Avinger Inc
Form S-1
October 04, 2018
As filed with the Securities and Exchange Commission on October 3, 2018.

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT

Under

The Securities Act of 1933

AVINGER, INC.

(Exact name of Registrant as specified in its charter)

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

400 Chesapeake Drive

Redwood City, California 94063

(650) 241-7900

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

Jeffrey M. Soinski

Chief Executive Officer

Avinger, Inc.

400 Chesapeake Drive

Redwood City, CA 94063

(650) 241-7900

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

Copies to:

Philip H. Oettinger

Wilson Sonsini Goodrich & Rosati

Professional Corporation

650 Page Mill Road

Palo Alto, California 94304

(650) 493-9300

Approximate date of commencement of proposed sale to the public:

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

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

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
			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)(2)**	**Amount of registration fee**
Class A Units consisting of:		
(i) Shares of common stock, par value $0.001 per share		
(ii) Warrants to purchase common stock		
Class B Units consisting of:		
(i) Shares of Series C preferred stock, par value $0.001 per share		
(ii) Shares of common stock issuable on conversion of Series C preferred stock(3)		
(iii) Warrants to purchase common stock		
Common stock issuable upon exercise of warrants		
Total	$10,000,000	$1,212

(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) Excludes the price of additional shares of common stock and warrants to purchase shares of common stock that the underwriter has the option to purchase to cover overallotments, if any.

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

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

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.

Prospectus Subject to Completion, dated October 3, 2018

Class A Units consisting of common stock and warrants and

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

(and shares of common stock underlying shares of Series C preferred stock and warrants)

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

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

The Class A Units and Class B Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The shares of common stock, Series C preferred stock and warrants comprising such units are immediately separable and will be issued separately in this offering. The warrants offered hereby may be exercised from time to time beginning on and expire on . The underwriter has the option to purchase up to additional shares of common stock and/or warrants to purchase up to shares of common stock solely to cover

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

Our common stock is listed on The Nasdaq Capital Market under the symbol "AVGR". The closing price of our common stock on October 2, 2018, as reported by The Nasdaq Capital Market, was $1.33 per share. We do not intend to apply for listing of the warrants offered hereby or the shares of Series C preferred stock on any securities exchange or trading system.

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

	Per Class A Unit	**Per Class B Unit**	**Total**
Public offering price(1)	$	$	$
Underwriting discount(2)(3)	$	$	$
Proceeds, before expenses, to Avinger, Inc.	$	$	$

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

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

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

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

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

Sole Book-Running Manager

Ladenburg Thalmann

The date of this prospectus is , 2018

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

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

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

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PROSPECTUS SUMMARY

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

Company Overview

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

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

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

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

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

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

We have assembled a team with extensive medical device development and commercialization capabilities. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $10.7 million in 2015, $19.2 million in 2016, $9.9 million in 2017, and $3.9 million for the six months ended June 30, 2018.

Recent Developments

Common Stock Offering

On July 12, 2018, we entered into a securities purchase agreement with certain investors pursuant to which we agreed to sell and issue, in a registered direct offering, an aggregate of 2,166,180 shares of our common stock at an offering price of $1.6425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 1,083,091 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately $3.55 million after deducting placement agent fees and other expenses payable by us and the conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to $1.58 per share as a result. The warrants have an exercise price of $1.58 per share of our common stock and may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021.

Series B Preferred Stock Financing

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

CRG Debt Conversion

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

Reverse Stock Split

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

Lincoln Park Purchase Agreement

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

Nasdaq Compliance

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

Resale S-1 Registration Statement for July 2018 Warrants

On September 12, 2018, we filed a registration statement on Form S-1 to fulfill our contractual obligations under a securities purchase agreement that we entered into on July 12, 2018 in a registered direct offering, an aggregate of 2,166,180 shares of our common stock at an offering price of $1.6425 per share. In a concurrent private placement, or the Private Placement, we agreed to issue to these investors warrants, which we refer to as the July 2018 Warrants, exercisable for one share of our common stock for each two shares purchased in the registered direct offering, which equals an aggregate of 1,083,091 shares of common stock. The closing of such registered direct offering and the concurrent Private Placement occurred on July 16, 2018, in connection with which we received net proceeds of approximately $3.55 million after deducting placement agent fees and other expenses payable by us. The conversion price of the outstanding shares of Series B preferred stock, issued in our February 2018 offering, was reduced to $1.58 per share as a result. The warrants have an exercise price of $1.58 per share of our common stock, may be exercised from time to time beginning on January 17, 2019 and expire on July 16, 2021.The registration statement was declared effective by the SEC on September 28, 2018. Subject to certain exceptions, we will be obligated to use our commercially reasonable efforts to keep such registration statement effective until no purchaser owns any July 2018 Warrants or shares issuable upon exercise of the July 2018 Warrants.

Preliminary September 30, 2018 Financial Results

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

In the three and nine months ended September 30, 2018, our revenue is expected to be between approximately $ million and $ million and approximately $ million and $ million, respectively, as compared to $2.1 million and $8.0 million, respectively, for the three and nine months ended September 30, 2017. In the three and nine months ended September 30, 2018, our loss from operations is expected to be between approximately $

million and $ million and $ million and $ million, respectively, as compared to $8.9 million and $34.0 million, respectively, for the three and nine months ended September 30, 2017. We expect gross margin for the nine months ended September 30, 2018 to to between approximately % and % compared to -40% for the nine months ended September 30, 2017. For the nine months ended September 30, 2018, we expect our operating expenses to be between approximately $ million and $ million, as compared to $30.7 million for the nine months ended September 30, 2017. As of September 30, 2018, our cash and cash equivalents balance is expected to be approximately $ million, our working capital is expected to be approximately $ million, and the principal and interest outstanding under our credit facilities is expected to be approximately $ million.

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

Risks Associated with Our Business

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

- Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our common stock.
- We have a history of net losses and we may not be able to achieve or sustain profitability.
- We may not be able to secure additional financing on favorable terms, or at all, to meet our future capital needs and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs and commercialization efforts or cause us to become insolvent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The warrants may not have any value.

Company Information

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

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

Implications of Being an Emerging Growth Company

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

- we have availed ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require shareholder non-binding advisory votes on executive compensation or golden parachute arrangements.

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

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

Available Information

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

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

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

THE OFFERING

Class A Units offered by us	We are offering Class A Units. Each Class A Unit consists of one share of common stock and a warrant to purchase one half of one share of our common stock (together with the shares of common stock underlying such warrants).
Offering price per Class A Unit	$
Class B Units offered by us	We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, Class B Units. Each Class B Unit consists of one share of Series C preferred stock, par value $0.001 per share, convertible into a number of shares of common stock equal to and a warrant to purchase shares of our common stock (together with the shares of our common stock underlying such shares of Series C preferred stock and warrants).
Offering price per Class B Unit	$
Overallotment option	The underwriter has the option to purchase up to additional shares of common stock, and/or warrants to purchase up to shares of common stock solely to cover overallotments, if any, at the price to the public less the underwriting discounts and commissions. The overallotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series C preferred stock) and warrants sold in the primary offering. The overallotment option is exercisable for 45 days from the date of this prospectus.
Description of warrants	The warrants will be exercisable beginning on the date of issuance and expire on the three (3) year anniversary of the date of issuance at an initial exercise price per share equal to $, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
Description of Series C preferred stock	Each share of Series C preferred stock is convertible at any time at the holder's option into shares of common stock. Notwithstanding the foregoing, we shall not effect any conversion of Series C preferred stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series C preferred stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see the section entitled "Description of Securities—Preferred Stock."

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

Shares of common stock outstanding after this offering	shares
Shares of Series C preferred stock outstanding after this offering	shares
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use net proceeds from this offering for working capital, payment of interest on our debt and general corporate purposes, which may include research and development of our Lumivascular platform products, preclinical and clinical trials and studies, regulatory submissions, expansion of our sales and marketing organizations and efforts, intellectual property protection and enforcement and capital expenditures. We may use a portion of the net proceeds to acquire complementary products, technologies or businesses or to repay principal on our debt; however, we currently have no agreements or commitments to complete any such transactions or to make any such principal repayments and are not involved in negotiations to do so. See the section entitled "Use of Proceeds" on page 39 of this prospectus.
Risk factors	This investment involves a high degree of risk. You should carefully read and consider the information set forth under "Risk Factors" on page 11 of this prospectus and the documents incorporated by reference herein before deciding to invest in our securities.
Nasdaq Capital Market common stock symbol	AVGR
No listing of Series C preferred stock or warrants	There is no established public trading market for the Series C preferred stock or the warrants, and we do not intend to apply for listing of the shares of the Series C preferred stock or warrants on any securities exchange or trading system. Without an active trading market, the liquidity of the warrants and the Series C preferred stock will be limited.

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

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

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

- 3,306 unvested restricted stock units;

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

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

- 200,000 shares of common stock reserved for future issuance under our Officer and Director Share Purchase Plan, or ODPP;

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

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

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

RISK FACTORS

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

Risks Related to Our Business

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

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

- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, and the timing of such clearances and approvals, particularly with respect to current and future generations of Pantheris;
- market acceptance of our Lumivascular platform and products, including Pantheris;
- the availability of reimbursement for our Lumivascular platform products;
- our ability to attract new customers and increase the amount of business we generate from existing customers;

- results of our clinical trials;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, political, industry and market conditions, including economic and political uncertainty caused by the recent U.S. presidential election;
- the regulatory environment;
- the hiring, training and retention of key employees, including our sales team;
- the cost and potential outcomes of existing and future litigation;
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

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

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

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

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

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

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

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

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris 3.0 and Pantheris SV, and any future versions of such products;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;
- the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations;
- the costs and timing of developing variations of our 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;

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

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

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

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

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

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

- increase our vulnerability to adverse changes in general economic, industry and competitive conditions;
- require us to dedicate a substantial portion of our cash flow from operations to make payments on our debt, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- restrict us from exploiting business opportunities;
- make it more difficult to satisfy our financial obligations, including payments on the Loan Agreement
- place us at a competitive disadvantage compared to our competitors that have less debt obligations; and
- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes on satisfactory terms or at all.

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

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

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

- incur or assume liens;
- incur additional debt or provide guarantees in respect of obligations of other persons;
- issue redeemable stock and preferred stock;
- pay dividends or make distributions on capital stock, repurchase, redeem or make payments on capital stock or repay, repurchase, redeem, retire, defease, acquire or cancel debt prior to the stated maturity thereof;
- make loans, investments or acquisitions;
- create or permit restrictions on the ability of our subsidiaries to pay dividends or make other distributions to us or to guarantee our debt, limit our or any of our subsidiaries ability to create liens, or make or pay intercompany loans or advances;
- enter into certain transactions with affiliates;
- sell, transfer, license, lease or dispose of our or our subsidiaries' assets, including the capital stock of our subsidiaries; and
- dissolve, liquidate, consolidate or merge with or into, or sell substantially all the assets of us and our subsidiaries, taken as a whole, to, another person.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

have a material adverse effect on our stock price.

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

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

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

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

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

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

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