Avinger Inc
Form POS AM
March 14, 2019

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

Registration No. 333-222517

333-223023

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

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

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AVINGER, INC.

(Exact name of registrant as specified in its charter)

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:
Nolan S. Taylor

David F. Marx

Michael R. Newton

Dorsey & Whitney LLP
111 S. Main St., 21st Floor
Salt Lake City, Utah 84111

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

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

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

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

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

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

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

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

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

EXPLANATORY NOTE

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

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

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

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

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

Subject to Completion, dated March 14, 2019

PROSPECTUS

Avinger, Inc.

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

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

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

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

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

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

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

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

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

Ladenburg Thalmann

The date of this prospectus is , 2019

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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.

This prospectus contains estimates, projections and other information concerning our industry, our business and the potential markets for our platform, including data regarding the estimated demand in those markets, their projected growth rates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

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

PROSPECTUS SUMMARY

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

Company Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select international markets. Our current products include our Lightbox imaging console, the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015 we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris, and we received additional 510(k) clearances for enhanced versions of Pantheris in March 2016 and May 2018 and commenced sales of Pantheris in the United States and select European countries promptly thereafter. We also offer the Wildcat and Kittycat 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 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 specifically include in-stent restenosis. We received CE Marking in December 2017 and 510(k) clearance in May 2018 for a next-generation version of our Pantheris atherectomy device, which we believe represents a significant improvement over our prior product. This next-generation version of Pantheris includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe improve usability and reliability of the device. The next-generation Pantheris atherectomy device is available for commercial sale in the United States and select international markets. On December 13, 2018 we announced the 500th patient treated with the next-generation Pantheris. All previous versions of Pantheris have been discontinued.

We are developing a line extension of our Pantheris image-guided atherectomy platform, Pantheris SV (Small Vessel), a lower profile version of Pantheris. The lower profile Pantheris has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels. We submitted a 510(k) application for Pantheris SV in August 2018 and received CE Marking approval in October 2018. On November 15, 2018 we announced the successful treatment of the first patients globally with Pantheris SV by a vascular surgeon in Münster, Germany. Pantheris SV is available in limited supply for commercial sale in the EU; it is not available for commercial sale in the United States at this time.

We have assembled a team with extensive medical device development and commercialization capabilities. In addition to the commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-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 $7.9 million in 2018.

Company Information

We were incorporated in Delaware on March 8, 2007. Our principal executive offices are located at 400 Chesapeake Drive, Redwood City, CA 94063, and our telephone number is (650) 241-7900. Our website address is www.avinger.com. 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 make available, free of charge on our corporate website at www.avinger.com, copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements, and all amendments to these reports, as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission, or the SEC, pursuant to Section 13(a) or 15(d) of the Securities Exchange Act. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. This information may also be obtained from the SEC’s on-line database, which is located at www.sec.gov.

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

THE OFFERING

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

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.

Series 1 warrants	The Series 1 warrants will be exercisable beginning on the date of issuance and expire on the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to $2.00, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
Series 2 warrants	The Series 2 warrants will be exercisable beginning on the date of issuance and expire on the earlier of (1) the 60th calendar day following the receipt and announcement of FDA clearance to market our Pantheris BTK device (or the same or similar product with a different name), and (2) the seven (7) year anniversary of the date of issuance at an initial exercise price per share equal to $2.00, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
	The Series 1 warrants and the Series 2 warrants are collectively referred to as the "warrants." The forms of each warrant are filed as an exhibit to the registration statement of which this prospectus forms a part.
No listing of Series B Preferred Stock or warrants	We do not intend to apply for listing of the shares of the Series B preferred stock or warrants on any securities exchange or trading system.

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

- 77,592 shares of common stock issuable upon the exercise of stock options outstanding as of March 7, 2019 with a weighted average exercise price of $161.19 per share;
- 24,858,785 shares of common stock issuable upon exercise of outstanding warrants, other than the Series 1 warrants and the Series 2 warrants;
- 2,869,725 unvested restricted stock units;
- 199,201 shares of common stock reserved for future issuance under our 2015 Equity Incentive Plan, or our 2015 Plan, and any additional shares that become available under our 2015 Plan pursuant to provisions thereof that automatically increase the share reserve under the plan each year;
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113,564 shares of common stock reserved for future issuance under our Officer and Director Share Purchase Plan, or ODPP;

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

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

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

RISK FACTORS

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

Risks Related to Our Business

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

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

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

results of our clinical trials;

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

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

changes in our pricing policies or those of our competitors;

general economic, political, industry and market conditions;

the regulatory environment;

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

the cost and potential outcomes of existing and future litigation;

our ability to obtain additional financing; and

advances and trends in new technologies and industry standards.

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

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $27.6 million in 2018 and $48.7 million in 2017. As of December 31, 2018, we had an accumulated deficit of approximately $328.9 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

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

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

We believe that our cash and cash equivalents at December 31, 2018, and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through at least the third quarter of 2019. Even though we received net proceeds of $10.2 million from the sale of our common stock and Series C convertible preferred stock in our November 2018 offering, net proceeds of $15.5 million from the sales of our Series B convertible preferred stock and warrants in our February 2018 offering, and net proceeds of $3.0 million from the sale of our common stock and warrants in our July 2018 offering, we will need to raise additional funds through future equity or debt financings within the next twelve months to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake could cause substantial dilution to our existing stockholders.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our “at-the-market” program, our initial public offering, or IPO, and our follow-on public offerings. The warrants issued in connection with the Series B and Series C preferred stock offering in February 2018 prohibit us from entering into certain transactions involving the issuance of securities for a variable price determined by reference to the trading price of our common stock or otherwise subject to modification following

the date of issuance, in each case until February 17, 2021. This prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities, challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

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

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

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

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

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

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

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