Cost of revenues increased \$0.6 million, or 5%, to \$11.3 million during the nine months ended September 30, 2017, compared to \$10.7 million during the nine months ended September 30, 2016. This increase was primarily attributable to a \$5.2 million charge in the nine months ended September 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories and a \$1.5 million charge related to scrapped inventories, partially offset by our decreased sales. Gross margin for the nine months ended September 30, 2017 decreased to 40%, compared to 26% in the nine months ended September 30, 2016. Gross margin was negatively impacted primarily by an increase of \$4.5 million in the charges for inventory excess and obsolescence and an increase of \$0.8 million of scrapped inventories during the nine months ended September 30, 2017 compared to the prior year period, partially offset by a decrease of \$0.6 million in warranty expenses.

*Research and Development Expenses.* R&D expenses decreased \$2.2 million, or 19%, to \$9.3 million during the nine months ended September 30, 2017, compared to \$11.5 million during the nine months ended September 30, 2016. This decrease was primarily due to a \$1.4 million decrease in personnel-related expenses, a decrease of \$0.6 million in product development materials and related costs, a decrease of \$0.1 million in outside services and a decrease of \$0.1 million relating to the allocation of facilities expense. Personnel-related expenses included stock-based compensation expense of \$1.6 million compared to \$2.0 million for the nine months ended September 30, 2017 and 2016, respectively.

*Selling, General and Administrative Expenses.* SG&A expenses decreased \$10.6 million, or 34%, to \$20.4 million during the nine months ended September 30, 2017, compared to \$31.0 million during the nine months ended September 30, 2016. This decrease was primarily due to a \$9.1 million decrease in personnel-related expenses, a decrease of \$2.0 million in marketing costs and a decrease of \$0.1 million relating to depreciation, partially offset by an increase of \$0.4 million relating to the allocation of facilities expense and an increase of \$0.3 million in consulting, legal and professional fees. Personnel-related expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. Personnel-related expenses included stock-based

Table of Contents

compensation expense of \$2.3 million compared to \$2.9 million for the nine months ended September 30, 2017 and 2016, respectively. Higher marketing costs for the nine months ended September 30, 2016 were associated with pre-commercial preparation expenses primarily relating to \$1.1 million of Pantheris devices being designated as training and demonstration units for use by our sales and marketing personnel.

*Restructuring.* In April 2017, we undertook an organizational realignment to conserve resources which included a reduction in force that lowered our total headcount by approximately 33% compared to December 31, 2016. We recorded a restructuring charge at that time of approximately \$0.5 million, which consisted of severance related costs specific to the termination of 44 employees. In September 2017, we effected a cost reduction plan, which included a company-wide reduction in force, lowering our total headcount by 24 employees. We recorded a restructuring charge at that time of approximately \$0.4 million, which consisted of severance related costs specific to the termination of 24 employees. As of September 30, 2017, \$0.5 million of the total severance related costs had been paid. We expect the remaining \$0.4 million in severance costs to be paid by December 31, 2017.

*Interest Income (Expense), Net.* Interest income (expense), net increased \$0.7 million, or 20%, to an expense of \$4.6 million during the nine months ended September 30, 2017, compared to an expense of \$3.9 million during the nine months ended September 30, 2016. This increased expense was attributable to the additional \$10.0 million borrowing on June 15, 2016 under our Loan Agreement with CRG.

*Other Income (Expense), Net.* Other income (expense), net increased to an income of \$9,000 during the nine months ended September 30, 2017, compared to expense of \$7,000 during the nine months ended September 30, 2016. Other income for the nine months ended September 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

**Liquidity and Capital Resources**

As of September 30, 2017, we had cash and cash equivalents of \$10.2 million and an accumulated deficit of \$291.2 million, compared to cash and cash equivalents of \$36.1 million and an accumulated deficit of \$252.4 million as of December 31, 2016. We believe that the net proceeds from this offering, net proceeds from the sale of our common stock to 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. We will need to raise additional funds through future equity or debt financings within the next nine months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next nine months could cause substantial dilution to our existing stockholders. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which divert resources from other activities. Additional financing may not be available at all, or if available, may not be in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and we may be required to significantly scale back our business and operations.

To date, our primary sources of capital have been private placements of preferred stock, debt financing agreements, our "at-the-market" program, our IPO and our follow-on public offering in August 2016. As previously disclosed, on April 20, May 24, and October 24, 2017 we received letters

Table of Contents

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

In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to \$50.0 million, of which \$30.0 million was immediately available and borrowed by us. Of the remaining \$20.0 million, we borrowed \$10.0 million on June 15, 2016 and the availability of the remaining \$10.0 million was contingent on the achievement of certain net revenue milestones prior to December 31, 2016, which were not achieved. As of September 30, 2017, we had \$43.1 million outstanding under the Loan Agreement. For more information, see Part I, Item 2 "*Contractual Obligations*."

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement, as amended, include a covenant that we maintain a minimum of \$5.0 million of cash and certain cash equivalents, that we achieve minimum revenue of \$7.0 million in 2015 and \$18.0 million in 2016, and that we 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. In addition, the Loan Agreement prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include our failure to make timely payments of amounts due under the Loan Agreement, the failure to adhere to the covenants set forth in the Loan Agreement, our insolvency or upon the occurrence of a material adverse change. We are currently in compliance with the covenants under the Loan Agreement, but if we default on any such covenants we will need, and may not be able to obtain, relief in the form of waivers or amendments to the applicable debt agreement. As of the date of this Quarterly Report on Form 10-Q we believe we will fail to meet the applicable minimum revenue threshold for 2017 and plan to seek to renegotiate this covenant before the end of the year but cannot provide any assurance that we will be successful in this renegotiation.

On February 3, 2016, we filed a universal shelf registration statement to offer up to \$150.0 million of our securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen, as sales agent, through which we issued and sold common stock with an aggregate value of approximately \$8.7 million between the registration statement's effectiveness on March 8, 2016 and September 2017. During the year ended December 31, 2016, we sold 27,374 shares of common stock through the "at-the-market" program at an average price of \$194.74 and raised net proceeds of \$5.2 million, after payment of \$0.2 million in commissions and fees to Cowen. During the nine months ended September 30, 2017, we sold 189,684 shares of common stock through the "at-the-market" program at an average price of \$17.68 and raised net proceeds of \$3.2 million, after payment of \$0.1 million in commissions and fees to Cowen. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, we are unable to issue more shares through our "at-the-market" program at this time. In addition, in August 2016, we issued and sold 246,445 shares of our common stock in a follow-on public offering at a public offering price of \$140.00 per share, for net proceeds of approximately \$31.5 million after deducting underwriting discounts and commissions of approximately \$2.4 million and other expenses of approximately



Table of Contents

\$0.6 million. The 246,445 shares include the exercise in full by the underwriters of their option to purchase an additional 32,145 shares of our common stock.

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. As a fee for Lincoln Park's commitment to purchase such shares, we issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Purchase Agreement, on November 6, 2017, we filed a registration statement on Form S-1 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 14, 2017. To the extent more than 248,750 shares of our common stock are issued to Lincoln Park pursuant to the Purchase Agreement, we are obligated to file additional registration statements for the resale of such shares.

**Cash Flows**

	<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (29,299)	\$ (42,271)
Investing activities	(41)	(868)
Financing activities	3,414	43,361
Net increase (decrease) in cash and cash equivalents	\$ (25,926)	\$ 222

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

Net cash used in operating activities for the nine months ended September 30, 2017 was \$29.3 million, consisting primarily of a net loss of \$38.6 million and an increase in net operating assets of \$3.2 million, offset by non-cash charges of \$12.5 million. The increase in net operating assets was due to an increase in inventories, prepaid expenses and other current assets. The decreases in accounts payable, accrued compensation and accrued expenses and other current liabilities, was due to our workforce reductions in April and September 2017 and efforts to reduce operating expenses, decreases in other liabilities related to the repayment of assigned interest to PDL, partially offset by a decrease in accounts receivable. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with CRG, and an increased reserve for excess and obsolescence in inventories.

Net cash used in operating activities for the nine months ended September 30, 2016 was \$42.3 million, consisting primarily of a net loss of \$42.6 million and an increase in net operating assets of \$8.2 million, offset by non-cash charges of \$8.5 million. The increase in net operating assets was primarily due to the commercial launch of Pantheris in March 2016 resulting in an increase in accounts receivable and inventories. The increase in net operating assets was also due to an increase in prepaids and other current assets, and decreases in accrued expenses and other current liabilities, due to timing of payments, decreases in other liabilities related to the repayment of assigned interest to PDL and a decrease in accrued compensation. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with CRG, and an increased reserve for excess and obsolescence in inventories.

Table of Contents

***Net Cash Used in Investing Activities***

Net cash used in investing activities in the nine months ended September 30, 2017 was \$41,000 consisting of purchases of property and equipment of \$45,000, partially offset by proceeds of \$4,000 from the sale of property and equipment.

Net cash used in investing activities in the nine months ended September 30, 2016 was \$0.9 million consisting of purchases of property and equipment.

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

Net cash provided by financing activities in the nine months ended September 30, 2017 of \$3.4 million primarily relates to net proceeds of \$3.2 million from the issuance of common stock under the Sales Agreement with Cowen and \$0.2 million proceeds from purchases under our employee stock purchase plan.

Net cash provided by financing activities in the nine months ended September 30, 2016 of \$43.4 million primarily relates to net proceeds of \$32.8 million from the issuance of common stock pursuant to our follow-on public offering and under the Sales Agreement with Cowen, net proceeds of \$9.7 million from the debt financing under the Loan Agreement with CRG, and \$0.9 million proceeds from purchases under our employee stock purchase plan and proceeds from the exercise of stock options.

**Off-Balance Sheet Arrangements**

We currently have no off-balance sheet arrangements and we currently do not use any structured finance, special purpose entities, or variable interest entities.

**Contractual Obligations**

Our principal obligations consist of the operating lease for our facilities, capital leases related to office equipment, our ongoing royalty obligations with PDL, our Loan Agreement with CRG and non-cancellable purchase commitments.

On October 19, 2017, we entered into an agreement to sublease one of our facilities. The sublease is estimated to commence on approximately December 1, 2017, and is scheduled to expire on November 15, 2019 (which is 15 days prior to the expiration of the facility lease). The sublessee will pay a base rent of \$3.25 per rentable square foot, or a total of \$79,950 per month, increasing to \$3.35 per rentable square foot, or a total of \$82,410 per month as of December 1, 2018. In addition to the base rent, the sublessee will pay for the Landlord's operating expenses and property taxes due and payable with respect to the subleased facility.

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

Table of Contents

**BUSINESS**

**Overview**

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

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

Our Lumivascular platform is the only technology that offers real-time visualization of the inside of the artery during PAD treatment 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 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

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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 December 2017, and we plan to file a 510(k) submission for Pantheris BTK in mid-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.

### **Our Products**

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

### **LUMIVASCULAR PRODUCTS**

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

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

Table of Contents

contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature. The Wildcat catheter is intended to be used to support steerable guidewires in accessing discrete regions of the peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices. It may also be used to deliver saline or contrast.

- (2) The Kittycat 2 catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including subtotal and chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Kittycat 2 catheter is contraindicated for use in the iliac, coronary, cerebral, renal and carotid vasculature.
- (3) This original clearance date is for the 7F version of Wildcat. The commercially available version of Wildcat is listed and was cleared in August 2010.

***Lumivascular Platform Overview***

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

***Lightbox***

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

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

***Pantheris***

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

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

We are developing 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

Table of Contents

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 December 2017, and we plan to file a 510(k) submission for Pantheris BTK in mid-2018.

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

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

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

***Other Products***

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

**Clinical Development**

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

***CONNECT (Wildcat)***

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

Table of Contents

***CONNECT II (Ocelot)***

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

***VISION (Pantheris)***

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

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

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



Table of Contents

Final VISION trial data are summarized in the table below.

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

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

**INSIGHT (Pantheris)**

INSIGHT is a prospective, global, single-arm, multi-center study to evaluate the safety and effectiveness of Pantheris for treating in-stent restenosis in lower extremity arteries. In-stent restenosis occurs when a blocked artery previously treated with a stent becomes narrowed again, thereby reducing blood flow. Physicians often face challenges when treating in-stent restenosis both in terms of safety and efficacy. From a safety standpoint, limitations in imaging techniques, such 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 mid-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

Table of Contents

knowledge of our products, clinical expertise and reputation. We also use continuing medical education programs and other opportunities to train interventional cardiologists, vascular surgeons, and interventional radiologists in the use of our Lumivascular platform products and educate them as to the benefits of our products as compared to alternative procedures such as angioplasty, stenting, bypass surgery or other atherectomy procedures. In addition, we work with physicians to help them develop their practices and with hospitals to market themselves as centers of excellence in PAD treatment by making our products available to physicians for treating patients.

Our sales team currently consists of a Vice President, Regional and Territory Sales Managers, Clinical Specialists, and one Director of International Sales. Territory Sales managers are responsible for all product sales, which include disposable catheters and sale and service of our Lightbox console, while Clinical Specialists are primarily responsible for case coverage and account support. We have an extensive hands-on sales training program, focused on our technologies, Lumivascular image interpretation, case management, sales processes, sales tools and implementing our sales and marketing programs and compliance with applicable federal and state laws and regulations. Our sales team is supported by our marketing team, which focuses primarily on clinical training and education, marketing communications and product management. We have partnered with a third party field service firm for the installation, service and maintenance of our Lightbox consoles.

As of December 31, 2017, we had 23 employees focused on sales and marketing. Our sales, general and administrative expenses for the years ended December 31, 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.

Table of Contents

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

procedural safety and efficacy;

acute and long-term outcomes;

ease of use and procedure time;

price;

size and effectiveness of sales force;

radiation exposure for physicians, hospital staff and patients; and

third-party reimbursement.

**Intellectual Property**

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

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

As of December 31, 2017, we held 17 issued U.S. patents and had 25 U.S. utility patent applications and 6 PCT applications pending. As of December 31, 2017, we also had 26 issued patents from outside of the United States. As of December 31, 2017, we had 41 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. As we continue to research and develop our products and technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of our devices. Our issued patents expire between the years 2028 and 2035.

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

As of 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

Table of Contents

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

Our manufacturing operations are subject to regulatory requirements of 21 CFR part 820 of the Federal Food, Drug and Cosmetic Act, or FDCA; 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

Table of Contents

components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply for them. Identifying and qualifying additional or replacement suppliers for any of the components used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

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

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

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

**Government Regulation**

In general, medical device companies must navigate a challenging regulatory environment. In the United States the FDA regulates the medical device market to ensure the safety and efficacy of these products. The FDA allows for two primary pathways for a medical device to gain approval for commercialization: a successful pre-market approval, or PMA application or 510(k) premarket notification submission. A completely novel product must go through the more rigorous premarket approval, or PMA, if it cannot receive authorization through a 510(k). The FDA has established three different classes of medical devices that indicate the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy. Class I and Class II devices are considered lower risk and often can gain approval for commercial distribution by submitting an application to the FDA, generally known as the 510(k) process. The devices regarded as the highest risk by the FDA are designated Class III status and generally require the submission of a PMA application for approval to commercialize a product. These generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA.

Table of Contents

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;

Table of Contents

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

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

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

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





Table of Contents

the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.

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

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

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

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

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

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

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and

Table of Contents

certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

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

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

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

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

Table of Contents

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

Table of Contents

or state level or the effect any future legislation or regulation in the United States may have on our business.

**Third-Party Reimbursement**

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

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

Type of procedure performed angioplasty, stent or atherectomy;

Patient-specific complexities and comorbidities;

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

Inpatient or outpatient status; and

Geographic region.

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

Medicare reimbursement levels for inpatient PAD procedures for fiscal year 2018 went into effect as of October 1, 2017 and range between approximately \$10,000 and \$18,000. Medicare reimbursement for outpatient PAD procedures for 2018 went into effect on January 1, 2018 and range between approximately \$7,000 and \$16,000. These amounts include the cost of disposable catheters such as Ocelot and Pantheris. While reimbursement varies based on the type of procedure performed (i.e., angioplasty, stent or atherectomy), additional device-specific reimbursement is not available. The amount of reimbursement can vary substantially by geographical region and by facility. Payment rates of other third-party payors may follow Medicare rates, or they may be higher or lower, depending on their particular reimbursement methodology. Because of the wide variability, it is not possible to identify an average rate for third-party payors other than Medicare.

**Employees**

As of 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.

Table of Contents

**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, rescission, and attorneys' fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California ("Federal Court"), where they were captioned *Grotewiel v. Avinger, Inc.*, No. 17-cv-03400, *Gonzalez v. Avinger, Inc.*, No. 17-cv-03401, and *Olberding v. Avinger, Inc.*, No. 17-cv-03398, and where the actions were related and assigned to the same judge.

On 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. We believe that our maximum liability under the legal proceedings is equal to the self-insured retention amount under our directors and officers insurance liability insurance policy of \$2.5 million minus the amount of approximately \$900,000 already paid by us for a total of approximately \$1.6 million plus reimbursement of costs, legal fees and any damages incurred by the underwriters as a result of the legal proceedings. On February 8, 2018 we participated in a mediation to explore whether a settlement can be reached in the litigation to avoid the cost and disruption of continuing to defend against it. While the parties did not reach a resolution during the mediation, the parties are continuing their discussion of a mediator's proposal that contemplates that we would contribute the entirety of \$1.6 million amount mentioned above as part of a settlement of the litigation. There can be no assurance that these discussions will result in a settlement.

**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

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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](http://www.sec.gov). Our common stock is traded on the Nasdaq Capital Market under the symbol "AVGR".

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) December 31, 2019, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least \$1.07 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Table of Contents**MANAGEMENT****Executive Officers, Directors and Key Employees**

The following table sets forth information, as of December 31, 2017, regarding our executive officers, directors and key employees.

<b>Name</b>	<b>Age</b>	<b>Title</b>
Jeffrey M. Soinski	56	President, Chief Executive Officer and Director
Matthew B. Ferguson	50	Chief Business Officer and Chief Financial Officer
Himanshu N. Patel	57	Chief Technology Officer
James G. Cullen(2)(3)	75	Director and Non-executive Chairman of the Board of Directors
Donald A. Lucas(1)(2)(3)	55	Director
James B. McElwee(1)(2)(3)	65	Director

- 
- (1) Member of the audit committee.
- (2) Member of the compensation committee.
- (3) Member of the nominating and governance committee.

*James G. Cullen* has served as a member of our board of directors since December 2014, as our Lead Independent Director since January 2015 and as our Non-Executive Chairman since December 2017. During the last five years, Mr. Cullen has held board and committee positions with various companies. Mr. Cullen is currently the non-executive Chairman of the board of Neustar, Inc., a neutral provider of real-time information services and analytics, a director and member of the investment and finance committees of Prudential Financial, and a director of Agilent Technologies and Keysight Technologies. Mr. Cullen previously served as a director and chairman of the audit committee of Johnson & Johnson. From 1993 to 2000, Mr. Cullen was President, Vice Chairman and Chief Operating Officer of Bell Atlantic Corporation (now Verizon). From 1989 to 1993, he was President and Chief Executive Officer of Bell Atlantic-New Jersey. Mr. Cullen holds a B.A. in Economics from Rutgers University and an M.S. in Management Science from the Massachusetts Institute of Technology.

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

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

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

*James B. McElwee* has served as a member of our board of directors since March 2011. Mr. McElwee has served as an independent venture capital investor since 2010. Mr. McElwee served as general partner of Weston Presidio, a private equity and venture capital firm, from 1992 to 2010. During his tenure as a general partner and member of the investment committee, Weston Presidio led



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

the start up financing of JetBlue Airways and made investments in Fender Musical Instruments, The Coffee Connection, Guitar Center, Mapquest, Party City, Petzazz, RE/MAX, and

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

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

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

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

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

### **Director Independence**

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

Table of Contents

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

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

**Board Leadership Structure and Lead Independent Director**

We believe that the structure of our board of directors and its committees provides strong overall management of our company. Our board of directors does not have a formal policy on whether the roles of Chief Executive Officer and Chairman of our board of directors should be separate. The Chairman of our board of directors and our Chief Executive Officer roles are separate, and our current Non-Executive Chairman, James G. Cullen, is independent under the listing standards of The NASDAQ Stock Market and thus also serves as our lead independent director.

Our Chief Executive Officer, Jeffrey M. Soinski, is responsible for setting the strategic direction of our company, the general management and operation of the business and the guidance and oversight of senior management. As lead independent director, Mr. Cullen is expected to preside over periodic meetings of our independent directors, to serve as a liaison between our Chief Executive Officer and the independent directors, and to perform such additional duties as our Board may otherwise determine and delegate. At the end of each board meeting, the independent directors are expected to meet in executive session, without Mr. Soinski present. Following each meeting, Mr. Cullen is expected to provide feedback to Mr. Soinski on his performance and the performance of our employees during the meeting and to recommend new agenda items for the next meeting.

**Board Meetings and Committees**

During our fiscal year ended December 31, 2017, our board of directors held seventeen meetings (including regularly scheduled and special meetings), and each director attended at least 75% of the aggregate of (i) the total number of meetings of our board of directors held during the period for which he has been a director and (ii) the total number of meetings held by all committees of our board of directors on which he served during the periods that he served. Five of our directors attended our 2017 annual meeting of stockholders, either in person or telephonically.

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

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

Table of Contents

***Audit Committee***

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

appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is Moss Adams LLP;

reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;

preparing the audit committee report required by SEC rules to be included in our annual proxy statements;

monitoring our internal control over financial reporting, disclosure controls and procedures;

reviewing our risk management status;

establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;

meeting independently with our independent registered public accounting firm and management; and

monitoring compliance with the code of business conduct and ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our audit committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of The NASDAQ Stock Market. A copy of the charter of our audit committee is available on our website at [www.avinger.com](http://www.avinger.com) under "Investors Governance." During our fiscal year ended December 31, 2017, our audit committee held seven meetings.

***Compensation Committee***

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

annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;

## Edgar Filing: Avinger Inc - Form S-1/A

determining the compensation of our chief executive officer and our other executive officers;

reviewing and making recommendations to our board of directors with respect to director compensation; and

Table of Contents

overseeing and administering our equity incentive plans.

Our Chief Executive Officer and Chief Financial Officer make compensation recommendations for our other executive officers and initially propose the corporate and departmental performance objectives under our Executive Incentive Compensation Plan to the compensation committee. From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, we have periodically engaged Radford, a business unit of Aon Hewitt, to help develop our compensation philosophy, select a group of peer companies to use for compensation benchmarking purposes and advise on cash and equity compensation levels for our directors, executives and other employees based on current market practices. Our compensation committee operates under a written charter that satisfies the applicable rules and regulations of the SEC and the listing standards of The NASDAQ Stock Market. A copy of the charter of our compensation committee is available on our website at [www.avinger.com](http://www.avinger.com) under "Investors Governance." During our fiscal year ended December 31, 2017, our compensation committee held two meetings.

***Nominating and Corporate Governance Committee***

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

identifying individuals qualified to become members of our board of directors;

recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;

reviewing and making recommendations to our board of directors with respect to management succession planning;

developing, updating and recommending to our board of directors corporate governance principles and policies; and

overseeing the evaluation of our board of directors and committees.

Our nominating and corporate governance committee operates under a written charter that satisfies the applicable listing standards of The NASDAQ Stock Market. A copy of the charter of our nominating and corporate governance committee is available on our website at [www.avinger.com](http://www.avinger.com) under "Investors Governance." During our fiscal year ended December 31, 2017, our nominating and corporate governance committee held no meetings.

**Compensation Committee Interlocks and Insider Participation**

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

**Considerations in Evaluating Director Nominees**

Our nominating and corporate governance committee uses a variety of methods for identifying and evaluating director nominees. In its evaluation of director candidates, our nominating and corporate

Table of Contents

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

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

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

Our nominating and corporate governance committee will consider candidates for director recommended by stockholders, so long as such recommendations comply with our amended and restated certificate of incorporation, amended and restated bylaws and applicable laws, rules and regulations, including those promulgated by the SEC. Our nominating and corporate governance committee will evaluate such recommendations in accordance with its charter, our amended and restated bylaws, our policies and procedures for director candidates, as well as the regular director nominee criteria described above. This process is designed to ensure that our board of directors includes members with diverse backgrounds, skills and experience, including appropriate financial and other expertise relevant to our business. Eligible stockholders wishing to recommend a candidate for nomination should contact our Secretary in writing. Such recommendations must include information about the candidate, a statement of support by the recommending stockholder, evidence of the recommending stockholder's ownership of our common stock and a signed letter from the candidate confirming willingness to serve on our board of directors. Our nominating and corporate governance committee has discretion to decide which individuals to recommend for nomination as directors.

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

**Communications with the Board of Directors**

Interested parties wishing to communicate with our board of directors or with an individual member or members of our board of directors may do so by writing to our board of directors or to the particular member or members of our board of directors and mailing the correspondence to our

Table of Contents

Secretary at Avinger, Inc., 400 Chesapeake Drive, Redwood City, California 94063. Our Secretary, in consultation with appropriate members of our board of directors as necessary, will review all incoming communications and, if appropriate, all such communications will be forwarded to the appropriate member or members of our board of directors, or if none is specified, to the Executive Chairman of our board of directors.

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

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

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

**Limitation on Liability and Indemnification Matters**

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

any breach of the director's duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; and

any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered, and expect to continue to enter, into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

Table of Contents

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

**Risk Management**

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

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

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

**Director Compensation**

Our board of directors approved our Outside Director Compensation Policy in January 2015 to compensate each non-employee director for his or her service. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or appropriate. Under our Outside Director Compensation Policy, non-employee directors will receive compensation in the form of equity and cash, as described below:

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

\$35,000 per year for service as a board member;



Table of Contents

\$15,000 per year additionally for service as lead independent director and non-executive chairman;

\$20,000 per year additionally for service as chairman of the audit committee;

\$10,000 per year additionally for service as an audit committee member;

\$15,000 per year additionally for service as chairman of the compensation committee;

\$7,500 per year additionally for service as a compensation committee member;

\$10,000 per year additionally for service as chairman of the nominating and corporate governance committee; and

\$5,000 per year additionally for service as a nominating and corporate governance committee member.

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

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

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

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

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

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

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

The exercise price per share of each stock option granted under our outside director compensation policy, including Retainer Options, Initial Options and Annual Options, will be the fair market value of a share of our common stock, as determined in accordance with our 2015 Equity Incentive Plan, which we refer to as the 2015 Plan, on the date of the option grant. The grant date fair value is computed in accordance with the Black-Scholes option valuation methodology or such other methodology as our board of directors or compensation committee may determine.

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

### *Compensation for Fiscal Year 2017*

The following table sets forth a summary of the compensation received by our non-employee directors who received compensation during our fiscal year ended December 31, 2017:

Name	Fees earned or paid in cash(1)	Option awards(2)(3)	Total
James G. Cullen	\$ 77,500	\$ 75,000	\$ 152,500
Thomas J. Fogarty	\$	\$ 115,000	\$ 115,000
Donald A. Lucas	\$ 67,500	\$ 75,000	\$ 142,500
James B. McElwee	\$ 65,000	\$ 75,000	\$ 140,000

- (1) Dr. Fogarty elected to convert \$40,000 of his Retainer Cash Payments for 2017 into Retainer Options. Dr. Fogarty retired from our board of directors in August 2017.
- (2) During 2016, all non-employee directors received an Annual Option grant.
- (3) As of December 31, 2017, Messrs. Cullen, Lucas, McElwee and Dr. Fogarty had outstanding options to purchase a total of 130,685, 124,093 and 113,361 shares of our common stock, respectively.

Directors who are also our employees receive no additional compensation for their service as directors. During 2017, John B. Simpson and Jeffrey M. Soinski, two of our directors, were also our employees. See "Executive Compensation Fiscal 2017 Summary Compensation Table" for additional information about the compensation for Dr. Simpson and Mr. Soinski. Dr. Simpson resigned as director and Executive Chairman in December 2017.

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

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock to file with the SEC reports regarding their ownership and changes in ownership of our securities. We believe that, during fiscal 2017, our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements.

Table of Contents**EXECUTIVE COMPENSATION****Processes and Procedures for Compensation Decisions**

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

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

**Fiscal 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		Total (\$)
						Plan Compensation (\$)	All Other Compensation (\$)	
John B. Simpson, Ph.D., M.D.(2) <i>Executive Chairman</i>	2017	363,500		61,500	67,161		232,500	724,661
	2016	390,000		342,511	334,360	91,134		1,158,005
Jeffrey M. Soinski(3) <i>President and Chief Executive Officer</i>	2017	390,000		61,500	67,161		3,000	521,661
	2016	390,000		342,511	334,360	91,134	105,891	1,263,896
Matthew B. Ferguson(4) <i>Chief Financial Officer and Chief Business Officer</i>	2017	300,000		51,250	55,967		3,000	410,217
	2016	300,000		143,043	139,286	56,083	3,000	641,412

(1) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the named executive officer in 2016 and 2017, calculated in accordance with ASC Topic 718. Such grant-date fair value does not take into account any estimated forfeitures related to service-vesting conditions. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in the section of our Annual Report on Form 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-Based Compensation."

(2) In 2017, the amounts reported in All Other Compensation for Dr. Simpson include a cash severance payment of \$195,000 and reimbursement for accrued paid time off of \$37,500.

Table of Contents

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.

**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. In connection with Dr. Simpson's resignation, we and Dr. Simpson entered into a Separation Agreement and Release, dated December 6, 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 2017 Summary Compensation Table," and no further obligations exist under these provisions.

***Matthew B. Ferguson***

We entered into an employment offer letter in December 2010 with Matt Ferguson, our Chief Financial Officer and Chief Business Officer. The letter has no specific term and provides for at-will

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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.

### **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.

Name	Grant Date	Option Awards				Stock Awards	
		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 or Units of Stock That Have Not Vested (\$)(5)
John B. Simpson	5/1/2013(1)(6)	722		900.00	5/1/2018		
	12/31/2014(1)(7)	15,280		198.00	12/31/2024		
	3/7/2016(2)(7)	656		518.40	3/7/2026		
Jeffrey M. Soinski	12/31/2014(1)(7)	15,484		180.00	12/31/2024		
	3/7/2016(2)(7)	656	843	518.40	3/7/2026		
	3/7/2016(2)(8)					562	4,046
	3/13/2017(2)(7)		1,500	82.00	3/13/2027		
	3/13/2017(2)(8)					750	5,400
Matthew B. Ferguson	7/29/2011(1)(9)	849		504.00	7/29/2021		
	5/1/2013(1)(6)	170		810.00	5/1/2023		
	9/2/2014(1)	241		504.00	9/2/2019		
	12/31/2014(1)(7)	2,387		180.00	12/31/2024		
	3/3/2016(2)(7)	273	351	519.60	3/3/2026		
	3/3/2016(2)(8)					234	1,685
	3/13/2017(2)(7)		1,250	82.00	3/13/2027		
3/13/2017(2)(8)					625	4,500	

(1)

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

(2)

Each of the outstanding equity awards was granted pursuant to our 2015 Plan.

Table of Contents

- (3) All of our options granted pursuant to our 2009 Stock Plan are early exercisable subject to the Company's right to repurchase any unvested shares.
- (4) This column represents the fair value of a share of our common stock on the date of grant which, prior to our initial public offering in January 2015, was determined by our board of directors. Subsequently, the fair value of our common stock is determined based on the closing price of our common stock, as reported on the Nasdaq Global Market or Nasdaq Capital Market, as applicable.
- (5) This column represents the market value of the unvested shares of our common stock underlying the RSUs as of December 29, 2017, based on the closing price of our common stock, as reported on the Nasdaq Global Market, of \$7.20 per share.
- (6) 25% of the shares of our common stock subject to this option vested on January 1, 2014, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.
- (7) 25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.
- (8) 25% of the shares of our common stock subject to this option vested on the one year anniversary of the grant date, and the balance vests in 3 successive equal annual installments, subject to continued service through each such vesting date.
- (9) 25% of the shares of our common stock subject to this option vested on December 31, 2011, and the balance vests in 36 successive equal monthly installments, subject to continued service through each such vesting date.

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

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

Table of Contents

(which may include any calculation of earnings, including but not limited to earnings before interest and taxes, earnings before taxes, earnings before interest, taxes, depreciation and amortization and net earnings), earnings per share, net income, net profit, net sales, operating cash flow, operating expenses, operating income, operating margin, overhead or other expense reduction, product defect measures, product release timelines, productivity, profit, return on assets, return on capital, return on equity, return on investment, return on sales, revenue, revenue growth, sales results, sales growth, stock price, time to market, total stockholder return, working capital, and individual objectives such as peer reviews or other subjective or objective criteria. Performance goals that include our financial results may be determined in accordance with GAAP or such financial results may consist of non-GAAP financial measures and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when performance goals that include our financial results may be determined in accordance with GAAP, or such financial results may consist of non-GAAP financial measures, and any actual results may be adjusted by the compensation committee for one-time items or unbudgeted or unexpected items when determining whether the performance goals have been met. The goals may be on the basis of any factors the compensation committee determines relevant, and may be adjusted on an individual, divisional, business unit or company-wide basis. The performance goals may differ from participant to participant and from award to award.

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

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

**Equity Compensation Plan Information**

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

<b>Plan Category</b>	<b>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>(b) Weighted Average Exercise Price of Outstanding Options, Warrants and Rights(2)</b>	<b>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>
Equity compensation plans approved by stockholders(1)	135,448	\$ 379.19	88,736

(1)

Includes the following plans: our 2009 Stock Plan, our 2015 Plan and our 2015 Employee Stock Purchase Plan. Our 2015 Plan provides that on the first day of each fiscal year commencing in fiscal year 2016, the number of shares authorized for issuance under the 2015 Plan is automatically increased by a number equal to the lesser of (i) 42,250 shares of common stock, (ii) 5.0% of the aggregate number of shares of common stock outstanding on the last day of the preceding fiscal year, or (iii) such number of shares that may be determined by our board of directors. Our 2015 Employee Stock Purchase Plan provides that on the first day of each fiscal year commencing in fiscal year 2016 the number of shares authorized for issuance under our 2015 Employee Stock



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

Purchase Plan is automatically increased by a number equal to the lesser of (i) 12,325 shares of common stock, (ii) 1.5% of the aggregate number of shares of common stock outstanding on such date, or (iii) an amount determined by our board of directors or a duly authorized committee of our board of directors.

(2)

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

Table of Contents**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information with respect to the beneficial ownership of our capital stock as of 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 833,409 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.

Name of Beneficial Owner	Shares Beneficially Owned	
	Number of Shares	Percentage
<b>Named Executive Officers and Directors</b>		
Jeffrey M. Soinski(1)	18,028	2.1%
Matthew Ferguson(2)	4,730	*
James G. Cullen(3)	1,364	*
Donald A. Lucas(4)	1,944	*
James B. McElwee(5)	1,610	*
All executive officers and directors as a group (6 individuals)(6)	35,748	4.1%

\*

Represents ownership of less than 1%

(1)

Consists of (i) 1,826 shares of common stock held of record by Mr. Soinski and (ii) 16,202 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(2)

Consists of (i) 788 shares of common stock held of record by Mr. Ferguson, (ii) warrants to purchase 241 shares of common stock and (iii) 3,701 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2017.

(3)

Consists of (i) 1,845 shares of common stock held by Gilbert Investments, LLC, (ii) warrants to purchase 621 shares of common stock held by Gilbert Investments, LLC, (iii) 327 shares of common stock held by 2000 James Cullen Generation Skipping Family Trust and (iv) 1,529 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

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

pecuniary interest in the James Cullen Generation Skipping Family Trust and disclaims beneficial ownership in Gilbert Investments, LLC except to the extent of his pecuniary interest therein.

- (4) Consists of (i) 580 shares of common stock held of record by Lucas Venture Group III, LP and (ii) 1,364 shares of common stock issuable upon exercise of options exercisable within 60 days of December 31, 2017.
- (5) Consists of (i) 377 shares of common stock held of record by Mr. McElwee, (ii) warrants to purchase 138 shares of common stock and (iii) 1,095 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.
- (6) Consists of (i) 8,165 shares of common stock outstanding, (ii) warrants to purchase 1,458 shares of common stock (iii) 29,083 shares issuable upon exercise of options exercisable within 60 days of December 31, 2017.

Table of Contents

**DESCRIPTION OF SECURITIES WE ARE OFFERING**

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 833,409 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 53,715 shares of common stock subject to outstanding warrants, and 76,644 shares of common stock subject to outstanding options.

*Dividend Rights*

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

*Voting Rights*

There are 100,000,000 shares of common stock authorized for issuance. Pursuant to our amended and restated certificate of incorporation, each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of stockholders; provided, however, that, except as otherwise required by law, holders of our common stock, as such, shall not be entitled to vote on any amendment to our amended and restated certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to our amended and restated certificate of incorporation. Pursuant to our amended and restated certificate of incorporation and amended and restated bylaws, corporate actions can generally be taken by a majority of our board and/or stockholders holding a majority of our outstanding shares, except as otherwise indicated in the section entitled "Anti-takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws," where certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws require the vote of at least 66 2/3% of our then outstanding voting securities. Additionally, our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a plurality of the votes cast at a meeting of stockholders will be able to elect all of the directors then standing for election.

Table of Contents

*Right to Receive Liquidation Distributions*

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

*Rights and Preferences*

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

*Fully Paid and Nonassessable*

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

**Preferred Stock**

Under our restated certificate of incorporation, we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares of preferred stock, par value \$0.001 per share, in one or more series. As of December 31, 2017, no shares of preferred stock were issued or outstanding.

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

In connection with this offering, our board of directors will designate shares of our preferred stock as Series B convertible preferred stock (the "Series B preferred stock"). The preferences and rights of the Series B preferred stock will be as set forth in a Certificate of Designation of Series B preferred stock (the "Series B Certificate of Designation") filed as an exhibit to the registration statement of which this prospectus is a part. The following is a summary of the material terms of our Series B Preferred stock and is qualified in its entirety by the Series B Certificate of Designation. Please refer Series B Certificate of Designation for more information on the preferences, rights and limitations of Series B preferred stock, which certificate is filed as an exhibit to the registration statement of which this prospectus is a part.

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

Table of Contents

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

*Conversion.* Each share of Series B preferred stock is convertible, at any time and from time to time at the option of the holder thereof, into that number of shares of common stock determined by dividing \$1,000 by the assumed conversion price of \$4.23 (subject to adjustment described below). This right to convert is limited by the beneficial ownership limitation described below.

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

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

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

*Conversion Price Adjustment*

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

*Stock Dividends and Stock Splits.* If we pay a stock dividend or otherwise make a distribution payable in shares of common stock on shares of common stock or any other common stock equivalents,

Table of Contents

subdivide or combine outstanding common stock, or reclassify common stock, the conversion price will be adjusted by multiplying the then conversion price by a fraction, the numerator of which shall be the number of shares of common stock outstanding immediately before such event, and the denominator of which shall be the number of shares outstanding immediately after such event.

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

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

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

The Series B preferred stock will be issued in book-entry form under a preferred stock agent agreement between American Stock Transfer & Trust as preferred stock agent, and us, and 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 B preferred stock and we do not expect a market to develop. We do not plan on applying to list the Series B preferred stock on The Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

We do not intend to apply for listing of the Series B preferred stock on any securities exchange or other trading system.

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

**Series 1 and Series 2 Warrants Being Offered**

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 and is qualified in its entirety by the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part. Pursuant to a warrant agency agreement between us and American Stock Transfer



Table of Contents

& Trust Company, LLC, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each share of Series B convertible preferred stock will be issued with: (a) the number of warrants equal to 100% of the number of shares of our common stock initially issuable upon conversion of the share of Series B preferred stock, which will be immediately exercisable and expire on the seventh anniversary of the date of issuance (the "Series 1 Warrants"), and (b) the number of warrants equal to 100% of the number of shares of our common stock initially issuable upon conversion of the shares of Series B preferred stock, which will be immediately exercisable and expire on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60<sup>th</sup> calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name) (the "Series 2 Warrants"); provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. Each whole warrant is exercisable to purchase one share of our common stock at an exercise price of \$ per share at any time prior to expiration. The warrants issued in this offering will each be governed by the terms of a global warrant certificate deposited with DTC. The holder of a warrant will not be deemed a holder of our underlying common stock until the warrant is exercised, except as set forth in the warrant.

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 holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

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, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. 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. 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. Further, as more fully described in the warrants, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the warrants on the date of consummation of such transaction.

Table of Contents

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

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

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.

**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

Table of Contents

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.

Table of Contents

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

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

*Amendment of charter provisions.* Any amendment of the above provisions in our amended and restated certificate of incorporation would require approval by holders of at least  $66\frac{2}{3}\%$  of the voting power of our then outstanding voting securities.

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

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219. Our shares of common stock are issued in uncertificated form only, subject to limited circumstances.

**Market Listing**

Our common stock is listed on the Nasdaq Capital Market under the symbol "AVGR".

Table of Contents

**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.

<b>Underwriters</b>	<b>Fixed Combinations of Series B Convertible Preferred Stock and Warrants</b>
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 securities directly to the public at the public offering price set forth on the cover page of this prospectus. 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 per fixed combination of a share of Series B convertible preferred stock, a Series 1 warrant and a Series 2 warrant.

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 securities offered by this prospectus.

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

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

Table of Contents

**Underwriting Discount and Expenses**

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

	<b>Per Share of Series B Convertible Stock and Warrants</b>	<b>Total</b>
Public offering price		
Underwriting discount to be paid to the underwriters by us		
Proceeds to us (before expenses)		

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

**Determination of Offering Price**

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "AVGR." On February 7, 2018 the closing price of our common stock was \$4.23 per share. We do not intend to apply for listing of the Series B Preferred Stock or warrants on any securities exchange or other trading system.

The 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 shares of preferred stock and warrants were:

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

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

**Lock-up Agreements**

Our officers, directors and each of their respective affiliates and associated persons have agreed with the representative to be subject to a lock-up period of ninety (90) days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The



Table of Contents

lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

**Other Relationships**

Upon completion of this offering, we have granted the representative a right of first refusal to act as lead bookrunner, lead placement agent or financial advisor in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends 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 underwriters may engage in stabilizing transactions for the purpose of pegging, fixing or maintaining the price of our common stock. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum. These stabilizing transactions may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that stabilizing transactions may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

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

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

**Indemnification**

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



Table of Contents

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

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

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

insurance companies;

tax-exempt organizations;

banks or other financial institutions;

brokers or dealers in securities;

regulated investment companies or mutual funds;

pension plans;

controlled foreign corporations;

passive foreign investment companies;

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

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

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

persons that have a "functional currency" other than the U.S. dollar;

## Edgar Filing: Avinger Inc - Form S-1/A

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

**U.S. Holders**

***Exercise of Warrants***

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we

Table of Contents

pay to a non-corporate U.S. holder generally will constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains.

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

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

**Non-U.S. Holders**

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

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

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

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an

Table of Contents

income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

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

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

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

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

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

Table of Contents

**Information Reporting and Backup Withholding**

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

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

**Foreign Account Tax Compliance Act**

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

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

Table of Contents

**LEGAL MATTERS**

Certain legal matters relating to the issuance of the securities offered by this prospectus will be passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California. Certain members of, and investment partnerships comprised of members of, and persons associated with, Wilson Sonsini Goodrich & Rosati, P.C. own an interest representing less than 1% of the shares of our common stock. Certain legal matters in connection with this offering will be passed upon for the underwriter by Ellenoff Grossman & Schole LLP.

**EXPERTS**

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

**WHERE YOU CAN FIND MORE INFORMATION**

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

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



Table of Contents

**AVINGER, INC.**  
**INDEX TO FINANCIAL STATEMENTS**  
**As of December 31, 2016 and 2015, and the**  
**Years Ended December 31, 2016, 2015 and 2014**

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
Financial Statements:	
<u>Balance Sheets</u>	<u>F-3</u>
<u>Statements of Operations and Comprehensive Loss</u>	<u>F-4</u>
<u>Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	<u>F-5</u>
<u>Statements of Cash Flows</u>	<u>F-6</u>
<u>Notes to Financial Statements</u>	<u>F-7</u>

F-1

---

Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Avinger, Inc.

We have audited the accompanying balance sheets of Avinger, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule included in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Avinger, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations and its need for additional capital raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments 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.

/s/ Ernst & Young LLP

San Francisco, California  
March 14, 2017,  
except for Note 18, as to which the date is  
February 9, 2018

F-2

---

Table of Contents

## AVINGER, INC.

## BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2016	December 31, 2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,096	\$ 43,059
Accounts receivable, net of allowance for doubtful accounts of \$21 at December 31, 2016 and \$20 at December 31, 2015	3,570	2,060
Inventories	8,462	5,405
Prepaid expenses and other current assets	662	533
<b>Total current assets</b>	<b>48,790</b>	<b>51,057</b>
Property and equipment, net	4,555	2,822
Other assets	212	225
<b>Total assets</b>	<b>\$ 53,557</b>	<b>\$ 54,104</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,607	\$ 1,113
Accrued compensation	2,807	3,083
Accrued expenses and other current liabilities	3,067	3,285
Borrowings, current portion	41,289	
<b>Total current liabilities</b>	<b>48,770</b>	<b>7,481</b>
Borrowings, net of current portion		29,565
Other long-term liabilities	546	1,469
<b>Total liabilities</b>	<b>49,316</b>	<b>38,515</b>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock issuable in series, par value of \$0.001		
Shares authorized: 5,000,000 at December 31, 2016 and December 31, 2015		
Shares issued and outstanding: none at December 31, 2016 and December 31, 2015		
Common stock, par value of \$0.001		
Shares authorized: 100,000,000 at December 31, 2016 and December 31, 2015		
Shares issued and outstanding: 594,321 at December 31, 2016 and 316,020 at December 31, 2015		
Additional paid-in capital	256,629	211,850
Accumulated deficit	(252,389)	(196,261)
<b>Total stockholders' equity</b>	<b>4,241</b>	<b>15,589</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 53,557</b>	<b>\$ 54,104</b>

See accompanying notes.

F-3

---

Table of Contents

## AVINGER, INC.

## STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Revenues	\$ 19,214	\$ 10,713	\$ 11,213
Cost of revenues	14,445	6,478	6,513
Gross profit	4,769	4,235	4,700
Operating expenses:			
Research and development	15,536	15,694	11,224
Selling, general and administrative	39,950	29,231	18,503
Total operating expenses	55,486	44,925	29,727
Loss from operations	(50,717)	(40,690)	(25,027)
Interest income	125	40	2
Interest expense	(5,524)	(5,167)	(6,016)
Other income (expense), net	(12)	(1,527)	(909)
Loss before provision for income taxes	(56,128)	(47,344)	(31,950)
Provision for income taxes			14
Net loss and comprehensive loss	(56,128)	(47,344)	(31,964)
Adjustment to net loss resulting from convertible preferred stock modification		(2,384)	
Net loss and comprehensive loss attributable to common stockholders	\$ (56,128)	\$ (49,728)	\$ (31,964)
Net loss attributable to common stockholders per share, basic and diluted	\$ (135.57)	\$ (175.10)	\$ (5,327.33)
Weighted average common shares used to compute net loss per share, basic and diluted	414	284	6

See accompanying notes.

Table of Contents

AVINGER, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series D Convertible Preferred Stock		Series E Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31,	8,161	\$ 6,183	5,630	\$ 6,649	18,865	\$ 27,272	14,014	\$ 22,397	18,004	\$ 37,153		\$	6,122	\$	1,787	\$ (114,569)	\$ (112,782)
Issuance of Common Stock													64		28		
Employee based compensation															641		
Issuance of Series E convertible preferred stock, initial issuance											66,719	32,606					
Issuance of Common stock warrants																175	
Change in contingent liability from contingent additional paid-in capital and comprehensive																34	
																	(31,964)
Balance at December 31,	8,161	6,183	5,630	6,649	18,865	27,272	14,014	22,397	18,004	37,153	66,719	32,606	6,186	2,665	(146,533)	(143,867)	
Issuance of Common Stock													1,240	432			
Employee based compensation															5,899		
Issuance of Series E convertible preferred stock, initial issuance																18	
Issuance of Common stock warrants																804	
Change in contingent liability from contingent additional paid-in capital and comprehensive																	
	(8,161)	(6,183)	(5,630)	(6,649)	(18,865)	(27,272)	(14,014)	(22,397)	(18,004)	(37,153)	(78,979)	(37,978)	861	323			
													143,653	137,632		137,632	

Edgar Filing: Avinger Inc - Form S-1/A

Conversion of preferred stock to common stock in connection with the initial public offering of common stock upon the conversion of preferred stock to common stock due to dilution of common stock			30,375		
Proceeds from the sale of common stock, net of underwriting fees, commissions and issuance costs		125,000	56,898		56,898
Proceeds from the sale of common stock to CRG, net of issuance costs		8,705	4,795		4,795
Convertible preferred stock liquidation preference and comprehensive			2,384	(2,384)	
				(47,344)	(47,344)
<b>Balance at December 31,</b>		316,020	211,850	(196,261)	151,609
Proceeds from the sale of common stock		4,098	805		4,098
Employee-based compensation			7,392		7,392
Increase of common stock warrants			384		384
Proceeds from the sale of common stock to public investors, net of underwriting fees, commissions and issuance costs		273,819	36,582		36,582
Convertible preferred stock liquidation preference and comprehensive				(56,128)	(56,128)
<b>Balance at December 31,</b>	\$	\$	\$	\$	\$
		594,321	256,629	(252,389)	448,561

See accompanying notes.





Table of Contents

## AVINGER, INC.

## STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
<b>Cash flows from operating activities</b>			
Net loss	\$ (56,128)	\$ (47,344)	\$ (31,964)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,506	1,300	1,451
Amortization of debt issuance costs and debt discount	222	199	212
Stock-based compensation	7,392	5,899	641
Remeasurement of embedded derivatives		(835)	(378)
Write off of embedded derivatives		1,066	
Noncash interest expense and other charges	1,812	2,074	3,485
Loss on extinguishment of convertible notes		86	1,234
Provision for doubtful accounts receivable	3		
Provision for excess and obsolete inventories	797	(26)	(48)
Changes in operating assets and liabilities:			
Accounts receivable	(1,512)	7	(441)
Inventories	(6,099)	(2,307)	1,714
Prepaid expenses and other current assets	(130)	(363)	444
Other assets	13	(35)	2
Accounts payable	470	84	17
Accrued compensation	(275)	1,936	(128)
Accrued expenses and other current liabilities	(191)	(962)	2,080
Other long-term liabilities and accrued interest	(949)	(1,662)	(122)
Net cash used in operating activities	(53,069)	(40,883)	(21,801)
<b>Cash flows from investing activities</b>			
Purchase of property and equipment	(971)	(577)	(117)
Restricted cash		255	
Net cash used in investing activities	(971)	(322)	(117)
<b>Cash flows from financing activities</b>			
Principal paydown of capital lease obligations	(27)	(22)	(17)
Payments on borrowing		(27,625)	
Proceeds from convertible notes, net of issuance costs			4,700
Proceeds from borrowings, net of issuance costs	9,716	29,124	
Proceeds from the issuance of convertible preferred stock, net of issuance costs		6,176	19,155
Proceeds from the issuance of common stock related to CRG loan, net of issuance costs		4,794	
Proceeds from public offerings, net of issuance costs	36,583	58,746	
Proceeds from the exercise of common stock warrants		323	
Payments for deferred initial public offering costs			(1,848)
Proceeds from the issuance of common stock	805	432	23
Net cash provided by financing activities	47,077	71,948	22,013
Net change in cash and cash equivalents	(6,963)	30,743	95
Cash and cash equivalents, beginning of period	43,059	12,316	12,221
Cash and cash equivalents, end of period	\$ 36,096	\$ 43,059	\$ 12,316

Edgar Filing: Avinger Inc - Form S-1/A

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$	4,354	\$	5,934	\$	2,281
Noncash investing and financing activities:						
Conversion of convertible preferred stock to common stock upon initial public offering	\$		\$	137,632	\$	
Accounts payable for purchases of property and equipment		24		16		
Modification of convertible preferred stock				2,384		
Reclass of warrant liability to additional paid-in capital						34
Vesting of common stock subject to repurchase				18		5
Issuance of common stock warrants				804		175
Transfer between inventory and property and equipment		2,245		921		(916)
Conversion of convertible notes and accrued interest into Series E convertible preferred stock						11,582

See accompanying notes.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements**

**1. Organization**

**Organization, Nature of Business**

Avinger, Inc. (the "Company"), a Delaware corporation, was founded in March 2007 by cardiologist and medical device entrepreneur Dr. John B. Simpson. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("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. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ("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. The Company's Lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company's current products include its non-imaging catheters, Wildcat and Kitty cat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). In March 2016, the Company also received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for commercialization of Pantheris, the Company's image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company commenced sales of Pantheris in the U.S. and select international markets promptly thereafter. The Company is located in Redwood City, California.

**Liquidity Matters**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company adopted FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) effective December 31, 2016, which requires the Company to make certain disclosures if it concludes that there is substantial doubt about the entity's ability to continue as a going concern within one year from the date of the issuance of these financial statements. In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of December 31, 2016, the Company had an accumulated deficit of \$252,389,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$36,096,000 at December 31, 2016, expected revenues and the net proceeds from its "at-the-market" program will be sufficient to allow the Company to fund its current operations until approximately September 30, 2017. The Company will seek additional sources of funding in the form of debt financing or equity issuances. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these financial statements. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding. Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**1. Organization (Continued)**

material adverse change clause in the Term Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of borrowings at December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

**Public Offerings**

In January 2015, the Company issued and sold 125,000 shares of its common stock in its initial public offering ("IPO") at a public offering price of \$520.00 per share, for net proceeds of approximately \$56,897,000 after deducting underwriting discounts and commissions of approximately \$4,550,000 and expenses of approximately \$3,553,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 174,028 shares of common stock resulting in the reclassification of \$137,626,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to \$150,000,000 of its securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company ("Cowen"), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, the Company sold 27,374 shares of common stock under the "at-the-market" program at an average price of \$194.74 and raised net proceeds of \$5,171,000, after payment of \$160,000 in commissions and fees to Cowen. In August 2016, the Company issued and sold 246,445 shares of its common stock in its follow-on public offering, which includes the exercise in full by the underwriters of their option to purchase 32,145 shares of common stock, at a public offering price of \$140.00 per share. Net proceeds from the follow-on public offering were approximately \$31,549,000 after deducting underwriting discounts and commissions of approximately \$2,415,000 and expenses of approximately \$538,000.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

On January 14, 2015, the Company's Board of Directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-45 reverse stock split of the Company's common stock and convertible preferred stock. The par value of the common stock and convertible preferred stock was not adjusted as a result of the reverse stock split. All common stock, convertible preferred stock, stock options and warrants, and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split. The reverse stock split was effected on January 28, 2015.

The financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC").

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuation of the common stock warrants, the valuation of compound embedded derivatives, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

**Fair Value of Financial Instruments**

The Company has evaluated the estimated fair value of its financial instruments as of December 31, 2016 and 2015. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the borrowings approximate their fair value. Fair value accounting was applied to the warrant liabilities and embedded derivatives. No warrant liabilities or embedded derivatives were outstanding as of December 31, 2016 and 2015.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of December 31, 2016 and 2015, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit). There were no unrealized gains and losses as of December 31, 2016 and 2015. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

**Restricted Cash**

At December 31, 2014, a deposit of \$255,000 was restricted from withdrawal. The restricted cash secured obligations of the Company associated with its corporate credit card. The restricted deposit account was included in prepaid expenses and other current assets. During 2015, the Company was no longer required to secure its corporate card obligations. The release of the restriction against the Company's cash was included within investing activities on its statement of cash flows for the year ended December 31, 2015.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Concentration of Credit Risk, and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the balance sheets.

The Company's policy is to invest in cash and cash equivalents, consisting of money market funds. These financial instruments are held in Company accounts at one financial institution. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing.

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at December 31, 2016 and 2015.

The Company's accounts receivable are due from a variety of health care organizations in the United States and select international markets. At December 31, 2016 and 2015, there were none and one, respectively, of the Company's customers that represented 10% or more of the Company's accounts receivable. For the years ended December 31, 2016, 2015 and 2014, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

The Company manufactures its commercial products in-house, including Pantheris and the Ocelot family of catheters. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payors to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this may have a material adverse impact on the Company.

**Accounts Receivable**

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

in the Company's existing accounts receivable. The Company determines the allowance for doubtful accounts based upon an aging of accounts receivable, historical experience, and management judgment. Accounts receivable balances are reviewed individually for collectability. To date, the Company has not experienced significant credit-related losses.

**Inventories**

Inventories are valued at the lower of cost or market. Cost is determined using the first-in, first-out method for all inventories. The Company's policy is to write down inventory that has expired or become obsolete, inventory that has a cost basis in excess of its expected net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on the estimates of future demand for a particular product. If the estimate of future demand is too high, the Company may have to increase the reserve for excess inventory for that product and record a charge to the cost of revenues. Inventory used in clinical trials is expensed at the time of production and recorded as research and development expense.

**Property and equipment**

Property and equipment are recorded at cost. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets of three to five years. Depreciation expense includes the amortization of assets acquired under capital leases and equipment located at customer sites. Equipment held by customers is comprised of the Lightboxes located at customer sites under a lease or placement agreement and are recorded at cost. Upon execution of a lease or placement agreement, the related equipment is reclassified from inventory to the property and equipment account. Depreciation expense for equipment held by customers is recorded as a component of cost of revenues. Leasehold improvements and assets recorded under capital leases are amortized using the straight-line method over the shorter of the lease term or estimated useful economic life of the asset.

**Deferred Offering Costs**

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to an offering of equity securities, were capitalized. As of December 31, 2016, there were no deferred offering costs capitalized in other assets on the balance sheet. Deferred offering costs of \$29,000 were capitalized as of December 31, 2015.

**Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived asset exceeds its fair value. The Company has not recorded any impairment of long-lived assets since inception through December 31, 2016.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Convertible Preferred Stock**

Prior to its IPO the Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs and classified the convertible preferred stock outside of stockholders' equity (deficit) on the balance sheets as events triggering the liquidation preferences were not solely within the Company's control. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 174,028 shares of common stock resulting in the reclassification of \$137,626,000 from outside of stockholders' equity (deficit) to additional paid-in capital.

**Warrant Liability and Embedded Derivative Instruments**

The Company accounts for its warrants for shares of common stock in accordance with the accounting guidance for derivatives. The accounting guidance provides a two-step model to be applied in determining whether a financial instrument is indexed to an entity's own stock and, therefore, qualifies for a scope exception. The two-step model requires a contract for a financial instrument to be both (1) indexed to the entity's own stock and (2) classified in the stockholders' equity (deficit) section of the balance sheet. If a financial instrument qualifies for a scope exception, it would not be considered a derivative financial instrument.

As the price per share of the common stock warrants issued with the convertible notes was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, these warrants were initially classified as a derivative liability. As a derivative liability, the warrants were initially recorded at fair value and were subject to remeasurement at each balance sheet date until September 2014. Any change in fair value as a result of a remeasurement was recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. The Company re-evaluated the terms of the common stock warrants issued with the convertible notes after the issuance of the Series E Convertible Preferred Stock in September 2014 and determined that they then met the first criterion of the two-step model. Accordingly, the associated current fair value of the warrant liability was reclassified to additional paid-in capital in the stockholders' equity (deficit) section of the balance sheet at that time, thus satisfying the second criterion of the two-step model.

The Company issued convertible notes in 2013 and 2014 that included features which were determined to be embedded derivatives requiring bifurcation and separate accounting. Prior to their extinguishment in September 2015, the Company recorded a compound derivative asset or liability related to redemption features embedded within its outstanding convertible notes. The embedded derivatives were initially recorded at fair value and are subject to remeasurement as of each balance sheet date. Any change in fair value is recognized as a component of other income (expense), net in the statements of operations and comprehensive loss. In September 2015, the Company repaid the outstanding convertible notes and accrued interest obligations in their entirety. Accordingly, the associated current fair value of the embedded derivative asset was expensed as a component of other income (expense), net in the statements of operations and comprehensive loss at that time.

**Revenue Recognition**

The Company's revenues are derived from (1) sale of its Lightbox (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company



Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

recognizes revenue in accordance with Accounting Standards Codification ("ASC") 605-10, Revenue Recognition, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement.

The Company's revenue recognition policies generally result in revenue recognition at the following points:

1. Lightbox sales: The Company sells its products directly to hospitals and medical centers. Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form by the customer acknowledging that the training and installation process is complete.
2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.
3. Service revenue: Service revenue is recognized ratably over the term of the service period. To date service revenue has been insignificant.

The Company offers its customers the ability to purchase or lease its Lightbox. In addition, the Company provides a Lightbox under a limited commercial evaluation program to allow certain strategic accounts to install and utilize the Lightbox for a limited trial period of three to six months. When a Lightbox is placed under a lease agreement or under a commercial evaluation program, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these placed Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these placed Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in ASC 840, *Leases* and ASC 605-25, *Revenue Recognition Multiple Element Arrangements*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price of the deliverables, using a specific hierarchy. The hierarchy is as follows: vendor-specific objective evidence of fair value of the respective elements, third-party evidence of selling price, or best estimate of selling price ("BESP"). The Company allocates arrangement consideration using BESP.

The Company assessed whether the embedded lease is an operating lease or sales-type lease. Based on the Company's assessment of the guidance and given that any payments under the lease agreements are dependent upon contingent future sales, it was determined that collectability of the minimum lease payments is not reasonably predictable. Accordingly, the Company concluded the embedded lease did not meet the criteria of a sales-type lease and accounts for it as an operating lease. The Company recognizes revenue allocated to the lease as the contingent disposable product purchases are delivered and are included in revenues within the statement of operations and comprehensive loss.

For sales through distributors, the Company recognizes revenue when title to the product and the risk of loss transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

The Company estimates reductions in revenue for potential returns of products by customers. In making such estimates, management analyzes historical returns, current economic trends and changes in customer demand and acceptance of its products. The Company expenses shipping and handling costs as incurred and includes them in the cost of revenues. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

**Cost of Revenues**

Cost of revenues consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of the Company's cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of revenues also includes depreciation expense for the Lightboxes under lease agreements and certain direct costs such as shipping costs.

**Product Warranty Costs**

The Company typically offers a one-year warranty for parts and labor on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. Warranty costs are reflected in the statement of operations and comprehensive loss as a cost of revenues. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Warranty provisions and claims are summarized as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Balance beginning of year	\$ 70	\$ 167	\$ 105
Warranty provision	1,048	70	140
Usage/Release	(609)	(167)	(78)
Balance end of year	\$ 509	\$ 70	\$ 167

**Research and Development**

The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with pre-clinical and clinical development activities, and costs for prototype products that are manufactured prior to market approval for that prototype product; internal and external costs associated with the Company's regulatory compliance and quality assurance functions, including the costs of outside consultants and

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

contractors that assist in the process of submitting and maintaining regulatory filings; and overhead costs, including allocated facility and related expenses.

**Clinical Trials**

The Company accrues and expenses costs for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services.

**Advertising Costs**

The Company expenses advertising costs as incurred. Advertising costs include design and production costs, including website development, physician and patient testimonial videos, written media campaigns, and other items. Advertising costs of approximately \$526,000, \$515,000 and \$720,000 were expensed during the years ended December 31, 2016, 2015 and 2014, respectively.

**Common Stock Valuation and Stock-Based Compensation**

Stock-based compensation for the Company includes amortization related to all stock options, restricted stock units ("RSUs") and shares issued under the employee stock purchase plan, based on the grant-date estimated fair value. The fair value of stock options is estimated on the date of grant using the Black-Scholes option pricing model and recognized as expense on a straight-line basis over the vesting period of the award. The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. Because noncash stock-based compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. The Company estimates a forfeiture rate for its stock options and RSUs based on an analysis of its actual forfeiture experience and other factors. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

Prior to the Company's IPO in January 2015, the fair value of the Company's common stock was determined by its Board of Directors with assistance from management and third-party valuation specialists. Management's approach to estimate the fair value of the Company's common stock is consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. Management considered several factors to estimate enterprise value, including significant milestones that would generally contribute to increases in the value of the Company's common stock. Following the closing of the Company's IPO, the fair value of its common stock is determined based on the closing price of its common stock on The NASDAQ Global Market.

**Foreign Currency**

The Company records net gains and losses resulting from foreign exchange transactions as a component of foreign currency exchange losses in other income (expense), net. During the years ended

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

December 31, 2016, 2015 and 2014, the Company recorded \$12,000, \$18,000 and \$21,000 of foreign currency exchange net losses, respectively.

**Income Taxes**

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense when they occur. During the years ended December 31, 2016, 2015 and 2014, the Company did not recognize accrued interest or penalties related to unrecognized tax benefits.

**Net Loss per Share Attributable to Common Stockholders**

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. For the computation of net loss per share attributable to common stockholders, common stock shares subject to repurchase of none, none and 14 were excluded from the calculations as of December 31, 2016, 2015 and 2014, respectively. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

Prior to its IPO in January 2015, the Company calculated its basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for companies with participating securities. The shares of the Company's convertible preferred stock participated in any dividends declared by the Company and were therefore considered to be participating securities. The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company.

Net loss per share attributable to common stockholders was determined as follows (in thousands, except per share data):

	<b>Year Ended December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
Net loss	\$ (56,128)	\$ (47,344)	\$ (31,964)
Adjustment to net loss resulting from convertible preferred stock modification		(2,384)	
Net loss attributable to common stockholders	\$ (56,128)	\$ (49,728)	\$ (31,964)
Weighted average common stock outstanding	414	284	6
Net loss attributable to common stockholders per share, basic and diluted	\$ (135.57)	\$ (175.10)	\$ (5,327.33)

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

In addition to the outstanding convertible notes as of December 31, 2014 (Note 8), the following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an antidilutive impact due to losses reported:

	December 31,		
	2016	2015	2014
Convertible preferred stock outstanding			131,393
Common stock options	92,509	83,445	75,076
Unvested restricted stock units	5,355	2,271	
Common stock warrants	53,715	54,748	43,925
	151,579	140,464	250,394

**Comprehensive Loss**

For the years ended December 31, 2016, 2015 and 2014, there was no difference between comprehensive loss and the Company's net loss.

**Segment and Geographical Information**

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the years ended December 31, 2016, 2015 and 2014, 96%, 98% and 99%, respectively, of the Company's revenues, were in the United States, based on the shipping location of the external customer.

**Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB"), jointly with the International Accounting Standards Board, issued a comprehensive new standard on recognition from contracts with customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company currently plans to adopt this accounting standard in the first quarter of fiscal year 2018 using the modified retrospective approach, with the cumulative effect being recorded within retained earnings on January 1, 2018. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

obtain or fulfill a contract. The Company has not completed its assessment of the adoption on its financial statements.

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in the standard should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02), which increases transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, using a modified retrospective approach, and early adoption is permitted. The Company is evaluating the impact of the adoption of this standard on its financial statements. The Company does expect that the adoption will increase its lease assets and correspondingly increase its lease liabilities.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee share-based payments, including income tax consequences, application of award forfeitures to expense, classification on the statement of cash flows, and classification of awards as either equity or liabilities. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company plans to adopt this new standard on January 1, 2017 and do not expect a material impact on its financial statements given the full valuation allowance position on its deferred tax assets.

**3. Fair Value Measurements**

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****3. Fair Value Measurements (Continued)**

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of December 31, 2016 and 2015, cash equivalents were all categorized as Level 1 and consisted of money market funds. In connection with the convertible notes issuances in 2013 and 2014 (Note 8), the Company issued warrants to purchase shares of its common stock. As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date until September 2014. The convertible notes also contained redemption features which were determined to be a compound embedded derivative which, prior to their extinguishment in September 2015, required fair value accounting. The common stock warrant liability and embedded derivatives in the convertible notes were categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Any change in fair value is recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss.

There were no transfers between fair value hierarchy levels during the years ended December 31, 2016, 2015 and 2014.

***Common Stock Warrant Liability***

As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date. Contemporaneous with the Series E Convertible Preferred Stock issuance, the Company determined that these common stock warrants met the requirements for equity classification and the current fair value of the common stock warrant liability was reclassified to additional paid-in capital. Subsequent to September 2014, there were no changes in fair value. The following table sets forth a summary of the changes in the estimated fair value of the Company's common stock warrant liability, which represents a financial instrument classified as Level 3. Accordingly, the expense in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Fair value beginning of year	\$	\$	\$ (6)
Issuance of warrants			
Change in fair value recorded in other income (expense), net			(28)
Reclass of warrant liability to additional paid-in capital			34
Fair value end of year	\$	\$	\$

The fair value of the common stock warrants liability was determined by using an option pricing model to allocate the total enterprise value to the various securities within the Company's capital structure. The model's inputs reflect assumptions that market participants would use in pricing the

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****3. Fair Value Measurements (Continued)**

instrument in a current period transaction. The following table summarizes these various assumptions as of September 2, 2014, the date the price per share of the common stock warrants was fixed:

	<b>September 2, 2014</b>
Time to liquidity (years)	0.7
Expected volatility	45%
Discounted cash flow rate	23%
Risk-free interest rate	0.07%
Marketability discount rate	17%

The time to liquidity input was based on the Company's estimate of when potential liquidity could be provided to stockholders. The volatility factor was based on the average historic price volatility for publicly-traded industry peers. The discounted cash flow rate takes into consideration a company specific risk premium, market risk premium and an assumed risk free rate of return. The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities similar to the time to liquidity. The marketability discount is used to reflect that private company securities are generally less liquid than the securities of a public company. These assumptions are inherently subjective and involve significant management judgment. Generally, increases (decreases) in the fair value of the underlying common stock would result in a directionally similar impact to the fair value measurement. Subsequent to September 2014, there were no changes in fair value.

***Embedded Derivatives in Convertible Notes***

The following table sets forth a summary of the changes in the estimated fair value of the Company's compound embedded derivative associated with its convertible notes, which represent a financial instrument classified as Level 3. Upon the extinguishment of the convertible notes in September 2015, the fair value of the compound embedded derivatives at the date of extinguishment was expensed to other income (expense), net. The income (expense) in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
Fair value of asset (liability) beginning of year	\$	\$ 231	\$ (175)
Issuance of convertible notes			
Change in fair value recorded in other income (expense), net		835	406
Reversal of fair value recorded in other income (expense), net		(1,066)	
Fair value of asset (liability) end of year	\$	\$	\$ 231

Through December 31, 2014, the Company determined the value of the compound derivative utilizing a Monte Carlo Simulation model. The inputs used to determine the estimated fair value of the derivative instrument include the probability of an underlying event triggering the embedded derivative occurring and its timing. The fair value measurement is based upon significant inputs not observable in



Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****3. Fair Value Measurements (Continued)**

the market. The inputs included the probability that the Company would need to raise additional equity in 2014, as well as various financing and exit events in 2015. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions as of December 31, 2014:

	<b>Year Ended December 31, 2014</b>
Equity financing in 2014	100.0%
Equity financing in 2015	14.3%
Liquidation	0.1%
Initial public offering	79.5%
Change of control	6.2%

Subsequent to the Company's IPO and through the extinguishment of the convertible notes on September 22, 2015, the value of the compound derivative was determined utilizing a Black-Derman-Toy model. The inputs used to determine the estimated fair value of the derivative instrument include the term structure of yields which are observed in the market, the credit spread, which was estimated by the Company, and the volatility, which was estimated using an analysis of comparable bonds in the market. The fair value measurement is based upon significant inputs not observable in the market. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions as of September 22, 2015, the date of extinguishment:

	<b>September 22, 2015</b>
Time to first call option (years)	
Credit spread	17.6%
Expected volatility	40.0%

***Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis***

The Company measures certain non-financial assets (including property, plant and equipment) at fair value on a non-recurring basis in periods after initial measurement in circumstances when the fair value of such asset is impaired below its recorded cost.

**4. Inventories**

Inventories consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
Raw materials	\$ 5,706	\$ 2,662
Work-in-process		372
Finished products	2,756	2,371
Total inventories	\$ 8,462	\$ 5,405

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****5. Property and Equipment, Net**

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2016	2015
Computer software	\$ 456	\$ 436
Computer equipment	1,268	1,096
Machinery and equipment	4,313	3,372
Furniture and fixtures	636	578
Leasehold improvements	679	655
Equipment held by customers	3,475	1,718
	10,827	7,855
Less: Accumulated depreciation and amortization	(6,389)	(5,044)
Add: Construction-in-progress	117	11
	\$ 4,555	\$ 2,822

Depreciation expense for the years ended December 31, 2016, 2015 and 2014, was \$1,506,000, \$1,300,000 and \$1,451,000, respectively. Amortization of capital leased assets included in depreciation for the years ended December 31, 2016, 2015 and 2014, was \$11,000, \$17,000 and \$17,000, respectively. Property and equipment includes certain equipment that is leased to customers and located at customer premises. The Company retains the ownership of the leased equipment and has the right to remove the equipment if it is not being utilized according to expectations. Depreciation expense relating to the leased equipment held by customers of \$539,000, \$260,000 and \$378,000, was recorded in cost of revenues during the years ended December 31, 2016, 2015 and 2014, respectively. The net book value of this equipment was \$2,587,000 and \$1,236,000 at December 31, 2016 and 2015, respectively.

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2016	2015
Accrued interest payable	\$ 1,220	\$ 1,220
Accrued professional services	43	563
Accrued travel expenses	429	550
Accrued sales, use and other taxes	40	82
Accrued warranty	509	70
Sales return allowance	43	59
Accrued clinical trial costs	134	55
Other accrued liabilities	649	686
	\$ 3,067	\$ 3,285

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****7. Borrowings***CRG*

On September 22, 2015, the Company entered into a Term Loan Agreement (the "Loan Agreement") with CRG under which, subject to certain conditions, the Company may borrow up to \$50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed \$30,000,000 on September 22, 2015. The Company borrowed an additional \$10,000,000 on June 15, 2016 under the Loan Agreement. The Company would have been eligible to borrow an additional \$10,000,000, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions, but those milestones were not achieved. Under the Loan Agreement, the first sixteen quarterly payments are interest only payments, and the last eight quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 12.5% per annum. The Company makes quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, the Company may elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind ("PIK") for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the borrowings. To date, the Company has elected the PIK interest option to the extent available and has made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amounts borrowed plus any PIK is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company's assets. The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that the Company maintain a minimum of \$5,000,000 of cash and certain cash equivalents, and the Company had to achieve minimum revenue of \$7,000,000 in 2015, and must achieve minimum revenue of \$23,000,000 in 2016, \$40,000,000 in 2017, \$50,000,000 in 2018, \$60,000,000 in 2019 and \$70,000,000 in 2020 and in each year thereafter, as applicable. On October 28, 2016, the Company amended the terms of the Loan Agreement, to reduce the minimum revenue that the Company must achieve in 2016 to \$18,000,000. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of

Table of Contents

## AVINGER, INC.

## Notes to Financial Statements (Continued)

## 7. Borrowings (Continued)

the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of December 31, 2016, the Company was in compliance with all applicable covenants.

As of December 31, 2016, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,	Principal and PIK Loan Repayments
2017	\$
2018	
2019	10,000
2020	20,000
2021	10,000
	40,000
Add: Accretion of closing fees	399
Add: PIK	1,809
	42,208
Less: Amount representing debt financing costs	(919)
<b>Borrowings</b>	<b>\$ 41,289</b>

Contemporaneous with the execution of the Loan Agreement, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with CRG which allowed it to purchase up to \$5,000,000 of the Company's common stock. CRG purchased 8,705 shares of common stock on September 22, 2015 at a price of \$574.38 per share, which is the 10-day average of closing prices of the Company's common stock ending on September 21, 2015. The closing price on September 22, 2015 was \$558.80 yielding a \$15.58 per share premium. Both the premium and the issuance costs were allocated to the borrowings under Loan Agreement and the common stock purchase under the Securities Purchase Agreement based on the relative fair values of each security. The portion of the premium allocated to the borrowings is being amortized over the term of the Loan Agreement. Pursuant to the Securities Purchase Agreement, the Company filed a shelf registration statement covering, among other things, the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

In connection with the initial drawdown under the Loan Agreement, the Company recorded a debt discount of \$876,000. The debt discount comprised financing fees of \$450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and Securities Purchase Agreement with CRG of \$541,000 net of the common stock premium of \$115,000 based on the relative fair values of each security. In connection with the June 2016 drawdown under the Loan Agreement, the Company recorded a debt discount of \$275,000 which comprised financing fees of \$150,000, paid directly to CRG, and other costs directly attributable to the Loan Agreement with CRG of \$125,000. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of December 31, 2016 and 2015, the balance of the aggregate debt discount was \$919,000 and \$834,000, respectively.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**7. Borrowings (Continued)**

As noted in Note 1 to these financial statements, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the CRG Loan Agreement, the entire amount of borrowings at December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

*PDL BioPharma*

On April 18, 2013, the Company entered into a Credit Agreement ("Agreement") with PDL BioPharma, Inc. ("PDL") whereby PDL agreed to loan up to \$40,000,000. Contemporaneous with the execution of the Agreement the Company borrowed an initial \$20,000,000 ("Term Note").

The Term Note was scheduled to mature April 18, 2018, had a stated interest rate of 12.0% per annum and could be prepaid by the Company at any time. The Company paid interest-only through the first ten quarters and, thereafter, repayment of principal in equal installments including accrued and unpaid interest, payable each quarter. As provided under the terms of the Agreement, for the first eight quarterly interest payments, or through 2015, on the Term Note the Company elected to convert an amount of interest, up to 1.5% per annum, into additional loans, referred to as PIK loans. The PIK loans accrued interest and were added to the aggregate principal balance of the Term Note.

In September 2015, in connection with the consummation of the Loan Agreement with CRG, the Company repaid all amounts outstanding under the Agreement. The payoff amount of \$21,363,000 included accrued interest through the repayment date of \$563,000 and \$200,000 as an end-of-term final payment fee recorded in other income (expense), net on the statement of loss and comprehensive loss. For the years ended December 31, 2016, 2015 and 2014, the Company incurred interest expense of \$380,000, \$2,785,000 and \$3,380,000, respectively.

In addition to the interest and principal payments, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company's quarterly net revenues. Upon the prepayment of the Term Note, the Company's obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable monthly. The ongoing obligation was determined to be an embedded element of the Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interests obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2016, was used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. At the time of the repayment the resulting increase in the carrying value of the Assigned Interests, of \$942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interests obligations of \$1,463,000 and \$2,303,000, representing the net present value of the future minimum royalty obligation as of December 31, 2016 and 2015, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities and within other long-term liabilities as of December 31, 2016 and 2015, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion on the balance sheet.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**7. Borrowings (Continued)**

Additionally, until April 2018, the Company must periodically pay PDL a percentage of its net revenue and comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company was in compliance with the covenants under the Agreement as of December 31, 2016.

**8. Convertible Notes**

On October 29, 2013, the Company entered into a Note and Warrant Purchase Agreement (the "Convertible Note Agreement"), as amended in May 2014, with certain existing convertible preferred stockholders, third-parties and employees for the issuance of convertible notes for up to an aggregate principal amount of \$25,000,000. Under the terms of the Convertible Note Agreement, the Company issued convertible notes in October and November 2013 for total proceeds of \$13,472,000, and in May and July 2014 for additional total proceeds of \$4,720,000. The Company was required to pay interest on these convertible notes at a rate of 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20%. The notes will mature and the accrued interest thereon would have become payable upon the earlier of: (i) October 29, 2018, (ii) an event of default, or (iii) a change of control event.

The principal and accrued interest on the notes were convertible, at the option of the holder, upon a future issuance of the Company's convertible preferred stock or common stock (the "Equity Financing") into that same stock at a conversion price equal to 85% of the price paid by other investors in the financing event. For holders who elected not to convert their notes upon the closing of the Company's Series E Preferred Stock financing or upon its IPO, the Company may repay the holder, at its sole election, a payment equal to the greater of (i) 125% of the outstanding principal and accrued and unpaid interest, or (ii) the amount providing the investor with a 20% minimum internal rate of return, at any time prior to their maturity date.

In conjunction with the issuance of the convertible notes, the Company issued warrants to purchase up to the number of shares of common stock equal to 15% of the principal amount of the convertible notes divided by an exercise price per share equal to the lesser of \$1,566.00 per share, or the price per share paid by the investors in the first bona fide preferred stock financing subsequent to the date of the convertible notes. Upon the Series E Convertible Preferred Stock issuance in September 2014, the exercise price per share was fixed at \$504.00 per share and the Company issued warrants to purchase a total of 5,413 shares of common stock. The warrants, which were immediately exercisable, expired upon the closing of the Company's IPO. The estimated fair value of the warrants upon issuance, of \$1,000, was based on an option pricing model. The Company recorded the fair value of the warrants at issuance as a debt discount and as a warrant liability. The debt discount was accreted using the effective interest method as additional interest expense over the term of the convertible notes. Immediately prior to the closing of the Company's IPO, 3,732 of the warrants to purchase common stock were net exercised, 610 of the warrants to purchase common stock were exercised and the remaining balance of 1,071 warrants to purchase common stock expired.

The convertible notes have redemption features that were determined to be compound embedded derivatives requiring bifurcation and separate accounting. The fair value of the compound embedded derivative upon issuance was determined to be a liability of \$179,000. The fair value of these derivative instruments was recognized as an additional discount and as a derivative liability on the balance sheets

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****8. Convertible Notes (Continued)**

upon issuance of the convertible notes. The compound embedded derivative associated with the convertible notes required periodic re-measurements to fair value while the instruments are still outstanding. In September and November 2014, in connection with the issuance of the Series E Convertible Preferred Stock, \$11,582,000 of the outstanding convertible notes and accrued interest thereon was converted into shares of Series E Convertible Preferred Stock (Note 11). Upon the conversion of the convertible notes, the Company recorded a net loss from the extinguishment of the debt in the amount of \$1,234,000 which is reflected in other income (expense), net in the statement of operations and comprehensive loss.

In September 2015, in connection with the consummation of the Loan Agreement, the Company repaid all amounts outstanding under the convertible notes. The carrying value of the convertible notes and accrued interest was \$9,867,000 prior to payoff. The Company recorded a loss on extinguishment of the convertible notes of \$86,000 as a component of other income (expense), net, on the statements of operations and comprehensive loss.

The Company's interest expense associated with the convertible notes amounted to none, \$1,230,000 and \$2,633,000 during the years ended December 31, 2016, 2015 and 2014, respectively, based on the minimum internal rate of return of 20%.

**9. Capital Leases**

Capital lease obligations consist of leased office equipment. As of December 31, 2016 and 2015, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is \$39,000 and \$39,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of December 31, 2016, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2017	\$ 26
2018	13
2019	1
Total minimum payments	40
Less: Amount representing future interest	1
Present value of minimum lease payments	\$ 39

**10. Commitments and Contingencies****Lease Commitments**

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****10. Commitments and Contingencies (Continued)**

includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In connection with the facility lease, the landlord also provided incentives of \$369,000 to the Company in the form of leasehold improvements. These amounts were reflected as deferred rent and were amortized as a reduction to rent expense over the original term of the Company's operating lease. In February 2016, the Company entered into an additional non-cancelable operating lease for warehouse and storage space that expires in November 2019. Rent expense was \$1,098,000, \$938,000 and \$922,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

The future aggregate minimum lease payments as of December 31, 2016, are as follows (in thousands):

Year ending December 31,	Future Minimum Lease Payments
2017	\$ 1,974
2018	2,033
2019	1,915
Total minimum lease payments	\$ 5,922

**Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had noncancellable commitments to suppliers for purchases totaling \$3,542,000 and \$4,347,000 as of December 31, 2016 and 2015, respectively

**Indemnification**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future, but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.



Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**10. Commitments and Contingencies (Continued)**

**Legal Proceedings**

The Company was not party to any legal proceedings at December 31, 2016 and 2015. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable.

On February 15, 2014, the Company entered into an engagement letter with a financial advisor which provided for such firm to serve as its placement agent and for the Company to make certain payments to them in connection with its Series E Convertible Preferred Stock financing. After the entry into such engagement letter, the financial advisor did not provide the level of service the Company was expecting and was not responsible for introducing the Company to any of the Series E Convertible Preferred Stock investors. In December 2014, the Company and its former financial advisor agreed to amend and to terminate their engagement letter, effective immediately. Pursuant to the terms of the amended engagement letter, the Company agreed to pay the former financial advisor a transaction fee of \$650,000, to be paid in four equal quarterly installments starting on December 31, 2014, and ending on September 30, 2015 and \$35,000 for reimbursement of the former financial advisor's out-of-pocket expenses, which were due upon execution of the amendment. The transaction fee and out-of-pocket expenses were reflected as additional Series E Convertible Preferred Stock issuance costs during the year ended December 31, 2014.

**11. Convertible Preferred Stock**

Upon the closing of the Company's IPO in February 2015, all shares of convertible preferred stock then outstanding converted into an aggregate of 174,028 shares of common stock. As of December 31, 2016 and 2015, the Company does not have any convertible preferred stock issued or outstanding.

**12. Stockholders' Equity (Deficit)**

**Preferred Stock**

At December 31, 2016, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with \$0.001 par value per share, of which no shares were issued and outstanding.

**Common Stock**

At December 31, 2016, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with \$0.001 par value per share, of which 594,321 shares were issued and outstanding.

**Common Stock Warrants**

In connection with the issuance of the Company's Series E Convertible Preferred Stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible Preferred Stock, warrants to purchase up to the number of shares of common stock equal to 50% of the number of shares of the Company's Series E Convertible Preferred Stock purchased.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**12. Stockholders' Equity (Deficit) (Continued)**

The warrants are immediately exercisable, at an exercise price per share of \$504.00, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company. The Company determined that these common stock warrants meet the requirements for equity classification. In connection with the issuance of its Series E Convertible Preferred Stock in September through December 2014, the Company issued warrants to purchase an aggregate of 33,314 shares of common stock. The common stock warrants were recorded at their allocated fair value of \$175,000 within stockholders' equity (deficit).

In connection with the issuance of the Company's Series E Convertible Preferred Stock in January 2015, the Company issued warrants to purchase an aggregate of 6,129 shares of common stock. The common stock warrants were recorded at their allocated fair value of \$804,000 within stockholders' equity (deficit).

On January 14, 2015, the Company amended its Series E Convertible Preferred Stock Purchase Agreement to provide for the issuance of common stock warrants to each investor who purchased shares of Series E Convertible Preferred Stock equal to 70% of the number of shares of the Company's Series E Convertible Preferred Stock purchased by such investor. As with the common stock warrants previously issued, any new common stock warrants were immediately exercisable, at an exercise price of \$504.00 per share, and expire upon the earlier of September 2, 2019 or upon consummation of a change in control of the Company. As a result of this amendment to the Series E Convertible Preferred Stock Purchase Agreement, the Company issued additional warrants to purchase 15,801 shares of common stock to investors who previously acquired shares of Series E Convertible Preferred Stock from September 2014 through January 2015.

As of December 31, 2016 and 2015, warrants to purchase an aggregate of 53,715 and 54,748 shares of common stock were outstanding, respectively.

The Company determined that the amendment to the Series E Convertible Preferred Stock Purchase Agreement should be accounted for as a modification. Accordingly, the incremental fair value from the modification, the additional warrants to purchase 15,801 shares of common stock warrants, of \$2,384,000, was recorded as an increase to stockholders' equity (deficit) and as an adjustment to net loss attributable to common stockholders in the Company's statement of operations and comprehensive loss for the year ended December 31, 2015. This amount represents a return to the preferred stockholders and is treated in a manner similar to the treatment of dividends paid to holders of preferred stock in the computation of earnings per share. As a result, the "deemed dividend" is subtracted from net loss available to common stockholders in reconciling net loss to net loss available for common stockholders.

**Stock Plans**

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). The 2015 Plan replaced the 2009 Stock Plan (the "2009 Plan") which was terminated immediately prior to consummation of the Company's IPO, collectively the "Plans." The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of nonstatutory stock options ("NSOs"), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 33,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan,

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****12. Stockholders' Equity (Deficit) (Continued)**

plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 42,250 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the 2015 Plan was increased by 15,804 shares of common stock. As of December 31, 2016, 24,926 shares were available for grant under the 2015 Plan.

Pursuant to the Plans, ISOs and NSOs may be granted with exercise prices at not less than 100% of the fair value of the common stock on the date of grant and the exercise price of ISOs granted to a stockholder, who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of the stock of the Company, shall be not less than 110% of the fair market value per share of common stock on the date of grant. The Company's Board of Directors determines the vesting schedule of the options. Options granted generally vest over four years and expire ten years from the date of grant.

Stock option activity under the Plans is set forth below:

	Number of Shares	Options Outstanding Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2013	9,810	\$ 645.19	\$
Options granted	67,928	\$ 187.33	
Options exercised	(59)	\$ 365.72	
Options cancelled	(2,603)	\$ 665.17	
Balance at December 31, 2014	75,076	\$ 230.47	\$ 13,188
Options granted	15,352	\$ 668.76	
Options exercised	(436)	\$ 180.61	
Options cancelled	(6,547)	\$ 384.39	
Balance at December 31, 2015	83,445	\$ 299.29	\$ 50,827
Options granted	17,468	\$ 472.18	
Options exercised	(572)	\$ 180.74	
Options cancelled	(7,832)	\$ 511.20	
Balance at December 31, 2016	92,509	\$ 314.73	\$ 5

Table of Contents

## AVINGER, INC.

## Notes to Financial Statements (Continued)

## 12. Stockholders' Equity (Deficit) (Continued)

Additional information related to the status of options as of December 31, 2016 is summarized as follows:

Options Outstanding and Vested as of December 31, 2016					
Options Outstanding			Options Vested		
Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$142.00	688	9.84	\$ 142.00		\$ 142.00
\$147.20	828	9.82	\$ 147.20		\$ 147.20
\$162.00	105	2.44	\$ 162.00	105	\$ 162.00
\$180.00	41,453	8.01	\$ 180.00	20,727	\$ 180.00
\$198.00	21,564	7.87	\$ 198.00	11,086	\$ 198.00
\$204.80	739	9.57	\$ 204.80		\$ 204.80
\$250.40	37	5.06	\$ 250.40	37	\$ 250.40
\$436.40	630	8.18	\$ 436.40	289	\$ 436.40
\$439.20	100	8.33	\$ 439.20	41	\$ 439.20
\$440.40	234	9.44	\$ 440.40		\$ 440.40
\$495.20	1,598	9.33	\$ 495.20		\$ 495.20
\$504.00	1,649	4.54	\$ 504.00	1,649	\$ 504.00
\$518.40	2,999	9.19	\$ 518.40		\$ 518.40
\$519.60	7,339	9.18	\$ 519.60	178	\$ 519.60
\$594.00	994	5.05	\$ 594.00	994	\$ 594.00
\$608.40	1,325	8.58	\$ 608.40	493	\$ 608.40
\$708.80	50	8.83	\$ 708.80	14	\$ 708.80
\$784.40	6,965	8.98	\$ 784.40	1,964	\$ 784.40
\$810.00	2,312	6.53	\$ 810.00	2,080	\$ 810.00
\$882.00	178	5.75	\$ 882.00	178	\$ 882.00
\$900.00	722	5.57	\$ 900.00	706	\$ 900.00
	92,509	8.10		40,541	\$ 294.47

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2016, 2015 and 2014 was \$219.91, \$329.37 and \$269.46 per share, respectively. As of December 31, 2016, the weighted average remaining contractual life of options outstanding and vested was 7.63 years. As of December 31, 2016, the aggregate intrinsic value of options outstanding and vested was \$0. The aggregate intrinsic value of options exercised was \$135,000, \$236,000 and none during the years ended December 31, 2016, 2015 and 2014, respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the years ended December 31, 2016, 2015 and 2014.

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****12. Stockholders' Equity (Deficit) (Continued)**

The Company's RSUs vest annually over four years in equal increments. A summary of all RSU activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Awards outstanding at December 31, 2014		\$		\$
Awarded	2,271	\$ 756.56		
Awards outstanding at December 31, 2015	2,271	\$ 756.56	3.88	\$ 2,063
Awarded	4,633	\$ 519.20		
Released	(467)	\$ 721.60		
Forfeited	(1,082)	\$ 598.40		
Awards outstanding at December 31, 2016	5,355	\$ 561.90	3.09	\$ 793

As of December 31, 2016, \$2,780,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.05 years. The Company used the closing market price of \$148.00 per share at December 31, 2016, to determine the aggregate intrinsic value.

**2015 Employee Stock Purchase Plan**

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ("ESPP") under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. Initially 12,500 shares of common stock were reserved for issuance, which is subject to an automatic increase on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 12,325 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the ESPP was increased by 4,741 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of December 31, 2016, approximately 13,596 shares of common stock remained reserved for issuance under the ESPP. The Company incurred \$372,000 and \$217,000 in stock-based compensation expense related to the ESPP for the year ended December 31, 2016 and 2015, respectively.

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****13. Stock-Based Compensation**

Stock-based compensation for the Company includes amortization related to all stock options, RSUs and shares issued under the ESPP, based on the grant-date estimated fair value. The Company estimates the fair value of stock options and shares issued under the ESPP on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company's common stock, and the volatility over the expected term of the awards. The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Prior to the Company's IPO in January 2015, due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, stage of development, risk profile, and position within the industry as well as selecting companies with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the share-based payments. Following the closing of the Company's IPO, the Company supplements its own available company specific historical volatility with the volatility of the previously selected peer group of publicly traded companies. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options. The expected dividend assumption is based on the Company's history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

As noncash stock-based compensation expense recognized in the financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The Company estimates a forfeiture rate for its stock options and RSUs based on an analysis of its actual forfeitures based on actual forfeiture experience and other factors. Forfeitures are estimated at the time of grant and revised, if necessary, over the service period to the extent that actual forfeitures differ, or are expected to differ, from prior estimates. Forfeitures are estimated based on estimated future employee turnover and historical experience. The fair value for the Company's employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following average assumptions:

	<b>Year Ended December 31,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
Expected term (years)	6.1	6.3	6.3
Expected volatility	49.7%	49.8%	59.1%
Risk-free interest rate	1.5%	1.8%	1.8%
Dividend rate			

F-34

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****13. Stock-Based Compensation (Continued)**

As of December 31, 2016 and 2015, the total unamortized compensation expense related to stock options granted to employees and directors was \$12,312,000 and \$16,871,000, which is expected to be amortized over the next 2.33 and 3.15 years, respectively.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following assumptions:

	Year Ended December 31,	
	2016	2015
Expected term (years)	0.5	0.5
Expected volatility	72.1%	46.2%
Risk-free interest rate	0.41%	0.17%
Dividend rate		

The Company measures the fair value of RSUs using the closing stock price of a share of the Company's common stock on the grant date and is recognized as expense on a straight-line basis over the vesting period of the award. The total fair value of shares vested pursuant to RSUs in the year ended December 31, 2016 and 2015 was \$486,000 and zero, respectively. As of December 31, 2016, total unamortized stock-based compensation expense related to unvested RSUs was \$2,780,000, with a weighted-average remaining recognition period of 3.05 years.

Total noncash stock-based compensation expense relating to the Company's stock options, ESPP and RSUs recognized, before taxes, during the years ended December 31, 2016, 2015 and 2014, is as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Cost of revenues	\$ 608	\$ 346	\$ 55
Research and development expenses	2,732	2,489	155
Selling, general and administrative expenses	4,052	3,064	431
	\$ 7,392	\$ 5,899	\$ 641

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****14. Income Taxes**

For the years ended December 31, 2016, 2015 and 2014, the Company's provision for income taxes consisted of state income tax expense of none, none and \$14,000, respectively. A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Tax at federal statutory rate	\$ (19,077)	\$ (16,905)	\$ (10,863)
State taxes, net of federal benefit			14
Permanent differences	1,023	1,722	730
Change in valuation allowance	18,321	15,250	10,316
Research credits	(245)	(218)	(219)
Other	(22)	151	36
<b>Provision for taxes</b>	<b>\$</b>	<b>\$</b>	<b>\$ 14</b>

Significant components of the Company's net deferred tax assets as of December 31, 2016 and 2015 consist of the following (in thousands):

	As of December 31,	
	2016	2015
Deferred tax assets:		
Federal, state, and foreign net operating losses	\$ 82,353	\$ 64,739
Research and other credits	2,953	2,521
Fixed assets	623	215
Interest	581	899
Accruals and other	4,906	2,810
<b>Total deferred tax assets</b>	<b>91,416</b>	<b>71,184</b>
Less: Valuation allowance	(91,416)	(71,184)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

The valuation allowance increased by \$20,232,000, 15,076,000 and \$12,193,000 during the years ended December 31, 2016, 2015 and 2014, respectively.

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately \$219,087,000, which begin to expire in 2027, and state net operating loss carryforwards of approximately \$161,812,000, which begin to expire in 2017.

As of December 31, 2016, the Company had federal research and development credit carryforwards of approximately \$2,469,000, which expire in the years 2027 through 2035, and state research and development credit carryforwards of approximately \$2,651,000. The state research and development credit can be carried forward indefinitely.

Federal and state tax laws impose substantial restrictions on the utilization of the net operating loss, and credit carryforwards in the event of an ownership change as defined in Section 382 of the Internal Revenue Code. Accordingly, the Company's ability to utilize these carryforwards may be





Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****14. Income Taxes (Continued)**

limited as a result of such ownership change. Such a limitation could result in the expiration of carryforwards before they are utilized.

The Company had unrecognized tax benefits of approximately \$1,536,000 and \$3,902,000, as of December 31, 2016 and 2015, of which \$1,266,000 and \$2,792,000, respectively, would affect the effective tax rate if recognized, before consideration of the valuation allowance.

A reconciliation of the unrecognized tax benefits from January 1, 2014 through December 31, 2016 is as follows (in thousands):

	As of December 31,		
	2016	2015	2014
Balance at beginning of year	\$ 3,902	\$ 1,121	\$ 919
Increase/decrease based on the tax positions in the current year	(2,593)	2,593	202
Additions for tax positions of prior years	227	188	
Balance at end of year	\$ 1,536	\$ 3,902	\$ 1,121

The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next twelve months for items that arise in the ordinary course of business. The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. In the normal course of business, the Company is subject to examination by taxing authorities throughout the nation. The Company is not currently under audit by the Internal Revenue Service or other similar state and local authorities. All tax years remain open to examination by major taxing jurisdictions to which the Company is subject.

**15. Related-Party Transactions**

During the years ended December 31, 2016, 2015 and 2014, the Company purchased marketing services from Recreation, Inc., a brand strategy and design agency headquartered in San Francisco, California for \$697,000, \$1,016,000 and \$984,000, respectively. John D. Simpson, the Company's Senior Vice President of Sales, was the Chief Executive Officer of Recreation, Inc. until March 2015 and is the son of Dr. John B. Simpson, the Company's founder and the Executive Chairman of the Board of Directors. As of December 31, 2016 and 2015, amounts due to Recreation, Inc., included in accounts payable and accrued liabilities, were \$6,000 and \$76,000, respectively.

From October 2013 through July 2014, the Company entered into convertible notes with certain investors, including existing stockholders, some members of the Board of Directors and their affiliated companies and some members of management for a total aggregate principal amount of \$18,192,000 (Note 8) and issued warrants to purchase shares of the Company's common stock at an exercise price of \$504.00 per share. The issuance of \$5,122,000 of the total aggregate principal amount of the convertible notes was considered a related-party transaction. In September 2015, the Company repaid all amounts outstanding under the convertible notes. As of December 31, 2016 and 2015, the carrying value of the related-party convertible notes was none. For the years ended December 31, 2016, 2015 and 2014, the Company recognized none, \$388,000 and \$1,021,000, respectively, of interest expense related to the related-party convertible notes within interest expense in the Company's statements of operations and comprehensive loss.

Table of Contents

**AVINGER, INC.**

**Notes to Financial Statements (Continued)**

**15. Related-Party Transactions (Continued)**

In April 2015, the Company entered into an agreement with Chansu Consulting, LLC ("Chansu") to provide consulting services related to regulatory affairs. The General Partner of Chansu is the son-in-law of Dr. John B. Simpson, the Company's founder and the Executive Chairman of the Board of Directors. For the year ended December 31, 2016 and 2015, Chansu provided regulatory consulting services of \$3,000 and \$17,000, respectively. As of December 31, 2016 and 2015, there were no amounts due to Chansu included in accounts payable and accrued liabilities.

In October 2015, the Company entered into an agreement with Consensys Imaging Service ("Consensys") to provide field engineers to assist the Company with the installation, service and maintenance of its Lightbox consoles. Jeffrey M. Soinski, the Company's President, Chief Executive Officer and a member of its Board of Directors is also a member of the Board of Directors of Consensys. For the year ended December 31, 2016 and 2015, Consensys provided services of \$123,000 and none, respectively. As of December 31, 2016 and 2015, amounts due to Consensys included in accounts payable and accrued liabilities, were \$20,000 and none, respectively.

**16. 401(k) Plan**

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code ("IRC") under which participants may contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. The Company may make a discretionary matching contribution to the 401(k) plan, and may make a discretionary employer contribution to each eligible employee each year. Eligible employees vest in the Company's contributions over a graded four year schedule. To date, the Company has made no contributions to the 401(k) plan.

**17. Subsequent Events**

**2015 Equity Incentive Plan**

In January 2017, the number of shares of common stock authorized for issuance under the 2015 Plan was automatically increased by 29,720 shares, which was ratified by the Company's Board of Directors.

**2015 Employee Stock Purchase Plan**

In January 2017, the number of shares of common stock authorized for issuance under the 2015 ESPP was automatically increased by 8,916 shares, which was ratified by the Company's Board of Directors.

**18. Reverse Stock Split**

On January 30, 2018, the Company effected a 1-for-40 reverse stock split of the Company's capital stock. As of that date, each 40 shares of issued and outstanding preferred stock, common stock and common stock equivalents were converted into one share of the respective capital stock. This reverse stock split has been retroactively reflected in the financial statements for all periods presented.

**19. Selected Quarterly Financial Information (Unaudited)**

The following table represents certain unaudited quarterly information for the eight quarters ended December 31, 2016. This data has been derived from unaudited financial statements that, in the

Table of Contents**AVINGER, INC.****Notes to Financial Statements (Continued)****19. Selected Quarterly Financial Information (Unaudited) (Continued)**

opinion of the Company's management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of such information when read in conjunction with the Company's annual audited financial statements and notes thereto appearing elsewhere in this report. These operating results are not necessarily indicative of results for any future period (in thousands, except per share data):

	Mar 31, 2016	Three Months Ended			Mar 31, 2015	Three Months Ended		
		Jun 30, 2016	Sep 30, 2016	Dec 31, 2016		Jun 30, 2015	Sep 30, 2015	Dec 31, 2015
Revenues	\$ 4,539	\$ 4,680	\$ 5,316	\$ 4,679	\$ 2,088	\$ 3,047	\$ 2,721	\$ 2,857
Gross profit	1,179	1,035	1,574	981	800	1,413	971	1,051
Operating expenses	16,208	13,328	13,005	12,945	10,225	10,496	10,847	13,357
Net loss	(16,167)	(13,496)	(12,969)	(13,497)	(12,801)	(10,220)	(13,250)	(13,456)
Net loss per share attributable to common stockholders, basic and diluted	\$ (51.16)	\$ (42.44)	\$ (29.34)	\$ (23.39)	\$ (61.25)	\$ (33.40)	\$ (43.16)	\$ (42.72)

F-39

Table of Contents

**AVINGER, INC.**  
**INDEX TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS**

Unaudited Interim Condensed Financial Statements:

<u>Condensed Balance Sheets</u>	<u>F-41</u>
<u>Condensed Statements of Operations and Comprehensive Loss</u>	<u>F-42</u>
<u>Condensed Statements of Cash Flows</u>	<u>F-43</u>
<u>Notes to Unaudited Interim Condensed Financial Statements</u>	<u>F-44</u>

F-40

---

Table of Contents

## AVINGER, INC.

## CONDENSED BALANCE SHEETS

(unaudited)

(In thousands, except share and per share data)

	September 30, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,170	\$ 36,096
Accounts receivable, net of allowance for doubtful accounts of \$123 at September 30, 2017 and \$21 at December 31, 2016	1,197	3,570
Inventories	5,046	8,462
Prepaid expenses and other current assets	880	662
<b>Total current assets</b>	<b>17,293</b>	<b>48,790</b>
Property and equipment, net	3,458	4,555
Other assets	220	212
<b>Total assets</b>	<b>\$ 20,971</b>	<b>\$ 53,557</b>
<b>Liabilities and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 841	\$ 1,607
Accrued compensation	1,401	2,807
Accrued expenses and other current liabilities	2,151	3,067
Borrowings	43,112	41,289
<b>Total current liabilities</b>	<b>47,505</b>	<b>48,770</b>
Other long-term liabilities	177	546
<b>Total liabilities</b>	<b>47,682</b>	<b>49,316</b>
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred stock issuable in series, par value of \$0.001		
Shares authorized: 5,000,000 at September 30, 2017 and December 31, 2016		
Shares issued and outstanding: none at September 30, 2017 and December 31, 2016		
Common stock, par value of \$0.001		
Shares authorized: 100,000,000 at September 30, 2017 and December 31, 2016		
Shares issued and outstanding: 788,575 at September 30, 2017 and 594,321 at December 31, 2016	1	1
Additional paid-in capital	264,465	256,629
Accumulated deficit	(291,177)	(252,389)
<b>Total stockholders' equity (deficit)</b>	<b>(26,711)</b>	<b>4,241</b>
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 20,971</b>	<b>\$ 53,557</b>

See accompanying notes.

F-41

---

Table of Contents

## AVINGER, INC.

## CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues	\$ 2,071	\$ 5,316	\$ 8,021	\$ 14,535
Cost of revenues	3,274	3,742	11,268	10,747
Gross profit (loss)	(1,203)	1,574	(3,247)	3,788
Operating expenses:				
Research and development	2,322	3,591	9,342	11,505
Selling, general and administrative	4,928	9,414	20,435	31,036
Restructuring charges	416		935	
Total operating expenses	7,666	13,005	30,712	42,541
Loss from operations	(8,869)	(11,431)	(33,959)	(38,753)
Interest income	25	27	88	88
Interest expense	(1,599)	(1,553)	(4,720)	(3,959)
Other income (expense), net		(12)	9	(7)
Net loss and comprehensive loss	\$ (10,443)	\$ (12,969)	\$ (38,582)	\$ (42,631)
Net loss per share, basic and diluted	\$ (17.23)	\$ (29.34)	\$ (64.30)	\$ (118.75)
Weighted average common shares used to compute net loss per share, basic and diluted	606	442	600	359

See accompanying notes.



Table of Contents

## AVINGER, INC.

## CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2017	2016
<b>Cash flows from operating activities</b>		
Net loss	\$ (38,582)	\$ (42,631)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,162	1,095
Amortization of debt issuance costs and debt discount	186	160
Stock-based compensation	4,197	5,301
Noncash interest expense and other charges	1,649	1,284
Loss on disposal of property and equipment	2	
Provision for doubtful accounts receivable	102	
Provision for excess and obsolete inventories	5,180	656
Changes in operating assets and liabilities:		
Accounts receivable	2,270	(2,633)
Inventories	(1,789)	(4,137)
Prepaid expenses and other current assets	(219)	(241)
Other assets	(8)	14
Accounts payable	(766)	213
Accrued compensation	(1,406)	(260)
Accrued expenses and other current liabilities	(896)	(442)
Other long-term liabilities and accrued interest	(381)	(650)
Net cash used in operating activities	(29,299)	(42,271)
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(45)	(868)
Proceeds from sale of property and equipment	4	
Net cash used in investing activities	(41)	(868)
<b>Cash flows from financing activities</b>		
Principal paydown of capital lease obligations	(19)	(21)
Proceeds from borrowings, net of issuance costs		9,725
Proceeds from public offerings, net of issuance costs	3,187	32,801
Proceeds from the issuance of common stock	246	856
Net cash provided by financing activities	3,414	43,361
Net change in cash and cash equivalents	(25,926)	222
Cash and cash equivalents, beginning of period	36,096	43,059
Cash and cash equivalents, end of period	\$ 10,170	\$ 43,281
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	\$ 3,637	\$ 3,150

Edgar Filing: Avinger Inc - Form S-1/A

Noncash investing and financing activities:

Disposal of fully depreciated property and equipment	\$	158	\$
--	----	-----	----

Transfer between inventory and property and equipment	\$	24	\$	1,806
---	----	----	----	-------

See accompanying notes.

F-43

---

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements**

**1. Organization**

**Organization, Nature of Business**

Avinger, Inc. (the "Company"), a Delaware corporation, was founded in March 2007 by cardiologist and medical device entrepreneur Dr. John B. Simpson. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease ("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. The Company manufactures and sells a suite of products in the United States ("U.S.") and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography ("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. The Company's Lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company's current products include its non-imaging catheters, Wildcat and Kittykat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion ("CTO"). In March 2016, the Company also received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for commercialization of Pantheris, the Company's image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company commenced sales of Pantheris in the U.S. and select international markets promptly thereafter. The Company is located in Redwood City, California.

**Liquidity Matters**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of September 30, 2017, the Company had an accumulated deficit of \$291,177,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of \$10,170,000 at September 30, 2017 and expected revenues will be sufficient to allow the Company to fund its current operations until approximately January 31, 2018. The Company will seek additional sources of funding in the form of debt financing or equity issuances, however, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding. Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Term Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of borrowings at September 30, 2017 and December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause. On November 3, 2017, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"),

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**1. Organization (Continued)**

pursuant to which Lincoln Park is obligated to purchase, at the Company's request, up to \$15,000,000 of the Company's common stock over a 30-month period, subject to certain limitations set forth in the Purchase Agreement. As a fee for Lincoln Park's commitment to purchase such shares, the Company issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Purchase Agreement, the Company filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement has not yet been declared effective by the SEC. To the extent more than 248,750 shares of the Company's common stock are issued to Lincoln Park pursuant to the Purchase Agreement, the Company is obligated to file additional registration statements for the resale of such shares.

**Public Offerings**

In January 2015, the Company issued and sold 125,000 shares of its common stock in its initial public offering ("IPO") at a public offering price of \$520.00 per share, for net proceeds of approximately \$56,897,000 after deducting underwriting discounts and commissions of approximately \$4,550,000 and expenses of approximately \$3,553,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 174,028 shares of common stock resulting in the reclassification of \$137,626,000 from outside of stockholders' equity to additional paid-in capital.

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to \$150,000,000 of its securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company ("Cowen"), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to \$50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the three and nine months ended September 30, 2017, the Company sold 189,684 shares of common stock through the "at-the-market" program at an average price of \$17.68 per common share and raised net proceeds of \$3,187,000, after payment of \$101,000 in commissions and fees to Cowen. During the three and nine months ended September 30, 2016, the Company sold none and 3,129 shares, respectively, of common stock through the "at-the-market" program at an average price of \$448.37 per common share and raised net proceeds of \$1,252,000, after payment of \$42,000 in commissions and fees to Cowen. Due to the SEC's "baby shelf rules," which prohibit companies with a public float of less than \$75 million from issuing securities under a shelf registration statement in excess of one-third of such company's public float in a twelve-month period, the Company is unable to issue more shares in its "at-the-market" program at this time. In August 2016, the Company issued and sold 246,445 shares of its common stock in its follow-on public offering, which includes the exercise in full by the underwriters of their option to purchase 32,145 shares of common stock, at a public offering price of \$140.00 per share. Net proceeds from the follow-on public offering were approximately \$31,549,000 after deducting underwriting discounts and commissions of approximately \$2,415,000 and expenses of approximately \$538,000.

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the SEC. The accompanying unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial information. The results for the three and nine months ended September 30, 2017, are not necessarily indicative of results to be expected for the year ending December 31, 2017, or for any other interim period or for any future year. The December 31, 2016 condensed balance sheet data has been derived from audited financial statements. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. These unaudited condensed financial statements and notes should be read in conjunction with the financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on March 14, 2017. The Company's significant accounting policies are more fully described in Note 2 of the Notes to Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, provisions for doubtful accounts receivable and excess and obsolete inventories, the determination of useful lives and impairment of assets, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

**Fair Value of Financial Instruments**

The Company has evaluated the estimated fair value of its financial instruments as of September 30, 2017 and December 31, 2016. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of its borrowings approximate fair value.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

marketable securities and are recorded at fair value, using level 1 inputs, based on quoted market prices. As of September 30, 2017 and December 31, 2016, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit). There were no unrealized gains and losses as of September 30, 2017 and December 31, 2016. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

**Concentration of Credit Risk, and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable to the extent of the amounts recorded on the balance sheets.

The Company's policy is to invest in cash and cash equivalents, consisting of money market funds. These financial instruments are held in Company accounts at one financial institution. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing.

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at September 30, 2017 and December 31, 2016.

The Company's accounts receivable are due from a variety of health-care organizations in the United States and select European markets. At September 30, 2017 and December 31, 2016, there were no customers that represented 10% or more of the Company's accounts receivable. For the three months ended September 30, 2017 and 2016, there was one and no customers, respectively, that represented 10% or more of revenues. For the nine months ended September 30, 2017 and 2016, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

The Company manufactures its commercial products in-house, including Pantheris and the Ocelot family of catheters. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon third-party payors to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this may have a material adverse impact on the Company.

**Revenue Recognition**

The Company's revenues are derived from (1) sale of its Lightbox (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 605-10, *Revenue Recognition*, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement.

The Company's revenue recognition policies generally result in revenue recognition at the following points:

1. Lightbox sales: The Company sells its products directly to hospitals and medical centers. Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form by the customer acknowledging that the training and installation process is complete.
2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.
3. Service revenue: Service revenue is recognized ratably over the term of the service period. To date, service revenue has been insignificant.

The Company offers its customers the ability to purchase or lease its Lightbox. In addition, the Company provides a Lightbox under a limited commercial evaluation program to allow certain strategic accounts to install and utilize the Lightbox for a limited trial period of three to six months. When a Lightbox is placed under a lease agreement or under a commercial evaluation program, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these placed Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these placed Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in ASC 840, *Leases* and ASC 605-25, *Revenue Recognition Multiple Element Arrangements*. The guidance requires arrangement consideration to be allocated between a lease deliverable and a non-lease deliverable based upon the relative selling-price of the deliverables, using a specific hierarchy. The hierarchy is as follows: vendor-specific objective evidence of fair value of the respective elements, third-party evidence of selling price, or best estimate of selling price ("BESP"). The Company allocates arrangement consideration using BESP.

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

The Company assessed whether the embedded lease is an operating lease or sales-type lease. Based on the Company's assessment of the guidance and given that any payments under the lease agreements are dependent upon contingent future sales, it was determined that collectability of the minimum lease payments is not reasonably predictable. Accordingly, the Company concluded the embedded lease did not meet the criteria of a sales-type lease and accounts for it as an operating lease. The Company recognizes revenue allocated to the lease as the contingent disposable product purchases are delivered and are included in revenues within the statement of operations and comprehensive loss.

For sales through distributors, the Company recognizes revenue when title to the product and the risk of loss transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

The Company estimates reductions in revenue for potential returns of products by customers. In making such estimates, management analyzes historical returns, current economic trends and changes in customer demand and acceptance of its products. The Company expenses shipping and handling costs as incurred and includes them in the cost of revenues. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

**Cost of Revenues**

Cost of revenues consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of the Company's cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. The Company expenses all warranty costs and inventory provisions to cost of revenues. The Company records adjustments to its inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. Cost of revenues also includes depreciation expense for the Lightboxes under lease and commercial evaluation program agreements and certain direct costs such as shipping costs.

**Product Warranty Costs**

The Company typically offers a one-year warranty for parts and labor on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. Warranty costs are reflected in the statement of operations and comprehensive loss as a cost of revenues. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as



Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

necessary. The warranty liability is included within accrued liabilities on the balance sheet. Warranty provisions and claims are summarized as follows (in thousands):

	<b>Amount</b>
Balance at December 31, 2016	\$ 509
Warranty provision	193
Usage/Release	(306)
Balance at September 30, 2017	\$ 396

**Net Loss per Share**

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. For the computation of net loss per share, there were no common stock shares subject to repurchase excluded from the calculations as of September 30, 2017 and 2016. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

Net loss per share was determined as follows (in thousands, except per share data):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net loss	\$ (10,443)	\$ (12,969)	\$ (38,582)	\$ (42,631)
Weighted average common stock outstanding	606	442	600	359
Net loss per share, basic and diluted	\$ (17.23)	\$ (29.34)	\$ (64.30)	\$ (118.75)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported:

	<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>
Common Stock options	91,939	92,113
Unvested restricted stock units	8,097	5,835
Common stock warrants	53,715	53,715

Edgar Filing: Avinger Inc - Form S-1/A

153,751 151,663

F-50

---

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Comprehensive Loss**

For the three and nine months ended September 30, 2017 and 2016, there was no difference between comprehensive loss and the Company's net loss.

**Segment and Geographical Information**

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the three months ended September 30, 2017 and 2016, 95% and 96% of the Company's revenues were in the United States, respectively, based on the shipping location of the external customer. For the nine months ended September 30, 2017 and 2016, 96% and 96% of the Company's revenues were in the United States, respectively, based on the shipping location of the external customer.

**Accounting Pronouncements Adopted in 2017**

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee share-based payments, including income tax consequences, application of award forfeitures to expense, classification on the statement of cash flows, and classification of awards as either equity or liabilities. This guidance was effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods.

As a result of adopting ASU 2016-09, the Company has made an accounting policy election to account for forfeitures as they occur. This change has been applied on a modified retrospective basis, resulting in a cumulative-effect adjustment to increase accumulated deficit by \$206,000 as of January 1, 2017, the date of adoption. The adoption of ASU 2016-09 also requires that excess tax benefits and tax deficiencies be recorded in the statement of operations as opposed to additional paid-in capital when the awards vest or are settled. The adoption of ASU 2016-09 as it relates to the accounting for excess tax benefits and tax deficiencies has no impact on the Company's current financial statements or on any prior period financial statements presented. ASU 2016-09 also requires excess tax benefits to be classified as an operating activity, consistent with other income tax cash flows, and may be applied either on a retrospective or prospective basis. The Company has elected to apply this amendment on a prospective basis, as there is no impact to its prior period statements of cash flows. As such, prior periods have not been adjusted.

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance was effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company's elected to adopt

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

this standard as of January 1, 2017, on a prospective basis. The adoption had no impact on its financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740) Balance Sheet Classification of Deferred Taxes, which requires entities to present its deferred tax assets and deferred tax liabilities as noncurrent in its financial statements. The guidance was effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company's elected to adopt this standard as of January 1, 2017, on a prospective basis. The adoption of this new guidance does not create any impact to the Company's financial statements due to the fact that no deferred tax assets or liabilities have been reported in its financial statements. This will likely remain the case if the Company continues to incur additional losses, which requires it to maintain a full valuation allowance as it will be more-likely-than-not that its deferred tax assets are not realizable.

**Recent Accounting Pronouncements**

In May 2014, the FASB, jointly with the International Accounting Standards Board, issued a comprehensive new standard on revenue recognition from contracts with customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company has preliminarily decided to adopt this accounting standard in the first quarter of fiscal year 2018 using the modified retrospective approach, with the cumulative effect being recorded within accumulated deficit on January 1, 2018; however, the final determination will depend on a number of factors including finalizing our assessment of the impact to the Company's financial results as well as assessing the impacts of any additional disclosure requirements. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as companies and the accounting profession work to implement this new standard. The Company has not completed its assessment of the adoption on its financial statements as well as on its business processes, controls and systems. While the Company has not completed its evaluation, the Company currently believes that the impact to revenue and expense recognized will not be material to any of the years presented. As the Company completes its evaluation of this new standard, new information may arise that could change its current understanding of the impact to revenue and expense recognized. Additionally, the Company will continue to monitor industry activities and any additional guidance provided by regulators, standards setters, or the accounting profession and adjust its assessment and implementation plans accordingly.

In February 2016, the FASB issued ASU No. 2016-02, "Leases" (ASU 2016-02), which increases transparency and comparability among organizations by recognizing all lease transactions (with terms in excess of 12 months) on the balance sheet as a lease liability and a right-of-use asset (as defined). This

Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods, using a modified retrospective approach, and early adoption is permitted. The Company is evaluating the impact of the adoption of this standard on its financial statements. The Company does expect that the adoption will increase its lease assets and correspondingly increase its lease liabilities.

**3. Fair Value Measurements**

The Company measures certain financial assets and liabilities at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than quoted prices included within Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of September 30, 2017 and December 31, 2016, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of September 30, 2017 and December 31, 2016, there were no financial assets and liabilities categorized as Level 2 or 3. There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2017 and 2016.

**4. Inventories**

Inventories consisted of the following (in thousands):

	<b>September 30, 2017</b>	<b>December 31, 2016</b>
Raw materials	\$ 634	\$ 5,706
Work-in-process	434	
Finished products	3,978	2,756
Total inventories	\$ 5,046	\$ 8,462

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**5. Borrowings**

*CRG*

On September 22, 2015, the Company entered into a Term Loan Agreement (the "Loan Agreement") with CRG under which, subject to certain conditions, the Company may borrow up to \$50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed \$30,000,000 on September 22, 2015. The Company borrowed an additional \$10,000,000 on June 15, 2016 under the Loan Agreement. The Company would have been eligible to borrow an additional \$10,000,000, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions, but those milestones were not achieved. Under the Loan Agreement, the first sixteen quarterly payments are interest only payments, and the last eight quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 12.5% per annum. The Company makes quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, the Company may elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind ("PIK") for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the borrowings. To date, the Company has elected the PIK interest option to the extent available and has made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amounts borrowed plus any PIK is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company's assets. The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement, as amended, include a covenant that the Company maintain a minimum of \$5,000,000 of cash and certain cash equivalents, and the Company had to achieve minimum revenue of \$7,000,000 in 2015 and \$18,000,000 in 2016, and must achieve minimum revenue of \$40,000,000 in 2017, \$50,000,000 in 2018, \$60,000,000 in 2019 and \$70,000,000 in 2020 and in each year thereafter, as applicable. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change.

Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****5. Borrowings (Continued)**

Currently the Company is in compliance with all applicable covenants, however, the Company believes it will be unsuccessful in meeting the covenant regarding the minimum revenue threshold for 2017 and plans to seek to renegotiate this covenant before the end of the year. The Company can provide no assurance that it will be successful in renegotiating this covenant. As of September 30, 2017, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,	Principal and PIK Loan Repayments
2017	\$
2018	
2019	10,000
2020	20,000
2021	10,000
	40,000
Add: Accretion of closing fees	768
Add: PIK	3,090
	43,858
Less: Amount representing debt financing costs	(746)
<b>Borrowings, net of current portion</b>	<b>\$ 43,112</b>

Contemporaneously with the execution of the Loan Agreement, the Company entered into a Securities Purchase Agreement (the "CRG Purchase Agreement") with CRG which allowed it to purchase up to \$5,000,000 of the Company's common stock. CRG purchased 8,705 shares of common stock on September 22, 2015 at a price of \$559.64 per share, which is the 10-day average of closing prices of the Company's common stock ending on September 21, 2015. The closing price on September 22, 2015 was \$558.80 yielding a \$0.84 per share premium. Both the premium and the issuance costs were allocated to the borrowings under Loan Agreement and the common stock purchase under the CRG Purchase Agreement based on the relative fair values of each security. The portion of the premium allocated to the borrowings is being amortized over the term of the Loan Agreement. Pursuant to the CRG Purchase Agreement, the Company filed a shelf registration statement covering, among other things, the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

In connection with the initial drawdown under the Loan Agreement, the Company recorded a debt discount of \$876,000. The debt discount comprised financing fees of \$450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and CRG Purchase Agreement with CRG of \$541,000 net of the common stock premium of \$115,000 based on the relative fair values of each security. In connection with the June 2016 drawdown under the Loan Agreement, the Company recorded a debt discount of \$275,000 which comprised financing fees of \$150,000, paid directly to CRG, and other costs directly attributable to the Loan Agreement with CRG of \$125,000. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of September 30, 2017, the balance of the aggregate debt discount was \$746,000.

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**5. Borrowings (Continued)**

As noted in Note 1 to these financial statements, due to substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the CRG Loan Agreement, the entire amount of borrowings at September 30, 2017 and December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

*PDL BioPharma*

On April 18, 2013, the Company entered into a Credit Agreement (the "PDL Agreement") with PDL BioPharma, Inc. ("PDL") whereby PDL agreed to loan the Company up to \$40,000,000. Contemporaneously with the execution of the PDL Agreement the Company borrowed an initial \$20,000,000 ("Term Note").

In September 2015, in connection with the consummation of the Loan Agreement with CRG, the Company repaid all amounts outstanding under the PDL Agreement.

Under the PDL Agreement, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company's quarterly net revenues. Upon the prepayment of the Term Note, the Company's obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable monthly. The ongoing obligation was determined to be an embedded element of the PDL Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interest obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2016, is used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. At the time of the repayment the resulting increase in the carrying value of the Assigned Interests, of \$942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interests obligations of \$722,000 and \$1,463,000, representing the net present value of the future minimum royalty obligation as of September 30, 2017 and December 31, 2016, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities as of September 30, 2017 and was included within accrued expenses and other current liabilities and within other long-term liabilities as of December 31, 2016, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion, on the balance sheet.

Additionally, until there are no further obligations to periodically pay PDL a percentage of its net revenue in April 2018, the Company must comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company is in compliance with the covenants under the PDL Agreement.



Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****6. Capital Leases**

Capital lease obligations consist of leased office equipment. As of September 30, 2017 and December 31, 2016, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is \$20,000 and \$39,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of September 30, 2017, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2017	\$ 6
2018	13
2019	1
Total minimum payments	20
Less: Amount representing future interest	
Present value of minimum lease payments	\$ 20

**7. Commitments and Contingencies****Lease Commitments**

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. To date, deferred rent has been insignificant. In March 2016, the Company entered into an additional non-cancelable operating lease for warehouse and storage space that expires in November 2019. Rent expense was \$506,000 and \$259,000 for the three months ended September 30, 2017 and 2016, and \$1,519,000 and \$757,000 for the nine months ended September 30, 2017 and 2016, respectively.

Aggregate future minimum lease payments as of September 30, 2017, are as follows (in thousands):

Year ending December 31,	Future Minimum Lease Payments
2017	\$ 507
2018	2,033
2019	1,915
Total minimum lease payments	\$ 4,455

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**7. Commitments and Contingencies (Continued)**

**Purchase Obligations**

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancellable commitments to suppliers for purchases totaling \$1,688,000 and \$3,542,000 as of September 30, 2017 and December 31, 2016, respectively.

**Indemnification**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future, but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations under these agreements.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

**Legal Proceedings**

Except as set forth below, the Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business.

Between May 22, 2017 and May 25, 2017, three purported class action lawsuits were filed in the Superior Court of the State of California, County of San Mateo ("State Court"), against the Company, certain of its officers and directors and the underwriters of the Company's January 2015 IPO. 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 the Company's 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.

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**7. Commitments and Contingencies (Continued)**

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Grotewiel action ("Federal Action"). An amended complaint in the Federal Action is due on November 21, 2017. On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted the motions to remand the Olberding and Gonzalez actions to the State Court. On August 9, 2017, the State Court consolidated the Olberding and Grotewiel actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284 ("State Action"). On September 22, 2017, an amended complaint was filed in the State Action. On October 31, 2017, the parties in the State Action stipulated to a stay of proceedings until judgment is entered in the Federal Action. On November 2, 2017, pursuant to stipulation of the parties, the State Court entered an order staying proceedings in the State Action until judgment is entered in the Federal Action.

The Company and its directors believes that the foregoing lawsuits are entirely without merit and intend to vigorously defend against the actions.

**8. Stockholders' Equity (Deficit)**

**Preferred Stock**

As of September 30, 2017, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with \$0.001 par value per share, of which no shares were issued and outstanding.

**Common Stock**

As of September 30, 2017, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with \$0.001 par value per share, of which 788,477 shares were issued and outstanding.

**Common Stock Warrants**

In connection with the issuance of the Company's Series E Convertible Preferred Stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible Preferred Stock, warrants to purchase up to the number of shares of common stock equal to 70% of the number of shares of the Company's Series E Convertible Preferred Stock purchased by such investor.

The warrants are immediately exercisable, at an exercise price per share of \$504.00, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company. The Company determined that these common stock warrants meet the requirements for equity classification. The common stock warrants were recorded at their allocated fair value within stockholders' equity (deficit).

As of September 30, 2017 and December 31, 2016, warrants to purchase an aggregate of 53,715 shares of common stock were outstanding.

Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****8. Stockholders' Equity (Deficit) (Continued)****Stock Plans**

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Plan. The 2015 Plan replaced the 2009 Stock Plan ("2009 Plan" and together with the 2015 Plan, the "Plans") which was terminated immediately prior to consummation of the Company's IPO. The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of nonstatutory stock options ("NSOs"), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 33,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan, plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 42,250 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. For fiscal 2017, the common stock available for issuance under the 2015 Plan was increased by 29,720 shares of common stock. As of September 30, 2017, 43,041 shares were available for grant under the 2015 Plan.

Pursuant to the Plans, ISOs and NSOs may be granted with exercise prices at not less than 100% of the fair value of the common stock on the date of grant and the exercise price of ISOs granted to a stockholder, who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of the stock of the Company, shall be not less than 110% of the fair market value per share of common stock on the date of grant. The Company's Board of Directors determines the vesting schedule of the options. Options granted generally vest over four years and expire ten years from the date of grant.

Stock option activity under the Plans is set forth below:

	Number of Shares	Options Outstanding Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2016	92,509	\$ 314.73	\$ 5
Options granted	27,115	\$ 291.14	
Options exercised		\$	
Options cancelled	(27,685)	\$ 328.07	
Balance at September 30, 2017	91,939	\$ 303.76	\$

The weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2017 was \$30.65 per share. As of September 30, 2017, the aggregate intrinsic value of options outstanding and vested was zero. There were no options exercised during the nine months ended September 30, 2017. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the three and nine months ended September 30, 2017 and 2016.

Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****8. Stockholders' Equity (Deficit) (Continued)**

At September 30, 2017 and at December 31, 2016, there were 50,623 and 40,541 shares, respectively, vested with a weighted-average exercise price of \$298.62 and \$294.47 per share, respectively, and a weighted average contractual life of 7.17 and 7.63 years, respectively.

The Company's RSUs vest annually over four years in equal increments. A summary of all RSU activity for the nine months ended September 30, 2017 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Awards outstanding at December 31, 2016	5,355	\$ 561.90	3.09	\$ 793
Awarded	7,782	\$ 114.41		
Released	(948)	\$ 483.12		
Forfeited	(4,092)	\$ 317.76		
Awards outstanding at September 30, 2017	8,097	\$ 264.42	3.06	\$ 123

As of September 30, 2017, \$1,669,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.58 years. The Company used the closing market price of 15.20 per share at September 30, 2017, to determine the aggregate intrinsic value.

**2015 Employee Stock Purchase Plan**

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ("ESPP") under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. Initially 12,500 shares of common stock were reserved for issuance, which is subject to an automatic increase on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 12,325 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. For fiscal 2017, the common stock available for issuance under the ESPP was increased by 8,916 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of September 30, 2017, approximately 19,095 shares of common stock remained reserved for issuance under the ESPP. The Company incurred \$15,000 and \$94,000 in stock-based compensation expense related to the ESPP for the three months ended September 30, 2017 and 2016, and \$105,000 and \$311,000 for the nine months ended September 30, 2017 and 2016, respectively.

**9. Stock-Based Compensation**

Stock-based compensation for the Company includes amortization related to all stock options, RSUs and shares issued under the ESPP, based on the grant-date estimated fair value. The Company estimates the fair value of stock options and shares issued under the ESPP on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-



Table of Contents**AVINGER, INC.****Notes to Condensed Financial Statements (Continued)****9. Stock-Based Compensation (Continued)**

based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company's common stock, and the volatility over the expected term of the awards. The fair value for the Company's employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following weighted average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expected term (years)	5.6	6.1	5.9	6.0
Expected volatility	63.6%	51.7%	57.2%	49.3%
Risk-free interest rate	1.8%	1.2%	2.2%	1.4%

## Dividend rate

As of September 30, 2017 and December 31, 2016, the total unamortized compensation expense related to stock option awards granted to employees and directors was \$6,465,000 and \$12,312,000, which is expected to be amortized over the next 1.1 and 2.3 years, respectively.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expected term (years)	0.5	0.5	0.5	0.5
Expected volatility	117.1%	85.5%	109.2%	72.1%
Risk-free interest rate	9.40%	0.49%	7.80%	0.41%

## Dividend rate

Total stock-based compensation expense related to stock-based awards recognized during the three and nine months ended September 30, 2017 and 2016, is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of revenues	\$ 72	\$ 165	\$ 328	\$ 403
Research and development expenses	509	647	1,550	1,990
Selling, general and administrative expenses	739	900	2,319	2,908
	\$ 1,320	\$ 1,712	\$ 4,197	\$ 5,301

**10. Restructuring Charges and Expenses**

In April 2017, the Company undertook an organizational realignment which included a reduction in force, lowering its total headcount by approximately 33% compared to December 31, 2016, in order

Table of Contents

**AVINGER, INC.**

**Notes to Condensed Financial Statements (Continued)**

**10. Restructuring Charges and Expenses (Continued)**

to conserve resources. Accordingly, the Company recorded a restructuring charge of approximately \$519,000, relating to severance related costs at that time. As of September 30, 2017, \$493,000 of the total severance related costs related to the termination of 44 employees had been paid. The Company expects the remaining \$26,000 in severance costs to be paid by December 31, 2017.

In September 2017, the Company effected a cost reduction plan, which included a company-wide reduction in force, lowering its total headcount by 24 employees. Accordingly, the Company recorded a restructuring charge of approximately \$416,000, relating to severance related costs at that time. As of September 30, 2017, \$55,000 of the total severance related costs related to the termination of 24 employees had been paid. The Company expects the remaining \$361,000 in severance costs to be paid by December 31, 2017.

**11. Subsequent Events**

On October 19, 2017, the Company entered into an agreement to sublease one of its facilities. The sublease agreement is estimated to commence on approximately December 1, 2017 and is scheduled to expire on November 15, 2019 (which is 15 days prior to the expiration of the facility lease). The sublessee will pay a base rent of \$3.25 per rentable square foot, for a total of \$79,950 per month, increasing to \$3.35 per rentable square foot, for a total of \$82,410 per month as of December 1, 2018. In addition to the base rent, the sublessee will pay the Landlord's operating expenses and property taxes due and payable with respect to the subleased facility.

On November 3, 2017, the Company entered into a purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park is obligated to purchase, at the Company's request, up to \$15,000,000 of the Company's common stock over a 30-month period, subject to certain limitations in the Purchase Agreement. As a fee for Lincoln Park's commitment to purchase such shares, the Company issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Purchase Agreement, the Company filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 1, 2018. To the extent more than 248,750 shares of the Company's common stock are issued to Lincoln Park pursuant to the Purchase Agreement, the Company is obligated to file additional registration statements for the resale of such shares.



Table of Contents

**15,000 Shares of Series B Convertible Preferred Stock  
(and 3,540,000 Shares of Common Stock Underlying the Series B  
Convertible Preferred Stock)**

---

**Warrants to Purchase up to 7,080,000 Shares of Common Stock  
(and 7,080,000 Shares of Common Stock Issuable Upon Exercise of Warrants)**

---

**PROSPECTUS**

---

**Ladenburg Thalmann**

, 2018

---

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

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

	<b>Amount to be Paid</b>
SEC registration fee	\$ 5,596
FINRA filing fee	5,670
Printing and engraving	40,000
Legal fees and expenses	300,000
Accounting fees and expenses	130,000
Blue sky fees and expenses	20,000
Transfer agent and registrar fees	15,000
Miscellaneous	10,000
<b>Total</b>	<b>\$ 526,266</b>

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

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

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

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

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

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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

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

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

We have issued and sold the following securities since January 1, 2015 to February 4, 2018.

1. In January 2015 we issued and sold to 5 accredited investors an aggregate of 12,260 shares of Series E preferred stock (convertible into an aggregate of 12,260 shares of common stock) at a purchase price per share of \$504.00. In connection therewith, we issued warrants to purchase an aggregate of 8,581 shares of our common stock at an exercise price of \$504.00 per share.
2. On September 22, 2015, we issued and sold to CRG 8,705 shares of common stock at a purchase price per share of \$559.64.
3. On November 3, 2017, we issued to Lincoln Park 23,584 shares of common stock at a value of \$12.76 per share as a commitment fee for making the commitment to purchase our common stock under the purchase agreement dated November 3, 2017 entered into with Lincoln Park. Subsequently, on November 17, 2017, the SEC declared effective the registration statement filed in connection with the Lincoln Park transaction.

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

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

<b>Exhibit Number</b>	<b>Exhibit Title</b>
1.1	<u>Form of Underwriting Agreement.</u>
3.1(1)	<u>Amended and Restated Certificate of Incorporation of the registrant.</u>
3.2(1)	<u>Bylaws of the registrant.</u>
3.3(12)	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation.</u>
3.4	<u>Form of Certificate of Designation of Series A Preferred Stock.</u>
3.5	<u>Form of Certificate of Designation of Series B Preferred Stock.</u>
4.1(2)	<u>Specimen Common Stock certificate of the registrant.</u>
4.2	<u>Form of Warrant to be Issued in Offering.</u>
5.1	<u>Opinion of Wilson Sonsini Goodrich &amp; Rosati, Professional Corporation.</u>
10.1(3)	<u>Form of Indemnification Agreement for directors and executive officers.</u>
10.2(4)	<u>2009 Stock Plan and Form of Option Agreement thereunder.</u>
10.3(4)	<u>2014 Preferred Stock Plan.</u>
10.4(3)	<u>2015 Equity Incentive Plan.</u>
10.5(3)	<u>Form of Restricted Stock Unit Award Agreement.</u>



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

<b>Exhibit Number</b>	<b>Exhibit Title</b>
10.6(3)	<u>Form of Stock Option Agreement.</u>
10.7(3)	<u>2015 Employee Stock Purchase Plan.</u>
10.8(3)	<u>Executive Incentive Compensation Plan.</u>
10.9(4)	<u>Amended and Restated Investors' Rights Agreement dated September 2, 2014 by and among the registrant and certain stockholders.</u>
10.10(4)	<u>Lease Agreement, dated July 30, 2010, by and between the registrant and HCP LS Redwood City, LLC for office space located at 400 and 600 Chesapeake Drive, Redwood City, California.</u>
10.11(4)	<u>First Amendment to Lease Agreement dated September 30, 2011 by and between registrant and HCP LS Redwood City, LLC.</u>
10.12(5)	<u>Second Amendment to Lease Agreement dated March 4, 2016 by and between registrant and HCP LS Redwood City, LLC.</u>
10.13(4)	<u>Credit Agreement dated April 18, 2013 by and between registrant and PDL Biopharma.</u>
10.14(4)	<u>Security Agreement dated April 18, 2013 by and between registrant and PDL BioPharma.</u>
10.15(4)	<u>Employment Letter dated November 5, 2014 by and between registrant and John B. Simpson.</u>
10.16(4)	<u>Employment Letter dated April 2, 2014 by and between registrant and John D. Simpson.</u>
10.17(4)	<u>Employment Letter dated December 29, 2010 by and between registrant and Matthew B. Ferguson.</u>
10.18(4)	<u>Employment Letter dated November 28, 2011 by and between registrant and Sougata Banerjee.</u>
10.19(4)	<u>Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and John B. Simpson.</u>
10.20(4)	<u>Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and Matthew B. Ferguson.</u>
10.21(4)	<u>Change of Control and Severance Agreement dated March 1, 2012 by and between registrant and Sougata Banerjee.</u>
10.22(4)	<u>Employment Letter dated December 17, 2014 by and between registrant and Jeffrey M. Soinski.</u>
10.23(4)	<u>Note and Warrant Purchase Agreement dated October 29, 2013 by and between registrant and holders of convertible promissory notes.</u>
10.24(4)	<u>Amendment No. 1 to the Note and Warrant Purchase Agreement dated May 6, 2014 by and between registrant and holders of convertible promissory notes.</u>
10.25(6)	<u>Term Loan Agreement, dated as of September 22, 2015, by and among Avinger, Inc., certain of its subsidiaries from time to time party thereto as guarantors and CRG Partners III L.P. and certain of its affiliated funds, as lenders.</u>
10.26(6)	<u>Securities Purchase Agreement, dated as of September 22, 2015, by and among Avinger, Inc., and CRG Partners III L.P. and certain of its affiliated funds (collectively, "CRG"), as purchasers.</u>

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

<b>Exhibit Number</b>	<b>Exhibit Title</b>
10.27(7)	<u>Sales Agreement dated as of February 3, 2016, between the Registrant and Cowen and Company, LLC.</u>
10.28(8)	<u>Purchase Agreement, dated November 3, 2017, between the Registrant and Lincoln Park Capital Fund, LLC.</u>
10.29(8)	<u>Registration Rights Agreement, dated November 3, 2017, between the Registrant and Lincoln Park Capital Fund, LLC.</u>
10.30(10)	<u>Waiver and Consent, dated as of December 14, 2017, among the Registrant and the Lenders party to that certain Term Loan Agreement, dated as of September 22, 2015.</u>
10.31(11)	<u>Waiver and Consent, dated as of January 24, 2018, among the Registrant and the Lenders party to that certain Term Loan Agreement, dated as of September 22, 2015.</u>
10.32	<u>Form of Registration Rights Agreement, dated as of February , 2018, among the Registrant and CRG.</u>
10.33	<u>Form of Series A Preferred Stock Purchase Agreement, dated as of February , 2018, among the Registrant and CRG.</u>
10.34	<u>Amendment No. 2 to the Term Loan Agreement, dated as of February , 2018, among the Registrant and CRG.</u>
23.1	<u>Consent of Independent Registered Public Accounting Firm.</u>
23.2	<u>Consent of Wilson Sonsini Goodrich &amp; Rosati, Professional Corporation (See Exhibit 5.1).</u>
24.1	<u>Power of Attorney .</u>

---

Previously filed.

- (1) Previously filed an Exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2015, and incorporated by reference herein.
- (2) Previously filed as an Exhibit to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 28, 2015, and incorporated by reference herein.
- (3) Previously filed as an Exhibit to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-201322) filed with the Securities and Exchange Commission on January 20, 2015, and incorporated by reference herein.
- (4) Previously filed as an Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-201322), filed with the Securities and Exchange Commission on December 30, 2014, and incorporated by reference herein.
- (5) Previously filed as an Exhibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2016, and incorporated by reference herein.
- (6) Previously filed as an Exhibit to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2015, and incorporated by reference herein.
- (7) Previously filed as an Exhibit to the Registrant's Registration Statement on Form S-3 (File No. 333-209368), filed with the Securities and Exchange Commission on February 3, 2016, and incorporated by reference herein.



Table of Contents

- (8) Previously filed as an Exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-221368), filed with the Securities and Exchange Commission on November 6, 2017, and incorporated by reference herein.
- (9) Previously filed as an Exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 11, 2017.
- (10) Previously filed as an Exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2017.
- (11) Previously filed as an Exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2018.
- (12) Previously filed as an Exhibit to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2018.

**Item 17. Undertakings**

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes:

- (a) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
- (i) To include any prospectus required by section 10(a)(3) of the Act;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement; and
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

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



## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

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

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

(d) That, for the purpose of determining liability under the Act of to any purchaser:

(i) Each prospectus filed by the Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the Registration Statement as of the date the filed prospectus was deemed part of and included in the Registration Statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Act shall be deemed to be part of and included in the Registration Statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the Registration Statement relating to the securities in the Registration Statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the Registration Statement or made in a document incorporated or deemed incorporated by reference into the Registration Statement or prospectus that is part of the Registration Statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the Registration Statement or prospectus that was part of the Registration Statement or made in any such document immediately prior to such effective date;

(e) That, for purposes of determining any liability under the Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Act shall be deemed to be part of this Registration Statement as of the time it was declared effective;

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

(g) To deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934; and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information; and

(h) That, for purposes of determining any liability under the Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to

## Edgar Filing: Avinger Inc - Form S-1/A

### Table of Contents

section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

II-7

---

