Table of Contents

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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2017

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: **001-36817**

AVINGER, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-8873453**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

400 Chesapeake Drive
Redwood City, California 94063
(Address of principal executive offices and zip code)

(650) 241-7900
(Telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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 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 ☒ (Do not check if a smaller reporting company)	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 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of August 1, 2017, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 23,914,024.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the outcome of and expectations regarding our current clinical studies and any additional clinical studies we initiate;
- our plans to modify our current products, or develop new products, to address additional indications;
- our ability to obtain additional financing through our "at-the-market" program and future equity or debt financings;
- the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;
- our ability to continue as a going concern;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;
- our ability to identify and develop new and planned products and acquire new products;
- our financial performance;
- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally;
- our intention to vigorously defend against pending securities lawsuits; and
- developments and projections relating to our competitors or our industry.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly

Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. We urge you to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC as exhibits to the Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Table of Contents

AVINGER, INC.
AS OF AND FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

AVINGER, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(In thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 13,964	$ 36,096
Accounts receivable, net of allowance for doubtful accounts of $120 at June 30, 2017 and $21 at December 31, 2016	1,489	3,570
Inventories	6,699	8,462
Prepaid expenses and other current assets	1,130	662
Total current assets	23,282	48,790
Property and equipment, net	3,857	4,555
Other assets	252	212
Total assets	$ 27,391	$ 53,557
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,150	$ 1,607
Accrued compensation	1,909	2,807
Accrued expenses and other current liabilities	2,415	3,067
Borrowings	42,487	41,289
Total current liabilities	47,961	48,770
Other long-term liablities	215	546
Total liabilities	48,176	49,316
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Preferred stock issuable in series, par value of $0.001		
Shares authorized: 5,000,000 at June 30, 2017 and December 31, 2016	—	—
Shares issued and outstanding: none at June 30, 2017 and December 31, 2016		
Common stock, par value of $0.001		
Shares authorized: 100,000,000 at June 30, 2017 and December 31, 2016		
Shares issued and outstanding: 23,914,024 at June 30, 2017 and 23,776,033 at December 31, 2016	24	24
Additional paid-in capital	259,925	256,606
Accumulated deficit	(280,734)	(252,389)
Total stockholders' equity (deficit)	(20,785)	4,241
Total liabilities and stockholders' equity (deficit)	$ 27,391	$ 53,557

See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues	$ 2,459	$ 4,680	$ 5,950	$ 9,219
Cost of revenues	3,919	3,645	7,994	7,005
Gross profit (loss)	(1,460)	1,035	(2,044)	2,214
Operating expenses:				
Research and development	3,097	3,867	7,020	7,914
Selling, general and administrative	6,189	9,461	15,507	21,622
Restructuring charges	519	—	519	—
Total operating expenses	9,805	13,328	23,046	29,536
Loss from operations	(11,265)	(12,293)	(25,090)	(27,322)
Interest income	31	28	63	61
Interest expense	(1,571)	(1,235)	(3,121)	(2,406)
Other income (expense), net	6	4	9	5
Net loss and comprehensive loss	$ (12,799)	$ (13,496)	$ (28,139)	$ (29,662)
Net loss per share, basic and diluted	$ (0.54)	$ (1.06)	$ (1.18)	$ (2.34)
Weighted average common shares used to compute net loss per share, basic and diluted	23,914	12,734	23,867	12,702

See accompanying notes.

AVINGER, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (28,139)	$ (29,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	854	692
Amortization of debt issuance costs and debt discount	124	98
Stock-based compensation	2,877	3,588
Noncash interest expense and other charges	1,083	767
Provision for doubtful accounts receivable	99	—
Provision for excess and obsolete inventories	3,577	465
Changes in operating assets and liabilities:		
Accounts receivable	1,981	(1,343)
Inventories	(1,925)	(3,033)
Prepaid expenses and other current assets	(468)	(549)
Other assets	(39)	(34)
Accounts payable	(457)	(422)
Accrued compensation	(898)	(818)
Accrued expenses and other current liabilities	(640)	(510)
Other long-term liabilities and accrued interest	(340)	(426)
Net cash used in operating activities	(22,311)	(31,187)
Cash flows from investing activities		
Purchase of property and equipment	(45)	(729)
Net cash used in investing activities	(45)	(729)
Cash flows from financing activities		
Principal paydown of capital lease obligations	(12)	(15)
Payments on deferred offering costs	—	(163)
Proceeds from borrowings, net of issuance costs	—	9,725
Proceeds from public offerings, net of issuance costs	—	1,252
Proceeds from the issuance of common stock	236	497
Net cash provided by financing activities	224	11,296
Net change in cash and cash equivalents	(22,132)	(20,620)
Cash and cash equivalents, beginning of period	36,096	43,059
Cash and cash equivalents, end of period	$ 13,964	$ 22,439
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 2,406	$ 1,956
Noncash investing and financing activities:		
Accounts payable for purchases of property and equipment	$ —	$ 13
Transfer between inventory and property and equipment	$ 93	$ 1,046

See accompanying notes.

AVINGER, INC.

Notes to Condensed Financial Statements

1. Organization

Organization, Nature of Business

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

Liquidity Matters

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of June 30, 2017, the Company had an accumulated deficit of $280,734,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $13,964,000 at June 30, 2017 and expected revenues will be sufficient to allow the Company to fund its current operations until approximately December 31, 2017. The Company will seek additional sources of funding in the form of debt financing or equity issuances. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company's ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding. Additionally, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the Term Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively "CRG"), the entire amount of borrowings at June 30, 2017 and December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

Public Offerings

In January 2015, the Company issued and sold 5,000,000 shares of its common stock in its initial public offering ("IPO") at a public offering price of $13.00 per share, for net proceeds of approximately $56,897,000 after deducting underwriting discounts and commissions of approximately $4,550,000 and expenses of approximately $3,553,000. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock resulting in the reclassification of $137,626,000 from outside of stockholders' equity to additional paid-in capital.

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to $150,000,000 of its securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company ("Cowen"), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the three and six months ended June 30, 2017, the Company sold no shares of common stock under the "at-the-market" program. During the three and six months ended June 30, 2016, the Company sold 125,214 shares of common stock under the "at-the-market" program at an average price of $11.20 and raised net proceeds of $1,252,000, after payment of $42,000 in commissions and fees to Cowen.

During the year ended December 31, 2016, the Company sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5,171,000, after payment of $160,000 in commissions and fees to Cowen. In August 2016, the Company issued and sold 9,857,800 shares of its common stock in its follow-on public offering, which includes the exercise in full by the underwriters of their option to purchase 1,285,800 shares of common stock, at a public offering price of $3.50 per share. Net proceeds from the follow-on public offering were approximately $31,549,000 after deducting underwriting discounts and commissions of approximately $2,415,000 and expenses of approximately $538,000.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC"). The accompanying unaudited condensed interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial information. The results for the three and six months ended June 30, 2017, are not necessarily indicative of results to be expected for the year ending December 31, 2017, or for any other interim period or for any future year. The December 31, 2016 condensed balance sheet data has been derived from audited financial statements. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements. These unaudited condensed financial statements and notes should be read in conjunction with the financial statements included in the Company's Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on March 14, 2017. The Company's significant accounting policies are more fully described in Note 2 of the Notes to the Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

Use of Estimates

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

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of June 30, 2017 and December 31, 2016. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of its borrowings approximate fair value.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, using level 1 inputs, based on quoted market prices. As of June 30, 2017 and December 31, 2016, the Company's cash equivalents are entirely comprised of investments in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders' equity (deficit). There were no unrealized gains and losses as of June 30, 2017 and December 31, 2016. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

Concentration of Credit Risk, and Other Risks and Uncertainties

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

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

The Company provides for uncollectible amounts when specific credit problems arise. Management's estimates for uncollectible amounts have been adequate, and management believes that all significant credit risks have been identified at June 30, 2017 and December 31, 2016.

The Company's accounts receivable are due from a variety of health-care organizations in the United States and select European markets. At June 30, 2017 and December 31, 2016, there were no customers that represented 10% or more of the Company's accounts receivable. For the three and six months ended June 30, 2017 and 2016, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company's financial position and results of operations.

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

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

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

Revenue Recognition

The Company's revenues are derived from (1) sale of its Lightbox (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 605-10, *Revenue Recognition*, when persuasive evidence of an arrangement exists, the fee is fixed or determinable, collection of the fee is probable and delivery has occurred. For all sales, the Company uses either a signed agreement or a binding purchase order as evidence of an arrangement.

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

1. Lightbox sales: The Company sells its products directly to hospitals and medical centers. Provided all other criteria for revenue recognition have been met, the Company recognizes revenue for Lightbox sales directly to end customers when delivery and acceptance occurs, which is defined as receipt by the Company of an executed form by the customer acknowledging that the training and installation process is complete.

2. Sales of disposables: Disposable revenues consist of sales of the Company's catheters and accessories and are recognized when the product has shipped, risk of loss and title has passed to the customer and collectability is reasonably assured.

3. Service revenue: Service revenue is recognized ratably over the term of the service period. To date service revenue has been insignificant.

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

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

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

For sales through distributors, the Company recognizes revenue when title to the product and the risk of loss transfers from the Company to the distributor. The distributors are responsible for all marketing, sales, training and warranty in their respective territories. The standard terms and conditions contained in the Company's distribution agreements do not provide price protection or stock rotation rights to any of its distributors. In addition, its distributor agreements do not allow the distributor to return or exchange products, and the distributor is obligated to pay the Company upon invoice regardless of its ability to resell the product.

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

Cost of Revenues

Cost of revenues consists primarily of manufacturing overhead costs, material costs and direct labor. A significant portion of the Company's cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. The Company expenses all warranty costs and inventory provisions to cost of revenues. The Company records adjustments to its inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. Cost of revenues also includes depreciation expense for the Lightboxes under lease and commercial evaluation program agreements and certain direct costs such as shipping costs.

Product Warranty Costs

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

	Amount
Balance at December 31, 2016	$ 509
Warranty provision	175
Usage/Release	(243)
Balance at June 30, 2017	$ 441

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders' continued service to the Company. For the computation of net loss per share, there were no common stock shares subject to repurchase excluded from the calculations as of June 30, 2017 and 2016. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	$ (12,799)	$ (13,496)	$ (28,139)	$ (29,662)
Weighted average common stock outstanding	23,914	12,734	23,867	12,702
Net loss per share, basic and diluted	$ (0.54)	$ (1.06)	$ (1.18)	$ (2.34)

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an anti-dilutive impact due to losses reported:

	June 30,	
	2017	2016
Common stock options	4,071,506	3,801,543
Unvested restricted stock units	353,331	267,558
Common stock warrants	2,152,117	2,152,117
	6,576,954	6,221,218

Comprehensive Loss

For the three and six months ended June 30, 2017 and 2016, there was no difference between comprehensive loss and the Company's net loss.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment. For the three months ended June 30, 2017 and 2016, 96% and 94% of the Company's revenues were in the United States, respectively, based on the shipping location of the external customer. For the six months ended June 30, 2017 and 2016, 96% and 97% of the Company's revenues were in the United States, respectively, based on the shipping location of the external customer.

Accounting Pronouncements Adopted in 2017

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee share-based payments, including income tax consequences, application of award forfeitures to expense, classification on the statement of cash flows, and classification of awards as either equity or liabilities. This guidance was effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods.

As a result of adopting ASU 2016-09, the Company has made an accounting policy election to account for forfeitures as they occur. This change has been applied on a modified retrospective basis, resulting in a cumulative-effect adjustment to increase accumulated deficit by $206,000 as of January 1, 2017, the date of adoption. The adoption of ASU 2016-09 also requires that excess tax benefits and tax deficiencies be recorded in the statement of operations as opposed to additional paid-in capital when the awards vest or are settled. The adoption of ASU 2016-09 as it relates to the accounting for excess tax benefits and tax deficiencies has no impact on the Company's current financial statements or on any prior period financial statements presented. ASU 2016-09 also requires excess tax benefits to be classified as an operating activity, consistent with other income tax cash flows, and may be applied either on a retrospective or prospective basis. The Company has elected to apply this amendment on a prospective basis, as there is no impact to its prior period statements of cash flows. As such, prior periods have not been adjusted.

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance was effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company's elected to adopt this standard as of January 1, 2017, on a prospective basis. The adoption had no impact on its financial statements.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740) — Balance Sheet Classification of Deferred Taxes, which requires entities to present its deferred tax assets and deferred tax liabilities as noncurrent in its financial statements. The guidance was effective for public entities for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company's elected to adopt this standard as of January 1, 2017, on a prospective basis. The adoption of this new guidance does not create any impact to the Company's financial statements due to the fact that no deferred tax assets or liabilities have been reported in its financial statements. This will likely remain the case if the Company continues to incur additional losses, which requires it to maintain a full valuation allowance as it will be more-likely-than-not that its deferred tax assets are not realizable.

Recent Accounting Pronouncements

In May 2014, the FASB, jointly with the International Accounting Standards Board, issued a comprehensive new standard on revenue recognition from contracts with customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will become effective for the Company beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company has preliminarily decided to adopt this accounting standard in the first quarter of fiscal year 2018 using the modified retrospective approach, with the cumulative effect being recorded within accumulated deficit on January 1, 2018; however, the final determination will depend on a number of factors including finalizing our assessment of the impact to the Company's financial results as well as assessing the impacts of any additional disclosure requirements. The guidance requires an entity to recognize revenue in an amount that reflects the consideration to which an entity expects to be entitled in exchange for the transfer of goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company has not completed its assessment of the adoption on its financial statements.

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

3. Fair Value Measurements

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

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

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

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

As of June 30, 2017 and December 31, 2016, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of June 30, 2017 and December 31, 2016, there were no financial assets and liabilities categorized as Level 2 or 3. There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2017 and 2016.

4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	$ 1,955	$ 5,706
Work-in-process	451	—
Finished products	4,293	2,756
Total inventories	$ 6,699	$ 8,462

5. Borrowings

CRG

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

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amounts borrowed plus any PIK is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company's assets. The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement, as amended, include a covenant that the Company maintain a minimum of $5,000,000 of cash and certain cash equivalents, and the Company had to achieve minimum revenue of $7,000,000 in 2015 and $18,000,000 in 2016, and must achieve minimum revenue of $40,000,000 in 2017, $50,000,000 in 2018, $60,000,000 in 2019 and $70,000,000 in 2020 and in each year thereafter, as applicable. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company's capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of June 30, 2017, the Company was in compliance with all applicable covenants. As of June 30, 2017, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,	Principal and PIK Loan Repayments
2017	$ —
2018	—
2019	10,000
2020	20,000
2021	10,000
	40,000
Add: Accretion of closing fees	638
Add: PIK	2,653
	43,291
Less: Amount representing debt financing costs	(804)
Borrowings, net of current portion	$ 42,487

Contemporaneously with the execution of the Loan Agreement, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with CRG which allowed it to purchase up to $5,000,000 of the Company's common stock. CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of $14.357 per share, which is the 10-day average of closing prices of the Company's common stock ending on September 21, 2015. The closing price on September 22, 2015 was $13.97 yielding a $0.387 per share premium. Both the premium and the issuance costs were allocated to the borrowings under Loan Agreement and the common stock purchase under the Securities Purchase Agreement based on the relative fair values of each security. The portion of the premium allocated to the borrowings is being amortized over the term of the Loan Agreement. Pursuant to the Securities Purchase Agreement, the Company filed a shelf registration statement covering, among other things, the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect.

In connection with the initial drawdown under the Loan Agreement, the Company recorded a debt discount of $876,000. The debt discount comprised financing fees of $450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and Securities Purchase Agreement with CRG of $541,000 net of the common stock premium of $115,000 based on the relative fair values of each security. In connection with the June 2016 drawdown under the Loan Agreement, the Company recorded a debt discount of $275,000 which comprised financing fees of $150,000, paid directly to CRG, and other costs directly attributable to the Loan Agreement with CRG of $125,000. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of June 30, 2017, the balance of the aggregate debt discount was $804,000.

As noted in Note 1 to these financial statements, due to the substantial doubt about the Company's ability to continue operating as a going concern and the material adverse change clause in the CRG Loan Agreement, the entire amount of borrowings at June 30, 2017 and December 31, 2016 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

PDL BioPharma

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

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

In September 2015, in connection with the consummation of the Loan Agreement with CRG, the Company repaid all amounts outstanding under the Agreement. The payoff amount of $21,363,000 included accrued interest through the repayment date of $563,000 and $200,000 as an end-of-term final payment fee.

In addition to the interest and principal payments, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company's quarterly net revenues. Upon the prepayment of the Term Note, the Company's obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable monthly. The ongoing obligation was determined to be an embedded element of the Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interest obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2016, is used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. At the time of the repayment the resulting increase in the carrying value of the Assigned Interests, of $942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interests obligations of $980,000 and $1,463,000, representing the net present value of the future minimum royalty obligation as of June 30, 2017 and December 31, 2016, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities and within other long-term liabilities as of June 30, 2017 and December 31, 2016, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion, on the balance sheet.

Additionally, until there are no further obligations to periodically pay PDL a percentage of its net revenue in April 2018, the Company must comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company is in compliance with the covenants under the Agreement.

6. Capital Leases

Capital lease obligations consist of leased office equipment. As of June 30, 2017 and December 31, 2016, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $26,000 and $39,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of June 30, 2017, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2017	$ 13
2018	13
2019	1
Total minimum payments	27
Less: Amount representing future interest	1
Present value of minimum lease payments	$ 26

7. Commitments and Contingencies

Lease Commitments

The Company's operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In March 2016, the Company entered into an additional non-cancelable operating lease for warehouse and storage space that expires in November 2019. Rent expense was $506,000 and $268,000 for the three months ended June 30, 2017 and 2016, and $1,013,000 and $490,000 for the six months ended June 30, 2017 and 2016, respectively.

Aggregate future minimum lease payments as of June 30, 2017, are as follows (in thousands):

Year ending December 31,	Future Minimum Lease Payments
2017	$ 990
2018	2,033
2019	1,915
Total minimum lease payments	$ 4,938

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had noncancellable commitments to suppliers for purchases totaling $1,766,000 and $3,542,000 as of June 30, 2017 and December 31, 2016, respectively.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future, but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations under these agreements.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

Legal Proceedings

Except as set forth below, the Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business.

Between May 22, 2017 and May 25, 2017, three purported class actions were filed in the Superior Court of the State of California, County of San Mateo ("State Court"), against the Company and certain of its officers and directors. The actions were captioned Grotewiel v. Avinger, Inc., et al., No. 17-CIV-02240, Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, and Olberding v. Avinger, Inc., et al., No. 17-CIV-02307. The underwriters of the Company's IPO in January 2015 are also named as defendants. These lawsuits allege that the registration statement for the Company's IPO made false and misleading statements and omissions in violation of the Securities Act of 1933. Plaintiffs seek to represent a class of purchasers of the Company's common stock in and/or traceable to its IPO. Plaintiffs seek, among other things, unspecified compensatory damages, interest, costs, recission, and attorneys' fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California ("Federal Court"), where they were captioned Grotewiel v. Avinger, Inc., No. 17-cv-03400, Gonzalez v. Avinger, Inc., No. 17-cv-03401, and Olberding v. Avinger, Inc., No. 17-cv-03398, and where the actions were related and assigned to the same judge. On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted plaintiffs' motions to remand and entered an order to show cause, within 14 days, why the Grotewiel action should not be similarly remanded.

The Company and its directors believe that the foregoing lawsuits are entirely without merit and intend to vigorously defend against the actions.

8. Stockholders' Equity (Deficit)

Preferred Stock

At June 30, 2017, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At June 30, 2017, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 23,914,024 shares were issued and outstanding.

Common Stock Warrants

In connection with the issuance of the Company's Series E Convertible Preferred Stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible Preferred Stock, warrants to purchase up to the number of shares of common stock equal to 70% of the number of shares of the Company's Series E Convertible Preferred Stock purchased.

The warrants are immediately exercisable, at an exercise price per share of $12.60, and expire upon the earlier of September 2, 2019 or upon the consummation of a change of control of the Company. The Company determined that these common stock warrants meet the requirements for equity classification. The common stock warrants were recorded at their allocated fair value within stockholders' equity (deficit).

As of June 30, 2017 and December 31, 2016, warrants to purchase an aggregate of 2,152,117 shares of common stock were outstanding.

Stock Plans

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Equity Incentive Plan ("2015 Plan"). The 2015 Plan replaced the 2009 Stock Plan (the "2009 Plan") which was terminated immediately prior to consummation of the Company's IPO, collectively the "Plans." The 2015 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of nonstatutory stock options ("NSOs"), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 1,320,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan, plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 1,690,000 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. For fiscal 2017, the common stock available for issuance under the 2015 Plan was increased by 1,188,801 shares of common stock. As of June 30, 2017, 1,831,963 shares were available for grant under the 2015 Plan.

Pursuant to the Plans, ISOs and NSOs may be granted with exercise prices at not less than 100% of the fair value of the common stock on the date of grant and the exercise price of ISOs granted to a stockholder, who, at the time of grant, owns stock representing more than 10% of the voting power of all classes of the stock of the Company, shall be not less than 110% of the fair market value per share of common stock on the date of grant. The Company's Board of Directors determines the vesting schedule of the options. Options granted generally vest over four years and expire ten years from the date of grant.

Stock option activity under the Plans is set forth below:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2016	3,708,011	$ 7.86	$ 5
Options granted	1,073,751	$ 1.95	
Options exercised	—	$ —	
Options cancelled	(710,256)	$ 7.91	
Balance at June 30, 2017	4,071,506	$ 6.29	$ 6

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2017 was $1.05 per share. As of June 30, 2017, the aggregate intrinsic value of options outstanding and vested was zero. There were no options exercised during the six months ended June 30, 2017. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company's net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the three and six months ended June 30, 2017 and 2016.

At June 30, 2017 and at December 31, 2016, there were 1,989,895 and 1,630,917 shares, respectively, vested with a weighted-average exercise price of $7.59 and $7.40 per share, respectively, and a weighted average contractual life of 7.38 and 7.63 years, respectively.

The Company's RSUs vest annually over four years in equal increments. A summary of all RSU activity for the six months ended June 30, 2017 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Awards outstanding at December 31, 2016	214,176	$ 14.88	3.09	$ 792
Awarded	313,665	$ 2.05		
Released	(38,125)	$ 12.98		
Forfeited	(136,385)	$ 7.56		
Awards outstanding at June 30, 2017	353,331	$ 6.52	3.32	$ 158

As of June 30, 2017, $1,992,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.81 years. The Company used the closing market price of $0.45 per share at June 30, 2017, to determine the aggregate intrinsic value.

2015 Employee Stock Purchase Plan

In January 2015, the Board of Directors adopted and the Company's stockholders approved the 2015 Employee Stock Purchase Plan ("ESPP") under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. Initially 500,000 shares of common stock were reserved for issuance, which is subject to an automatic increase on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 493,000 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. For fiscal 2017, the common stock available for issuance under the ESPP was increased by 356,640 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of June 30, 2017, approximately 801,138 shares of common stock remained reserved for issuance under the ESPP. The Company incurred $25,000 and $127,000 in stock-based compensation expense related to the ESPP for the three months ended June 30, 2017 and 2016, and $90,000 and $217,000 for the six months ended June 30, 2017 and 2016, respectively.

9. Stock-Based Compensation

Stock-based compensation for the Company includes amortization related to all stock options, RSUs and shares issued under the ESPP, based on the grant-date estimated fair value. The Company estimates the fair value of stock options and shares issued under the ESPP on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company's common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company's common stock, and the volatility over the expected term of the awards.

The fair value for the Company's employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following weighted average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term (years)	5.5	6.0	5.9	6.0
Expected volatility	63.3%	49.0%	57.1%	49.1%
Risk-free interest rate	1.8%	1.4%	2.2%	1.5%
Dividend rate	—	—	—	—

As of June 30, 2017 and December 31, 2016, the total unamortized compensation expense related to stock option awards granted to employees and directors was $8,194,000 and $12,312,000, which is expected to be amortized over the next 1.9 and 2.3 years, respectively.

The fair value of the shares to be issued under the Company's ESPP was estimated using the Black-Scholes valuation model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Expected term (years)	0.5	0.5	0.5	0.5
Expected volatility	85.0%	77.6%	89.2%	61.4%
Risk-free interest rate	0.78%	0.50%	0.63%	0.38%
Dividend rate	—	—	—	—

Total stock-based compensation expense related to stock-based awards recognized during the three and six months ended June 30, 2017 and 2016, is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of revenues	$ 105	$ 107	$ 256	$ 239
Research and development expenses	500	662	1,041	1,343
Selling, general and administrative expenses	730	841	1,580	2,006
	$ 1,335	$ 1,610	$ 2,877	$ 3,588

10. Restructuring Charges and Expenses

In April 2017, the Company undertook an organizational realignment which included a reduction in force, lowering its total headcount by approximately 33% compared to December 31, 2016, in order to conserve resources. Accordingly, the Company recorded a restructuring charge of approximately $519,000, relating to severance related costs at that time. As of June 30, 2017, $493,000 of the total severance related costs related to the termination of 44 employees had been paid. The Company expects the remaining $26,000 in severance costs to be paid by September 30, 2017.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Quarterly Report on Form 10-Q entitled "Risk Factors."

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to dramatically 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, as well as our Wildcat, Kittycat 2, and the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. We received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris in October 2015, we received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the U.S. and select European countries promptly thereafter.

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

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. Although our sales and marketing efforts are directed at these physicians because they are the primary users of our technology, we consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products. We are designing future products to be compatible with our Lumivascular platform, which we expect to enhance the value proposition for hospitals to invest in our technology. We also believe that Pantheris will qualify for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

Prior to the introduction of our Lumivascular platform our non-imaging catheter products were manufactured by third parties. All of our products are now manufactured in-house at our facilities in Redwood City, California using components and sub-assemblies manufactured both in-house and by outside vendors. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors. We expect our current manufacturing facility will be sufficient through at least 2018.

In addition to 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 $6.0 million in the six months ended June 30, 2017 and $9.2 million in the six months ended June 30, 2016. During the six months ended June 30, 2017 and 2016, our net loss was $28.1 million and $29.7 million, respectively. We have not been profitable since inception, and as of June 30, 2017, our accumulated deficit was $280.7 million. Since

inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering, or IPO, of 5.0 million shares. As a result of our IPO, which closed in February 2015, we received net proceeds of approximately $56.9 million, after underwriting discounts and commissions of approximately $4.5 million and other expenses associated with our IPO of approximately $3.6 million.

In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we may borrow up to $50.0 million on or before March 29, 2017. We borrowed $30.0 million on September 22, 2015 and an additional $10.0 million on June 15, 2016 under the Loan Agreement. Contingent on achievement of certain revenue milestones, among other conditions, we would have been eligible to borrow an additional $10.0 million, on or prior to March 29, 2017; however, we did not achieve the level of revenues required to borrow the final $10.0 million. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of $14.357 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. During the six months ended June 30, 2017, we sold no shares of common stock under the "at-the-market" program. In addition, in August 2016, we completed a follow-on public offering of 9,857,800 shares of our common stock for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 9,857,800 shares include the exercise in full by the underwriters of their option to purchase an additional 1,285,800 shares of our common stock.

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

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

Components of Our Results of Operations

Revenues

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

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

Cost of Revenues and Gross Margin

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

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Interest Income (Expense), net

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

Other Income (Expense), net

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

Results of Operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands, except percentages)			
Revenues	$ 2,459	$ 4,680	$ 5,950	$ 9,219
Cost of revenues	3,919	3,645	7,994	7,005
Gross profit (loss)	(1,460)	1,035	(2,044)	2,214
Gross margin	-59%	22%	-34%	24%
Operating expenses:				
Research and development	3,097	3,867	7,020	7,914
Selling, general and administrative	6,189	9,461	15,507	21,622
Restructuring charges	519	—	519	—
Total operating expenses	9,805	13,328	23,046	29,536
Loss from operations	(11,265)	(12,293)	(25,090)	(27,322)
Interest income (expense), net	(1,540)	(1,207)	(3,058)	(2,345)
Other income (expense), net	6	4	9	5
Net loss and comprehensive loss	$ (12,799)	$ (13,496)	$ (28,139)	$ (29,662)

Comparison of Three Months Ended June 30, 2017 and 2016

Revenues. Revenues decreased $2.2 million, or 47%, to $2.5 million during the three months ended June 30, 2017, compared to $4.7 million during the three months ended June 30, 2016. For the three months ended June 30, 2017, revenues related to sales of our disposable catheters decreased by 43% to $2.0 million while revenues related to our Lightbox imaging consoles decreased by 60% to $0.5 million. The decreased revenues in the three months ended June 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris as well as a strategic decision we made at the beginning of the year to align the focus of our sales force on driving the utilization at our current installed base versus a focus on building the installed base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

Cost of Revenues and Gross Margin. Cost of revenues increased $0.3 million, or 8%, to $3.9 million during the three months ended June 30, 2017, compared to $3.6 million during the three months ended June 30, 2016. This increase was primarily attributable to a $2.3 million charge in the three months ended June 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories and a $0.3 million charge related to scrapped inventories, partially offset by our decreased sales. Gross margin for the three months ended June 30, 2017 decreased to -59%, compared to 22% in the three months ended June 30, 2016. Gross margin was negatively impacted by an increase of $2.1 million in the charge for inventory excess and obsolescence in the three months ended June 30, 2017 compared to the prior year period.

Research and Development Expenses. R&D expenses decreased $0.8 million, or 20%, to $3.1 million during the three months ended June 30, 2017, compared to $3.9 million during the three months ended June 30, 2016. This decrease was primarily due to a $0.4 million decrease in personnel-related expenses, a decrease of $0.3 million in product development materials and related costs and a decrease of $0.1 million in outside services. Personnel-related expenses included stock-based compensation expense of $0.5 million compared to $0.7 million for the three months ended June 30, 2017 and 2016, respectively.

Selling, General and Administrative Expenses. SG&A expenses decreased $3.3 million, or 35%, to $6.2 million during the three months ended June 30, 2017, compared to $9.5 million during the three months ended June 30, 2016. This decrease was primarily due to a $2.8 million decrease in personnel-related expenses and a decrease of $0.5 million in marketing costs. Personnel-related expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. For the three months ended June 30, 2017, our marketing costs decreased as a result of our workforce reduction and efforts to reduce operating expenses. Personnel-related expenses included stock-based compensation expense of $0.7 million compared to $0.8 million for the three months ended June 30, 2017 and 2016, respectively.

Restructuring. In April 2017, we undertook an organizational realignment to conserve resources which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016. We recorded a restructuring charge of approximately $0.5 million, which consisted of severance related costs specific to the termination of 44 employees, at that time. As of June 30, 2017, all except $26,000 of costs associated with the restructuring were paid.

Interest Income (Expense), Net. Interest expense, net increased $0.3 million, or 28%, to an expense of $1.5 million during the three months ended June 30, 2017, compared to an expense of $1.2 million during the three months ended June 30, 2016. This increased expense was attributable to the additional $10.0 million borrowing on June 15, 2016 under our Loan Agreement with CRG.

Other Income (Expense), Net. Other income, net increased $2,000 to an income of $6,000, during the three months ended June 30, 2017, compared to an income of $4,000 during the three months ended June 30, 2016. Other income for the three months ended June 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

Comparison of Six Months Ended June 30, 2017 and 2016

Revenues. Revenues decreased $3.2 million, or 35%, to $6.0 million during the six months ended June 30, 2017, compared to $9.2 million during the six months ended June 30, 2016. For the six months ended June 30, 2017, revenues related to sales of our disposable catheters decreased by 29% to $5.0 million while revenues related to our Lightbox imaging consoles decreased by 55% to $1.0 million. The decreased revenues in the six months ended June 30, 2017 reflect the impact of continued product performance issues with the current version of Pantheris as well as a strategic decision we made at the beginning of the year to align the focus of our sales force on driving the utilization at our current installed base versus a focus on building the installed base of Lightbox imaging consoles. The decrease in Lightbox imaging consoles revenue also relates to the increased flexibility in the Lightbox acquisition rental or placement programs being offered, which resulted in a lower portion of accounts acquiring Lightboxes through up-front purchases.

Cost of Revenues and Gross Margin. Cost of revenues increased $1.0 million, or 14%, to $8.0 million during the six months ended June 30, 2017, compared to $7.0 million during the six months ended June 30, 2016. This increase was primarily attributable to a $3.6 million charge in the six months ended June 30, 2017 for excess and obsolescence predominantly related to our Lightbox and Pantheris inventories and a $1.2 million charge related to scrapped inventories, partially offset by our decreased sales. Gross margin for the six months ended June 30, 2017 decreased to -34%, compared to 24% in the six months ended June 30, 2016. Gross margin was negatively impacted by an increase of $3.1 million in the charges for inventory excess and obsolescence and an increase of $0.7 million of scrapped inventories during the six months ended June 30, 2017 compared to the prior year period, partially offset by a decrease of $0.3 million in warranty expenses.

Research and Development Expenses. R&D expenses decreased $0.9 million, or 11%, to $7.0 million during the six months ended June 30, 2017, compared to $7.9 million during the six months ended June 30, 2016. This decrease was primarily due to a $0.5 million decrease in personnel-related expenses and a decrease of $0.4 million in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $1.0 million compared to $1.3 million for the six months ended June 30, 2017 and 2016, respectively.

Selling, General and Administrative Expenses. SG&A expenses decreased $6.1 million, or 28%, to $15.5 million during the six months ended June 30, 2017, compared to $21.6 million during the six months ended June 30, 2016. This decrease was primarily due to a $5.1 million decrease in personnel-related expenses, a decrease of $1.7 million in marketing costs and a decrease of $0.1 million relating to depreciation, partially offset by an increase of $0.6 million in consulting, legal and professional fees and an increase of $0.3 million relating to the allocation of facilities expense. Personnel-related expenses decreased due to a decrease in headcount and stock-based compensation expense as a result of our organizational realignment in April 2017. Personnel-related expenses included stock-based compensation expense of $1.6 million compared to $2.0 million for the six months ended June 30, 2017 and 2016, respectively. Higher marketing costs for the six months ended June 30, 2016 were associated with pre-commercial preparation expenses primarily relating to $1.1 million of Pantheris devices being designated as training and demonstration units for use by our sales and marketing personnel.

Restructuring. In April 2017, we undertook an organizational realignment to conserve resources which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016. We recorded a restructuring charge of approximately $0.5 million, which consisted of severance related costs specific to the termination of 44 employees, at that time. As of June 30, 2017, all except $26,000 of costs associated with the restructuring were paid.

Interest Income (Expense), Net. Interest income (expense), net increased $0.8 million, or 30%, to an expense of $3.1 million during the six months ended June 30, 2017, compared to an expense of $2.3 million during the six months ended June 30, 2016. This increased expense was attributable to the additional $10.0 million borrowing on June 15, 2016 under our Loan Agreement with CRG.

Other Income (Expense), Net. Other income (expense), net increased to an income of $9,000 during the six months ended June 30, 2017, compared to income of $5,000 during the six months ended June 30, 2016. Other income for the six months ended June 30, 2017 and 2016, was primarily attributable to the remeasurement of foreign exchange transactions.

Liquidity and Capital Resources

As of June 30, 2017, we had cash and cash equivalents of $14.0 million and an accumulated deficit of $280.7 million, compared to cash and cash equivalents of $36.1 million and an accumulated deficit of $252.4 million as of December 31, 2016. We currently believe our existing cash and cash equivalents, expected revenues and the net proceeds from our "at-the-market" program, will be sufficient to meet our capital requirements and fund our operations until at least December 31, 2017. We will need to raise additional funds through future equity or debt financings within the next six months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next six months could cause substantial dilution to our existing stockholders. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which diverts resources from other activities. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and significantly scale back our business and operations. To date, our primary sources of capital have been private placements of preferred stock, debt financing agreements, our "at-the-market" program, our IPO and our follow-on public offering in August 2016. As previously disclosed, on April 20 and May 24, 2017 we received letters from the Listing Qualifications Department of The NASDAQ Stock Market, LLC ("Nasdaq") notifying us that the Company was not in compliance with applicable listing rules. In the event that we do not regain compliance with those rules and our stock is delisted by Nasdaq, our access to public capital markets would be impaired. For more information on this risk, see Part II, Item 1A "*Risk Factors*."

In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to $50.0 million, of which $30.0 million was immediately available and borrowed by us. Of the remaining $20.0 million, we borrowed $10.0 million on June 15, 2016 and the availability of the remaining $10.0 million was contingent on the achievement of certain net revenue milestones prior to December 31, 2016, which were not achieved. As of June 30, 2017, we had $42.5 million outstanding under the Loan Agreement. For more information, see Part I, Item 2 *"Contractual Obligations."*

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement, as amended, include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents, and we had to achieve minimum revenue of $7.0 million in 2015 and $18.0 million in 2016, and must achieve minimum revenue of $40.0 million in 2017, $50.0 million in 2018, $60.0 million in 2019 and $70.0 million in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include our failure to make timely payments of amounts due under the Loan Agreement, the failure to adhere to the covenants set forth in the Loan Agreement, our insolvency or upon the occurrence of a material adverse change. We were in compliance with the covenants under the Loan Agreement as of June 30, 2017.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into an "at-the-market" program pursuant to a Sales Agreement with Cowen, as sales agent, through which we may, from time to time, issue and sell common stock with an aggregate value of up to $50.0 million. The shelf registration statement was declared effective by the Securities and Exchange Commission, or SEC, on March 8, 2016. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. Common stock sold in the "at-the-market" program is sold at prevailing market prices at the time of the sale, and, as a result, prices vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under the "at-the-market" program at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. During the six months ended June 30, 2017, we did not sell any shares of common stock under the "at-the-market" program. In addition, in August 2016, we issued and sold 9,857,800 shares of our common stock in a follow-on public offering at a public offering price of $3.50 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 9,857,800 shares include the exercise in full by the underwriters of their option to purchase an additional 1,285,800 shares of our common stock.

Cash Flows

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (22,311)	$ (31,187)
Investing activities	(45)	(729)
Financing activities	224	11,296
Net increase (decrease) in cash and cash equivalents	$ (22,132)	$ (20,620)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2017 was $22.3 million, consisting primarily of a net loss of $28.1 million and an increase in net operating assets of $2.8 million, offset by non-cash charges of $8.6 million. The increase in net operating assets was due to an increase in inventories, prepaid expenses and other current assets, decreases in accounts payable, accrued compensation and accrued expenses and other current liabilities, was due to our workforce reduction in April 2017 and efforts to reduce operating expenses, decreases in other liabilities related to the repayment of assigned interest to PDL, partially offset by a decrease in accounts receivable. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with CRG, and an increased reserve for excess and obsolescence in inventories.

Net cash used in operating activities for the six months ended June 30, 2016 was $31.2 million, consisting primarily of a net loss of $29.7 million and an increase in net operating assets of $7.1 million, offset by non-cash charges of $5.6 million. The increase in net operating assets was primarily due to the commercial launch of Pantheris in March 2016 resulting in an increase in accounts receivable and inventories. The increase in net operating assets was also due to an increase in prepaid expenses and other current assets, and decreases in accounts payable and accrued expenses and other current liabilities, due to timing of payments, and a decrease in accrued compensation. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with CRG, and an increased reserve for excess and obsolescence in inventories.

Net Cash Used in Investing Activities

Net cash used in investing activities in the six months ended June 30, 2017 was $45,000 consisting of purchases of property and equipment.

Net cash used in investing activities in the six months ended June 30, 2016 was $0.7 million consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2017 of $0.2 million primarily relates to proceeds from purchases under our employee stock purchase plan.

Net cash provided by financing activities in the six months ended June 30, 2016 of $11.3 million primarily relates to net proceeds of $9.7 million from the debt financing under the Loan Agreement with CRG, net proceeds of $1.3 million from the issuance of common stock under the Sales Agreement with Cowen and $0.5 million proceeds from purchases under our employee stock purchase plan and proceeds from the exercise of stock options, partially offset by the cash paid for deferred offering costs of $0.2 million.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as the use of structured finance, special purpose entities, or variable interest entities.

Contractual Obligations

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

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

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant and material changes in our critical accounting policies during the three months ended June 30, 2017, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical accounting policies and significant judgments and estimates" in our most recent Annual Report on Form 10-K, as filed with the SEC on March 14, 2017.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Due to the short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair value of our cash equivalents. We do not currently use or plan to use financial derivatives in our investment portfolio.

Credit Risk

As of June 30, 2017 and December 31, 2016, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our Lumivascular platform products to hospitals and medical centers in the United States. None of our customers represented more than 10% of our accounts receivable as of June 30, 2017 and December 31, 2016.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows. Based on our foreign currency balances of monetary assets and liabilities, we estimate that a 10% adverse change in Euro exchange rates versus the U.S. dollar would not have a material effect on the fair value of our monetary assets.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2017. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2017, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the second quarter of 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except as set forth below, as of the date of this Quarterly Report on Form 10-Q, we are not involved in any pending legal proceedings that we believe could have a material adverse effect on our financial condition, results of operations or cash flows. From time to time we may be involved in legal proceedings or investigations, which could harm our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Between May 22, 2017 and May 25, 2017, three purported class actions were filed in the Superior Court of the State of California, County of San Mateo ("State Court"), against us and certain of our officers and directors. The actions were captioned Grotewiel v. Avinger, Inc., et al., No. 17-CIV-02240, Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, and Olberding v. Avinger, Inc., et al., No. 17-CIV-02307. The underwriters of our IPO in January 2015 are also named as defendants. These lawsuits allege that the registration statement for our IPO made false and misleading statements and omissions in violation of the Securities Act of 1933. Plaintiffs seek to represent a class of purchasers of our common stock in and/or traceable to our IPO. Plaintiffs seek, among other things, unspecified compensatory damages, interest, costs, recission, and attorneys' fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California ("Federal Court"), where they were captioned Grotewiel v. Avinger, Inc., No. 17-cv-03400, Gonzalez v. Avinger, Inc., No. 17-cv-03401, and Olberding v. Avinger, Inc., No. 17-cv-03398, and where the actions were related and assigned to the same judge. On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted plaintiffs' motions to remand and entered an order to show cause, within 14 days, why the Grotewiel action should not be similarly remanded.

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition and results of operations. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. If any of the risks actually occur, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes. Please also see "Special 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 grow our business with existing customers;
- results of our clinical trials;
- the timing and success of new product and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- changes in our pricing policies or those of our competitors;
- general economic, political, industry and market conditions, including economic and political uncertainty caused by the recent U.S. presidential election;
- the regulatory environment;
- the hiring, training and retention of key employees, including our sales team;
- the ability of our remaining sales and marketing personnel to maintain and grow our revenues after the April 2017 organizational realignment;
- the cost and potential outcomes of existing and future litigation, including, without limitation, the purported stockholder class action described below under "*Risks Related to Ownership of our Common Stock—Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.*";
- our ability to obtain additional financing; and
- advances and trends in new technologies and industry standards.

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 $28.1 million for the six months ended June 30, 2017, $56.1 million in 2016, $47.3 million in 2015 and $32.0 million in 2014. As of June 30, 2017, we had an accumulated deficit of approximately $280.7 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 our "at-the-market" program, whereby we may issue and sell shares of common stock, together with our cash and cash equivalents at June 30, 2017 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations until at least December 31, 2017. We will need to raise additional funds through future equity or debt financings within the next six months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next six months could cause substantial dilution to our existing stockholders.

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

- the degree of success we experience in commercializing our Lumivascular platform products, particularly Pantheris, and any next-generation versions of such products;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products;
- the costs and expenses of maintaining or expanding our sales and marketing infrastructure and our manufacturing operations;
- the costs and timing of developing variations of our Lumivascular platform products, especially Pantheris and, if necessary, obtaining FDA clearance of such variations;
- the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;
- the number and types of future products we develop and commercialize;
- 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 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. If we raise additional funds through further issuances of equity or convertible debt securities, 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 affect our ability to operate our business and secure additional financing in the future.

As of June 30, 2017, we had $42.5 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG. Our debt with CRG is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, incur debt, grant liens, make investments, make acquisitions, make certain restricted payments and sell assets, in each case subject to certain exceptions. In particular, the covenants of the Loan Agreement, as amended, include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents, and we had to achieve minimum revenue of $7.0 million in 2015 and $18.0 million in 2016, and will have to achieve minimum revenue of $40.0 million in 2017, $50.0 million in 2018, $60.0 million in 2019 and $70.0 million in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if

we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. We are also subject to standard event of default provisions under the Loan Agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. We used the initial net proceeds under the Loan Agreement to repay and terminate our credit facility with PDL Biopharma, Inc., or PDL, however, our obligation to continue to make royalty payments to PDL out of our quarterly revenues through April 18, 2018 remain in effect. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The existing collateral pledged under the Loan Agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions. In addition, potential sources of equity financing may be deterred from investing in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

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

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

In addition, we have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have addressed certain of these concerns and plan to make additional product changes and improvements as a result of this feedback. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised. Even if these issues are resolved and physician concerns addressed, future product performance issues may occur and our reputation could suffer, which could lead to decreased sales of our products. In 2016 and in the first half of 2017, our revenue was adversely impacted by these product performance issues. We also had to incur additional expenses to make product changes and improvements, including improvements to the Pantheris imaging fiber connection, and to replace products in accordance with our warranty policy. This additional expense, and any future expense that we may incur as a result of future product performance issues, will negatively impact our financial performance and results of operations. If we are unable to improve the performance of our products to meet the concerns of physicians our revenue may decline further or fail to increase.

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

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of Pantheris and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA approval to market an enhanced version of Pantheris in March 2016, and Pantheris became commercially available in the United States and select

international markets promptly thereafter. As such acceptance among physicians of these products may not increase or may decline. Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Sales of Pantheris and our other Lumivascular platform products may decline as a result of the reduced sales and marketing personnel headcount after our organizational realignment in April 2017. In some cases 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. Also, although the OCT images created by our Lightbox may make it possible for physicians to reduce the degree to which fluoroscopy and contrast dye are used when using our Lumivascular platform products compared to competing endovascular products, physicians are still using both fluoroscopy and contrast dye, particularly with Pantheris. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it will require training for technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. These or other characteristics and features of our Lumivascular platform may cause our products not to be widely adopted and harm our business, financial condition and results of operation.

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

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

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

In addition, in April 2017, we undertook an organizational realignment, which included a reduction in force, lowering our total headcount by approximately 33% compared to December 31, 2016, and reducing our field sales personnel by nearly 50%. As of June 30, 2017, we had 28 sales professionals. Other sales professionals may leave voluntarily as a result of the reduction in force that we implemented. Given the significant reduction in our sales force, there can be no assurance that our remaining field sales personnel will be adequate to successfully commercialize our products. Further reductions in sales staff may have additional adverse impacts on our business.

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

Our gross margin decreased to -59% and -34% for the three and six months ended June 30, 2017, respectively, compared to 22% and 24% for the three and six months ended June 30, 2016, respectively. Gross margin for the three and six months ended June 30, 2017 was negatively impacted by an increase of $2.1 million and $3.1 million in charges related to excess and obsolete Lightbox and Pantheris inventories, respectively.

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

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

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

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

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

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

are misused, we may become subject to costly litigation initiated by our customers or their patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, the amount or breadth of our coverage may not be adequate for the claims that are made against us.

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

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

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

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

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

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

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

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

Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, Boston Scientific, Cardinal Health, Cook Medical, CR Bard and Medtronic. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic, Philips and Spectranetics. Some competitors have previously attempted to combine intravascular imaging with atherectomy and may have current programs underway to do so. These and other companies may attempt to incorporate on-board visualization into their products in the

future and may remain competitive with us in marketing traditional technologies. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of symptoms associated with mild to moderate PAD and companies that provide products used by surgeons in peripheral and coronary bypass procedures. These competitors and other companies may introduce new products that compete with our products. Many of our competitors have significantly greater financial and other resources than we do and have well-established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

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

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

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

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

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

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

- negative or inconclusive results that may cause us to decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;
- trial results that do not meet the level of statistical significance required by the FDA or other regulatory authorities;
- findings by the FDA or similar foreign regulatory authorities that the product is not sufficiently safe for investigational use in humans;
- interpretations of data from preclinical testing and clinical testing by the FDA or similar foreign regulatory authorities that may be different from our own;
- delays or failure to obtain approval of our clinical trial protocols from the FDA or other regulatory authorities;
- delays in obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites;

- findings by the FDA or similar foreign regulatory authorities that our or our suppliers' manufacturing processes or facilities are unsatisfactory;
- changes in the review policies of the FDA or similar foreign regulatory authorities or the adoption of new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- trouble in managing multiple clinical sites;
- delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- the suspension or termination by us, or regulators, of our clinical trials because the participating patients are being exposed to unacceptable health risks.

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

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

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

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

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

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

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

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

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

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

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

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

- any expansion in our manufacturing capacity, could require changes to our production processes;
- key components and sub-assemblies of our Lumivascular platform products are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities; and
- we have limited experience in complying with the FDA's QSR, which applies to the manufacture of our Lumivascular platform products.

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

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

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

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

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

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

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to consistently produce quality components;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of the manufacturer or supplier to comply with QSR as enforced by the FDA and state regulatory authorities;
- inability to control the quality of products manufactured by third parties;
- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and
- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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

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

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are

relatively few alternative sources of supply. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of the components or sub-assemblies used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components or sub-assemblies incorporated into our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

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

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

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business. In particular, our founder and Executive Chairman, Dr. John B. Simpson, is the visionary behind many of our product development activities and he actively supports our clinical trials and physician education and training efforts. If Dr. Simpson was no longer working at our company, our industry credibility, product development efforts and physician relationships would be harmed. We do not currently maintain key person life insurance policies on any of our employees, including Dr. Simpson.

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

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

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

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

As of December 31, 2016, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $219.1 million and $161.8 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2017 for state purposes. Generally, NOLs can be used to offset taxable income for U.S. federal income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. It is possible that prior transactions with respect to our stock may have caused, and that future issuances or sales of our stock (including certain transactions involving our stock that are outside of our control) could cause, an "ownership change." If an "ownership change" occurs, Section 382 would impose an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could (depending on the extent of such limitation and the NOLs previously used) result in our retaining less cash after payment of U.S. federal income taxes during any year in which we have taxable income (rather than losses) than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal income tax reporting purposes, which could harm our profitability.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of June 30, 2017, we held 15 issued U.S. patents and had 22 U.S. utility patent applications and 7 PCT applications pending. As of June 30, 2017, we also had 24 issued patents outside of the United States. As of June 30, 2017, we had 48 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business.

We use certain open source software in Lightbox. We may face claims from companies that incorporate open source software into their products or from open source licensors, claiming ownership of, or demanding release of, the source code, the open source software or derivative works that were developed using such software, or otherwise seeking to enforce the terms of the applicable open source license. These claims could result in litigation and could require us to cease offering Lightbox unless and until we can re- engineer it to avoid infringement. This re-engineering process could require significant additional research and development resources, and we may not be able to complete it successfully. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and operating results.

Risks Related to Government Regulation

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

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

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

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

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. The Affordable Care Act, among other things, imposed an excise tax of 2.3% on the sale of most medical devices, including ours, and any failure to pay this amount could result in the imposition of an injunction on the sale of our products, fines and penalties. Effective January 1, 2016, the excise tax of 2.3% on the sale of medical devices has been suspended for two years.

The current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the Affordable Care Act, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

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

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the HITECH Act, which protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such

actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations. In addition, the clearance or approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- quarterly variations in our or our competitors' results of operations;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- the loss of key personnel, including changes in our board of directors and management;
- legislation or regulation of our business;
- lawsuits threatened or filed against us;
- the announcement of new products or product enhancements by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

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

Our stock price has decreased significantly over the course of the past year and the Company is currently defending against a purported securities class action. For more information, see Part II, Item 1, "*Legal Proceedings*." Securities litigation, regardless of the outcome, can ultimately result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations, financial condition, reputation and cash flows as well as on the market price of our common stock. In addition, as a result of the decrease in our stock price, the options held by our employees are less valuable which make it more likely that certain of our employees may leave the Company. The loss of key employees could have an adverse effect on our business.

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

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

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

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

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

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

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

We maintain a shelf registration statement on Form S-3, or the Registration Statement, with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $150.0 million of our common stock, preferred stock, depositary shares, warrants, units, subscription rights or debt securities. The Registration Statement was declared effective by the SEC on March 8, 2016. In August 2016, we issued and sold 9,857,800 shares of our common stock in our follow-on public offering at a public offering price of $3.50 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. We have also established, and may in the future establish, "at-the-market" programs pursuant to which we may offer and sell shares of our common stock pursuant to the Registration Statement. During the year ended December 31, 2016, we sold 1,095,378 shares of common stock under our "at-the-market" program with Cowen at an average price of $4.87 and raised net proceeds of $5.2 million, after payment of $160,000 in commissions and fees to Cowen. During the six months ended June 30, 2017, we sold no shares of common stock under our "at-the-market" program with Cowen. In addition, pursuant to our Securities Purchase Agreement with CRG, the Registration Statement also registers for resale 348,262 shares of common stock held by CRG, which may be sold freely in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Sales of newly issued securities under the Registration Statement will result in dilution of our stockholders and could cause our stock price to fall.

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

Our directors, officers and their affiliates have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of August 1, 2017, our directors, officers and their affiliates collectively beneficially own approximately 18.0% of our outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

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

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

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities laws, rules and regulations. Compliance with these laws, rules and regulations have increased our legal and financial compliance costs and will make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company." The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other

things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. Our management and other personnel now need to devote a substantial amount of time to these compliance initiatives. As a result, management's attention may be diverted from other business concerns and our costs and expenses will increase, which could harm our business and operating results. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

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

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

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

Our common stock is currently listed on Nasdaq, which has qualitative and quantitative listing criteria. On April 20, 2017 we received a letter from the Listing Qualifications Department of Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) as the market value of the Company's listed securities, or MVLS, was below the minimum $50 million for the previous 30 consecutive business days. This letter also informed us that we were not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), as we did not have total assets and total revenue of at least $50 million each for the most recently completed fiscal year. We have a period of 180 calendar days, or until October 17, 2017, to regain compliance with these rules. To regain compliance, the MVLS of our common stock must reach at least $50 million for a minimum of 10 consecutive business days.

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

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

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

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

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholder's notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum for certain litigation against us to Delaware; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president (in the absence of a chief executive officer).

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

There were no sales of unregistered securities during the three months ended June 30, 2017.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On August 8, 2017, Thomas J. Fogarty, M.D. resigned from the Board of Directors of the Company effective immediately. Dr. Fogarty's resignation is not the result of any disagreement with the Company relating to the Company's operations, policies or practices.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying exhibit index are filed as part of, and incorporated by reference into, this Quarterly Report on Form 10-Q.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Avinger, Inc.
(Registrant)

Date: August 8, 2017

/s/ JEFFERY M. SOINSKI
Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2017

/s/ MATTHEW B. FERGUSON
Matthew B. Ferguson
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Title
31.1	Certification of the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Jeffrey Soinski, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 8, 2017

/s/ JEFFREY M. SOINSKI
Jeffrey M. Soinski
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Matthew Ferguson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avinger, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 8, 2017

/s/ MATTHEW B. FERGUSON
Matthew B. Ferguson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Avinger, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2017, as filed with the Securities and Exchange Commission (the "Report"), Jeffrey Soinski, Chief Executive Officer of the Company, and Matthew Ferguson, Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 8th day of August, 2017.

/s/ JEFFREY M. SOINSKI	/s/ MATTHEW B. FERGUSON
Jeffrey M. Soinski	Matthew B. Ferguson
Chief Executive Officer	*Chief Financial Officer*
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.