Avinger Inc
Form 10-Q
August 12, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

or

o 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 x No o

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 x No o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x

(Do not check if a smaller reporting company)

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

As of August 3, 2015, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 12,240,164.

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

- the outcome of our clinical studies, including VISION, and plans to conduct further clinical studies;
- our plans to modify our current products, or develop new products, to address additional indications;
- the expected timing of submission of a 510(k) to FDA for Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a 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 the time during which we will be an emerging growth company under the

Jumpstart Our Business Startups Act or a smaller reporting company under the Securities Act;

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

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AVINGER, INC.

AS OF AND FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

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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, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 60,697	$ 12,316
Accounts receivable, net	1,651	2,068
Inventories	3,759	3,991
Prepaid expenses and other current assets	1,117	562
Total current assets	67,224	18,937
Property and equipment, net	2,226	2,608
Other assets	1,114	3,235
Total assets	$ 70,564	$ 24,780
Liabilities, convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 998	$ 1,013
Accrued compensation	2,127	1,147
Accrued expenses and other current liabilities	3,659	4,850
Borrowings, current portion	5,618	1,873
Total current liabilities	12,402	8,883
Borrowings, net of current portion	14,887	18,537
Convertible notes and accrued interest	9,489	8,643
Other long-term liablities	154	325
Total liabilities	36,932	36,388
Commitments and contingencies (Note 8)		
Convertible preferred stock issuable in series, par value of $0.001		
Shares authorized: none at June 30, 2015 and 6,819,197 at December 31, 2014		
Shares issued and outstanding: none at June 30, 2015 and 5,262,728 at December 31, 2014		
Liquidation preference: none at June 30, 2015		132,260
Stockholders equity (deficit):		
Preferred stock issuable in series, par value of $0.001		
Shares authorized: 5,000,000 at June 30, 2015 and none at December 31, 2014		

Shares issued and outstanding: none at June 30, 2015 and December 31, 2014				
Common stock, par value of $0.001				
Shares authorized: 100,000,000 at June 30, 2015 and 15,555,555 at December 31, 2014				
Shares issued and outstanding: 12,240,164 at June 30, 2015 and 243,260 at December 31, 2014		12		
Additional paid-in capital		203,174		2,665
Accumulated deficit		(169,554)		(146,533)
Total stockholders equity (deficit)		33,632		(143,868)
Total liabilities, convertible preferred stock, and stockholders equity (deficit)	$	70,564	$	24,780

See accompanying notes.

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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,	
	2015	**2014**	**2015**	**2014**
Revenues	$ 3,047	$ 3,389	$ 5,135	$ 5,508
Cost of revenues	1,634	1,968	2,922	3,470
Gross profit	1,413	1,421	2,213	2,038
Operating expenses:				
Research and development	3,951	2,763	7,812	5,618
Selling, general and administrative	6,545	4,186	12,910	8,326
Total operating expenses	10,496	6,949	20,722	13,944
Loss from operations	(9,083)	(5,528)	(18,509)	(11,906)
Interest income	9		12	1
Interest expense	(1,344)	(1,620)	(2,667)	(3,193)
Other income (expense), net	204	83	534	84
Loss before provision for income taxes	(10,214)	(7,065)	(20,630)	(15,014)
Provision for income taxes	6	13	7	35
Net loss and comprehensive loss	(10,220)	(7,078)	(20,637)	(15,049)
Adjustment to net loss resulting from convertible preferred stock modification			(2,384)	
Net loss and comprehensive loss attributable to common stockholders	$ (10,220)	$ (7,078)	$ (23,021)	$ (15,049)
Net loss attributable to common stockholders per share, basic and diluted	$ (0.83)	$ (29.25)	$ (2.23)	$ (62.19)
Weighted average common shares used to compute net loss per share, basic and diluted	12,240	242	10,317	242

See accompanying notes.

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AVINGER, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Six Months Ended June 30,	
	2015	**2014**
Cash flows from operating activities		
Net loss	$ (20,637)	$ (15,049)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	639	787
Amortization of debt issuance costs and debt discount	101	111
Stock-based compensation	2,480	317
Remeasurement of warrant and embedded derivatives	(547)	(84)
Noncash interest expense	907	1,923
Provision for excess and obsolete inventories	(7)	(26)
Changes in operating assets and liabilities:		
Accounts receivable	417	292
Inventories	126	1,033
Prepaid expenses and other current assets	(810)	182
Other assets	(8)	8
Accounts payable	(25)	(284)
Accrued compensation	980	52
Accrued expenses and other current liabilities	(448)	205
Other liabilities	(154)	(113)
Net cash used in operating activities	(16,986)	(10,646)
Cash flows from investing activities		
Purchase of property and equipment	(107)	(8)
Restricted cash	255	
Net cash used in investing activities	148	(8)
Cash flows from financing activities		
Principal paydown of capital lease obligations	(10)	(9)
Proceeds from convertible notes, net of issuance costs		4,202
Proceeds from the issuance of convertible preferred stock, net of issuance costs	6,176	
Proceeds from initial public offering, net of issuance costs	58,745	
Proceeds from the exercise of common stock warrants	308	
Proceeds from the issuance of common stock		7
Net cash provided by financing activities	65,219	4,200
Net change in cash and cash equivalents	48,381	(6,454)
Cash and cash equivalents, beginning of period	12,316	12,221
Cash and cash equivalents, end of period	$ 60,697	$ 5,767
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,257	$ 1,158
Noncash investing and financing activities:		

Conversion of convertible preferred stock to common stock upon initial public offering	$	137,632	$	
Modification of convertible preferred stock		2,384		
Vesting of common stock subject to repurchase		16		5
Issuance of common stock warrants		804		
Transfer between inventory and property and equipment		113		325

See accompanying notes.

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AVINGER, INC.

Notes to Financial Statements

1. Organization

Organization, Nature of Business

Avinger, Inc. (the Company), a Delaware corporation, was founded in March 2007 by cardiologist and medical device entrepreneur Dr. John B. Simpson. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral arterial disease (PAD). Patients with PAD have a build-up of plaque in the arteries that supply blood to the arms and legs. The Company manufactures and sells a suite of products in the United States and in select European 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). The Company is also developing Pantheris, its image-guided atherectomy device, designed to allow physicians to precisely remove arterial plaque in PAD patients. Pantheris is currently undergoing a U.S. clinical trial intended to support a 510(k) submission to the U.S. Food and Drug Administration (FDA) in the second half of 2015. The Company is located in Redwood City, California.

Initial Public Offering

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 (deficit) to additional paid-in capital.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The 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 our financial information. The results for the three and six months ended June 30, 2015, are not necessarily indicative of results to be expected for the year ending December 31, 2015, or for any other interim period or for any future year. The December 31, 2014 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, 2014, which was filed with the SEC on March 27, 2015. 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, 2014.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuation of the common stock

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warrants, the valuation of compound embedded derivatives, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of June 30, 2015 and December 31, 2014. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities, borrowings, convertible notes and embedded derivatives. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of the borrowings and convertible notes approximate fair value. Fair value accounting is applied to the warrant liabilities and embedded derivatives that are recorded at fair value in the financial statements.

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, 2015 and December 31, 2014, 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, 2015 and December 31, 2014. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

Restricted Cash

At December 31, 2014, a deposit of $255,000 was restricted from withdrawal. The restricted cash secured obligations of the Company associated with its corporate credit card. The restricted deposit account was included in prepaid expenses and other current assets. As of June 30, 2015, the Company was no longer required to secure its corporate card obligations; accordingly the $255,000 is included within cash and cash equivalents. The release of the restriction against the Company s cash was included within investing activities on its statement of cash flows for the six months ended June 30, 2015.

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, 2015 and December 31, 2014.

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, 2015 and December 31, 2014, there were three customers and no customers that represented 10% or more of the Company s accounts receivable, respectively. For the three months ended June 30, 2015 and 2014, there were no customers that represented 10% or more of revenues. For the six months ended June 30, 2015 and 2014, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company s financial position and results of operations.

The Company manufactures certain of its commercial products in-house, including the production of 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.

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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 continue to be accepted in the marketplace, nor can there be any assurance that 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.

Deferred Initial Public Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the IPO, were capitalized. As of December 31, 2014, $2,608,000 of deferred offering costs were capitalized in other assets on the balance sheet, of which $1,848,000 had been paid. The Company incurred $3,553,000 in offering costs and in January 2015, these initial public offering costs were offset against the proceeds obtained from the Company s IPO.

Convertible Preferred Stock

Prior to its IPO the Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs and classified the convertible preferred stock outside of stockholders deficit on the balance sheets as events triggering the liquidation preferences were not solely within the Company s control. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into an aggregate of 6,967,925 shares of common stock resulting in the reclassification of $137,626,000 from outside of stockholders equity (deficit) to additional paid-in capital.

Warrant Liability and Embedded Derivative Instruments

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

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

The Company records a compound derivative asset or liability related to redemption features embedded within the outstanding convertible notes. The convertible notes issued in 2013 and 2014 included features which were determined to be embedded derivatives requiring bifurcation and separate accounting. The embedded derivatives were initially recorded at fair value and are subject to remeasurement as of each balance sheet date. Any change in fair value is recognized as a component of other income (expense), net in the statements of operations and comprehensive loss.

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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 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. The Company recovers the cost of providing the leased Lightbox through a premium in the amount charged for its disposable products in comparison to a standalone purchase. When a Lightbox is placed under a lease agreement, the Company retains title to the equipment and it remains capitalized on its balance sheet under property and equipment. Depreciation expense on these leased Lightboxes is recorded to cost of revenues on a straight-line basis. The costs to maintain these leased Lightboxes are charged to cost of revenues as incurred.

The Company evaluates its lease 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.

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

Cost of Revenues

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

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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. The warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from these estimates, revisions to the estimated warranty liability would be required. Periodically the Company assesses the adequacy of its recorded warranty liabilities and adjusts the amounts as necessary. Warranty provisions and claims are summarized as follows (in thousands):

		Amount
Balance at December 31, 2014	$	167
Warranty provision		63
Usage		(68)
Balance at June 30, 2015	$	162

Common Stock Valuation and Stock-Based Compensation

Stock-based awards issued to employees are recorded at fair value as of the grant date using the Black-Scholes option-pricing model and recognized as expense on a straight-line basis over the vesting period of the award. Because noncash stock-based compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates.

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

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders continued service to the Company. For the computation of net loss per share attributable to common stockholders, common stock shares subject to repurchase of 247 and 583 were excluded from the calculations as of June 30, 2015 and December 31, 2014, respectively. Since the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per

share attributable to common stockholders as the inclusion of all potential dilutive common shares would have been anti-dilutive.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company s convertible preferred stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$ (10,220)	$ (7,078)	$ (20,637)	$ (15,049)
Adjustment to net loss resulting from convertible preferred stock modification			(2,384)	
Net loss attributable to common stockholders	$ (10,220)	$ (7,078)	$ (23,021)	$ (15,049)
Weighted average common stock outstanding	12,240	242	10,317	242
Net loss attributable to common stockholders per share, basic and diluted	$ (0.83)	$ (29.25)	$ (2.23)	$ (62.19)

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In addition to the outstanding convertible notes (Note 6), 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, in common stock equivalent shares:

	June 30,	
	2015	2014
Convertible preferred stock outstanding		2,591,102
Common stock options	3,104,358	349,654
Common stock warrants	2,213,395	210,597
	5,317,753	3,151,353

Comprehensive Loss

For the three and six months ended June 30, 2015 and 2014, there was no difference between comprehensive loss and the Company s net loss.

Segment and Geographical Information

The Company operates in one segment. 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, 2015 and 2014, 100% and 99.3% of the Company s revenues, were in the United States, based on the shipping location of the external customer, respectively. For the six months ended June 30, 2015 and 2014, 99.7% and 99.6% of the Company s revenues, were in the United States, based on the shipping location of the external customer, respectively.

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued an accounting standard update that requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The updated standard requires retrospective adoption and is effective for financial statements issued for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its financial statements.

In April 2015, the FASB issued an accounting standard which provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If the arrangement does not include a software license, the customer should account for a cloud computing arrangement as a service contract. It is effective for annual periods beginning after December 15, 2015. Early adoption is permitted. The amendment may be adopted either prospectively to all arrangements entered into or materially modified after the effective date or retrospectively. The Company is currently evaluating the impact that this guidance will have on its financial statements.

In May 2014, the FASB, jointly with the International Accounting Standards Board, issued a comprehensive new standard on recognition from contracts with customers. The standard s core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, FASB voted to delay the effective date of the new standard by one year. The standard would become effective 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 is currently evaluating the impact of our adoption of this standard on its financial statements.

3. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and the derivative instruments related to redemption features embedded within its outstanding convertible notes. 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.

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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, 2015 and December 31, 2014, cash equivalents and restricted cash were all categorized as Level 1 and consisted of money market funds. The Company issued convertible notes in 2013 and 2014 (Note 6). In connection with the convertible notes, the Company agreed to issue warrants to purchase shares of its common stock. As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date until September 2014. The convertible notes also contained redemption features which were determined to be a compound embedded derivative requiring fair value accounting. The common stock warrant liability and embedded derivatives in the convertible notes were categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). Any change in fair value is recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss.

There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2015 and 2014.

Common Stock Warrant Liability

The Company s common stock warrant liability represented a financial instrument classified as Level 3. As the price per share of the common stock warrants was not fixed until the issuance of the Series E Convertible Preferred Stock in September 2014, they were classified as a derivative liability and were subject to remeasurement at each balance sheet date. Contemporaneous with the Series E Convertible Preferred Stock issuance, the Company determined that these common stock warrants met the requirements for equity classification and the fair value of the common stock warrant liability was reclassified to additional paid-in capital. Subsequent to September 2014, there were no changes in fair value.

Embedded Derivatives in Convertible Notes

The following table sets forth a summary of the changes in the estimated fair value of the Company s compound embedded derivative associated with its convertible notes, which represent a financial instrument classified as Level 3. Accordingly, the income (expense) in the table below includes changes in fair value due in part to observable factors that are part of the Level 3 methodology (in thousands):

	Amount
Fair value at December 31, 2014	$ 231

Issuance of convertible notes		
Change in fair value recorded in other income (expense), net		547
Fair value at June 30, 2015	$	778

Through December 31, 2014 the Company determined the value of the compound derivative utilizing a Monte Carlo Simulation model. The inputs used to determine the estimated fair value of the derivative instrument include the probability of an underlying event triggering the embedded derivative occurring and its timing. The fair value measurement is based upon significant inputs not observable in the market. The inputs included the probability that the Company would need to raise additional equity in 2014, as well as various financing and exit events in 2015. These assumptions are inherently subjective and involve significant management judgment. The following table summarizes these various assumptions:

	December 31, 2014
Equity financing in 2014	100.0%
Equity financing in 2015	14.3%
Liquidation	0.1%
Initial public offering	79.5%
Change of control	6.2%

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

	June 30, 2015
Time to first call option (years)	0.3
Credit spread	20.0%
Expected volatility	40.0%

The compound embedded derivative asset is included in other long-term assets as of June 30, 2015 and December 31, 2014, on the balance sheets.

4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Raw materials	$ 2,039	$ 2,265
Work-in-process	1	61
Finished products	1,719	1,665
Total inventories	$ 3,759	$ 3,991

5. Borrowings

On April 18, 2013, the Company entered into a Credit Agreement (Agreement) with PDL BioPharma, Inc. (PDL) whereby PDL agreed to loan up to $40,000,000. Contemporaneous with the execution of the Agreement the Company borrowed an initial $20,000,000 (Term Note). Under the terms of the Agreement, if the Company achieved certain net revenue milestones prior to June 30, 2014, the Company would be eligible to borrow an additional amount between $10,000,000 and $20,000,000 (net of fees) at the Company s election. The Company did not achieve the net revenue milestones and accordingly, there are no additional available funds to borrow under the Agreement.

The Term Note matures on April 18, 2018, has a stated interest rate of 12.0% per annum and can be prepaid by the Company at any time. A fee of 1.0% ($200,000) of the original principal amount is payable upon maturity or prepayment in full of the Term Note, and is being amortized into the Term Note. The Company pays interest-only through the first ten quarters and, thereafter, will commence repayment of principal in equal installments including accrued and unpaid interest, payable each quarter. Under the terms of the Agreement, for the first eight quarterly

interest payments, or through 2015, on the Term Note the Company may elect to convert an amount of interest, up to 1.5% per annum, into additional loans, referred to as paid-in-kind, or PIK, loans. The PIK loans will accrue, be capitalized and compounded, and added to the aggregate principal balance of the Term Note. In addition to the interest and principal payments, the Company also pays a royalty, referred to as Assigned Interests, equal to 1.8% of the Company s quarterly net revenues. Upon prepayment of the Term Note, the Company s obligations relating to Assigned Interests continue, and will be payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts as follows (in thousands), which are payable quarterly:

Period Ending December 31,		Mandatory Minimum Quarterly Payment
2015	$	153
2016		305
2017		305
2018		310
	$	1,073

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The Term Note grants PDL a security interest in substantially all current and future assets of the Company and contains customary affirmative covenants and customary negative covenants limiting the Company s ability to, among other things and for so long as any amounts are due and owing under the Agreement, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. Additionally, even if the Term Note is prepaid, until there are no further obligations relating to Assigned Interests, it must comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control and dispose of assets, in each case subject to certain exceptions. The Agreement and the security interest agreement also contain customary events of default including, among others, payment defaults, breaches of covenants, bankruptcy and insolvency events, cross defaults with certain material indebtedness, defaults upon the entry of certain judgments against the Company, and breaches of representations and warranties. Upon an event of default, all obligations may become immediately due and payable and the stated interest rate would likely be increased to a default rate of 14.0% per annum.

The Company incurred fees and legal expenses of $519,000 in connection with the Agreement, which have been recorded as deferred financing costs on the accompanying balance sheets and are amortized using the effective interest method. The Company also paid $200,000 in fees to PDL upon origination of the Term Note, which is reflected as a discount on the debt and is being accreted over the life of the Term Note. The Company calculated an effective interest rate of 27.2% upon origination of the Term Note based on its best estimate of future cash outflows. The Company reviews its estimate of forecasted Assigned Interests payable annually and revisions to estimated cash flows are reflected using the retrospective method. 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 of the Term Note. The new effective interest rate, 18.3% as of December 31, 2014, is then used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. For the three months ended June 30, 2015 and 2014, the Company incurred interest expense of $916,000 and $812,000, respectively. For the six months ended June 30, 2015 and 2014, the Company incurred interest expense of $1,816,000 and $1,707,000, respectively.

Principal and PIK loan repayments of the Term Note as of June 30, 2015 are as follows (in thousands):

Period Ending December 31,		Principal and PIK Loan Repayments
2015	$	1,818
2016		7,273
2017		7,273
2018		3,636
		20,000
Add: Payment in kind interest		600
		20,600
Less: Amount representing debt discount		(95)
		20,505
Less: Current portion of long-term borrowings		(5,618)
Borrowings, net of current portion	$	14,887

6. Convertible Notes

On October 29, 2013, the Company entered into a Note and Warrant Purchase Agreement (the Convertible Note Agreement), as amended in May 2014, with certain existing convertible preferred stockholders, third-parties and employees for the issuance of convertible notes for up to an aggregate principal amount of $25,000,000. Under the terms of the Convertible Note Agreement, the Company issued convertible notes in October and November 2013 for total proceeds of $13,472,000, and in May and July 2014 for additional total proceeds of $4,720,000. The

convertible notes bear interest at a rate of 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20%. The notes will mature and the accrued interest thereon will become payable on the earlier of: (i) October 29, 2018, (ii) an event of default, or (iii) a change of control event.

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

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repay the holder, at the election of such holder, a payment equal to the greater of (i) 125% of the outstanding principal and accrued and unpaid interest, (ii) an amount equal to the return the holders of Series D preferred stock would be entitled to receive in such change of control, or (iii) the amount providing the investor with a 20% minimum internal rate of return, provided that in the event that the change of control includes any contingent payments based on future performance, the amount due and payable under clause (ii) will be recalculated at the time each installment or contingent payment is made.

In conjunction with the issuance of the convertible notes, the Company issued warrants to purchase up to the number of shares of common stock equal to 15% of the principal amount of the convertible notes divided by an exercise price per share equal to the lesser of $39.15 per share, or the price per share paid by the investors in the first bona fide preferred stock financing subsequent to the date of the convertible notes. Upon the Series E Convertible Preferred Stock issuance in September 2014, the exercise price per share was fixed at $12.60 per share and the Company issued warrants to purchase a total of 216,547 shares of common stock. The warrants, which were immediately exercisable, expired upon the closing of the Company s IPO. The estimated fair value of the warrants upon issuance, of $1,000, was based on an option pricing model. The Company recorded the fair value of the warrants at issuance as a debt discount and as a warrant liability. The debt discount is being accreted using the effective interest method as additional interest expense over the term of the convertible notes.

The convertible notes have redemption features that were determined to be compound embedded derivatives requiring bifurcation and separate accounting. The fair value of the compound embedded derivative upon issuance was determined to be a liability of $179,000. The fair value of these derivative instruments was recognized as an additional discount and as a derivative liability on the balance sheets upon issuance of the convertible notes. The compound embedded derivative associated with the convertible notes requires periodic re-measurements to fair value while the instruments are still outstanding.

The Company incurred total debt issuance costs of $93,000 in connection with the issuance of the convertible notes. The deferred issuance costs will be amortized over the term of the convertible notes.

In September and November 2014, in connection with the issuance of the Series E Convertible Preferred Stock, $11,582,000 of the outstanding convertible notes and accrued interest thereon was converted into shares of Series E Convertible Preferred Stock. As of June 30, 2015, the Company had $9,489,000 in principal and accrued interest underlying outstanding convertible notes.

The Company s interest expense associated with the convertible notes amounted to $421,000 and $793,000 during the three months ended June 30, 2015 and 2014, and to $836,000 and $1,458,000 during the six months ended June 30, 2015 and 2014, respectively, based on the minimum internal rate of return of 20%.

7. Capital Leases

Capital lease obligations consist of leased office equipment. As of June 30, 2015 and December 31, 2014, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $51,000 and $12,000, 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, 2015, are as follows (in thousands):

Period ending December 31,		Future Minimum Lease Payments
2015	$	13
2016		19
2017		18
2018		4
Total minimum payments		54
Less: Amount representing future interest		3
Present value of minimum lease payments	$	51

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8. 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 2016. The lease agreement includes two renewal provisions allowing the Company to extend this lease for additional periods of three years each. 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 connection with the facility lease, the landlord also provided incentives of $369,000 to the Company in the form of leasehold improvements. These amounts have been reflected as deferred rent and are being amortized as a reduction to rent expense over the term of the Company s operating lease. Rent expense was $247,000 and $230,000 for the three months ended June 30, 2015 and 2014, and $477,000 and $461,000 for the six months ended June 30, 2015 and 2014, respectively.

The future minimum lease payments as of June 30, 2015, are as follows (in thousands):

Period ending December 31,		Future Minimum Lease Payments
2015	$	564
2016		1,060
Total minimum lease payments	$	1,624

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 $2,181,000 and $1,334,000 as of June 30, 2015 and December 31, 2014, 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.

In accordance with the Company s amended and restated certificate of incorporation and its amended and restated bylaws, the Company has indemnification obligations to its officers and directors, subject to some limits, with respect to their service in such capacities. The Company has also entered into indemnification agreements with its directors and certain of its officers. To date, the Company has not been subject to any claims, and it maintains director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims. 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. The Company believes that the fair value of these indemnification obligations is minimal, and accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

Legal Proceedings

The Company was not party to any legal proceedings at June 30, 2015 and December 31, 2014. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable.

On February 15, 2014, the Company entered into an engagement letter with a financial advisor which provided for such firm to serve as its placement agent and for the Company to make certain payments to them in connection with its Series E Convertible Preferred Stock financing. After the entry into such engagement letter, the financial advisor did not provide the level of service the Company was expecting and was not responsible for introducing the Company to any of the Series E Convertible Preferred Stock investors. In December 2014, the Company and its former financial advisor agreed to amend and to terminate their engagement letter, effective immediately. Pursuant to the terms of the amended engagement letter, the Company agreed to pay the former financial advisor a transaction fee of $650,000, to be paid in four equal quarterly installments starting on December 31, 2014, and ending on September 30, 2015 and $35,000 for reimbursement of the former financial advisor s out-of-pocket expenses, which were due upon execution of the amendment. The transaction fee and out-of-pocket expenses were reflected as additional Series E Convertible Preferred Stock issuance costs during the year ended December 31, 2014.

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9. Convertible Preferred Stock

At December 31, 2014, convertible preferred stock authorized and outstanding consisted of the following (in thousands except share amounts):

Series	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Preferential Liquidation Value
Series A	326,595	326,591	$ 6,183	$ 6,212
Series A-1	225,235	225,235	6,649	3,243
Series B	755,516	755,486	27,272	27,538
Series C	561,448	561,423	22,397	22,485
Series D	800,000	722,367	37,153	37,708
Series E	4,150,403	2,671,626	32,606	134,650
	6,819,197	5,262,728	$ 132,260	$ 231,836

On January 9, 2015, the Company issued a total of 490,472 shares of Series E Convertible Preferred Stock at $12.60 per share for total cash proceeds of $6,180,000. 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. As of June 30, 2015, the Company does not have any convertible preferred stock issued or outstanding.

10. Stockholders Equity (Deficit)

Preferred Stock

At June 30, 2015, 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, 2015, 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 12,240,164 shares were issued and outstanding.

Restricted Stock

In May 2012, the Company entered into two Restricted Stock Purchase Agreements with two individuals in return for certain intellectual property (IP) and ongoing consulting services. 1,666 shares of common stock were issued under each Restricted Stock Purchase Agreement for a total of 3,332 shares at a fair market value of $14.85 per share for a total purchase price of $49,500. The shares are subject to repurchase at cost, or $14.85 per share, with 20% being released from the repurchase option at the date of assignment of the IP and 1/48th of the remaining 80% being released monthly thereafter. Stock compensation expense of $49,500, representing the intrinsic value of the shares was recorded to consulting expense in 2012. Since it was not possible to value the IP, this noncash compensation expense was calculated at the fair market value of the shares of $14.85 per share.

As of June 30, 2015 and December 31, 2014, a total of 247 and 583 shares, respectively, were subject to repurchase, at cost, under these Restricted Stock Purchase Agreements.

Common Stock Warrants

In connection with the issuance of the Company s Series E Convertible Preferred Stock in September 2014 through January 2015, the Company issued, to each investor who purchased shares of Series E Convertible Preferred Stock, warrants to purchase up to the number of shares of common stock equal to 50% of the number of shares of the Company s Series E Convertible Preferred Stock purchased.

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. As of December 31, 2014, in connection with the issuance of its

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Series E Convertible Preferred Stock, the Company issued warrants to purchase an aggregate of 1,335,779 shares of common stock. The common stock warrants were recorded at their allocated fair value of $175,000 within stockholders equity (deficit).

In connection with the issuance of the Company s Series E Convertible Preferred Stock in January 2015, the Company issued warrants to purchase an aggregate of 245,235 shares of common stock. The common stock warrants were recorded at their allocated fair value of $804,000 within stockholders equity (deficit).

On January 14, 2015, the Company amended its Series E Convertible Preferred Stock Purchase agreement to provide for the issuance of common stock warrants to each investor who purchased shares of Series E Convertible Preferred Stock equal to 70% of the number of shares of the Company s Series E Convertible Preferred Stock purchased by such investor. As with the common stock warrants previously issued, any new common stock warrants are immediately exercisable, at an exercise price of $12.60 per share, and expire upon the earlier of September 2, 2019 or upon consummation of a change in control of the Company. As a result of this amendment, the Company issued additional warrants to purchase 632,381 shares of common stock to investors who previously acquired shares of Series E Convertible Preferred Stock from September 2014 through January 2015.

The Company determined that the amendment to the Series E Convertible Preferred Stock Purchase agreement should be accounted for as a modification. Accordingly, the incremental fair value from the modification, the additional warrants to purchase 632,381 shares of common stock warrants, of $2,384,000, was recorded as an increase to stockholders equity (deficit) and as an adjustment to net loss attributable to common stockholders in the Company s statement of operations and comprehensive loss for the six months ended June 30, 2015. This amount represents a return to the preferred stockholders and is treated in a manner similar to the treatment of dividends paid to holders of preferred stock in the computation of earnings per share. As a result, the deemed dividend is subtracted from net loss available to common stockholders in reconciling net loss to net loss available for common stockholders.

Stock Plans

In January 2015, the Company s 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 ISOs to employees and for the grant of NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 1,320,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. In addition, the shares reserved for issuance under the 2015 Plan will also include 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 will also include an 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.

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.

Activity under the Plans is set forth below:

	Shares Available for Grant	Options Outstanding Number of Shares	Options Outstanding Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2014	21,705	3,010,373	$ 5.78	$ 13,188
Additional shares reserved	1,320,000			
Granted	(146,244)	146,244	$ 10.96	
Exercised			$	
Cancelled	52,259	(52,259)	$ 7.10	
Balance at June 30, 2015	1,247,720	3,104,358	$ 6.00	$ 22,632

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2015 and 2014 was $5.72 and $0.13 per share, respectively. As of June 30, 2015, the aggregate intrinsic value of options outstanding and vested was $301,000. The aggregate intrinsic value of options exercised was none and none during the six months ended June 30, 2015 and 2014,

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respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value 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, 2015 and 2014.

At June 30, 2015 and at December 31, 2014, there were 227,950 and 201,018 shares, respectively, vested with a weighted-average exercise price of $14.66 and $5.38 per share, respectively, and a weighted average contractual life of 6.61 and 7.03 years, respectively.

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2015 Employee Stock Purchase Plan

In January 2015, the Company s 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. 500,000 shares of common stock are reserved for issuance and will be increased 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. 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. The Company incurred $43,000 and $66,000 in stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2015, respectively.

11. Stock-Based Compensation

The Company estimates the fair value of stock-based compensation on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company s common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company s common stock, and the volatility over the expected term of the awards. The Company has opted to use the simplified method for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Due to the Company s limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, stage of development, risk profile, and position within the industry as well as selecting companies with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies shares during the equivalent period of the calculated expected term of the share-based payments. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company s stock options. The expected dividend assumption is based on the Company s history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

As stock-based compensation expense recognized in the financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, over the service period to the extent that actual forfeitures differ, or are expected to differ, from prior estimates. Forfeitures are estimated based on estimated future employee turnover and historical experience. The fair value for the Company s employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Expected term (years)	6.3		6.3	6.9
Expected volatility	53.1%		53.5%	50.3%
Risk-free interest rate	1.6%		1.6%	2.1%
Dividend rate				

As of June 30, 2015 and December 31, 2014, the total unamortized compensation expense related to stock-based awards granted to employees and directors was $17,036,000 and $18,938,000, which is expected to be amortized over the next 3.46 and 3.92 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 average assumptions for the three and six months ended June 30, 2015:

	Three Months and Six Months Ended June 30, 2015
Expected term (years)	0.5
Expected volatility	47.2%
Risk-free interest rate	0.07%
Dividend rate	

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Total stock-based compensation expense recognized during the three and six months ended June 30, 2015 and 2014, is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Cost of revenues	$ 56	$ 14	$ 116	$ 27
Research and development expenses	557	23	1,109	73
Selling, general and administrative expenses	635	92	1,255	217
	$ 1,248	$ 129	$ 2,480	$ 317

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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. 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 arterial disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to the arms 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 European markets. Our current products include our Lightbox imaging console, as well as our Wildcat, Kittycat, 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. We are also developing Pantheris, our image-guided atherectomy device, designed to allow physicians to precisely remove arterial plaque in PAD patients. Pantheris is currently undergoing a U.S. clinical trial intended to support a 510(k) submission in the second half of 2015 to the U.S. Food and Drug Administration, or FDA. We believe that Pantheris, if cleared by FDA, will significantly enhance our market opportunity within PAD and can expand the overall addressable market for PAD endovascular procedures.

During the first quarter of 2015, we completed enrollment of patients in VISION, a clinical trial designed to support a filing with FDA for our Pantheris atherectomy device. VISION is designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging. We believe the data from VISION will also allow us to demonstrate that avoiding disruption of the membrane between the outermost layers of the artery, which we refer to as the black line, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. If Pantheris is cleared by FDA, we plan to commercialize it as part of our lumivascular platform in the United States and in select European countries after obtaining any required marketing authorizations.

We focus our direct sales force, marketing efforts and promotional activities on interventional cardiologists, vascular surgeons and interventional radiologists in the United States and select European countries. 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 expect 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 using components and sub-assemblies manufactured both in-house at our facilities in Redwood City, California and by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2016. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors.

As of June 30, 2015, we had approximately $9.5 million in principal and accrued interest underlying outstanding promissory notes, or the notes, that are due and payable upon the earlier of October 29, 2018 or upon certain specified events. We have also borrowed $20.5 million under our credit facility, or the credit agreement, with PDL Biopharma, or PDL. All outstanding amounts under this credit agreement must be repaid on April 18, 2018. We are required to make certain royalty payments on our net sales until April 18, 2018, regardless of whether we prepay the term loan, and we are required to pay an exit fee at maturity, or earlier prepayment in full, based on a percentage of the original principal amount borrowed.

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 have not been profitable since inception, and as of June 30, 2015, our accumulated deficit was $169.6 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 of 5.0 million shares. As a result of our initial public offering, which closed in February 2015, we received net proceeds of approximately

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$56.9 million, after underwriting discounts and commissions of approximately $4.5 million and other expenses associated with our initial public offering of approximately $3.6 million.

Components of Our Results of Operations

Revenues

All of our revenues are currently derived from sales of our Lightbox console and our various PAD catheters and related services in the United States and select European markets. We expect our revenues to increase as we continue to expand our sales and marketing infrastructure and introduce new lumivascular platform products including, if cleared by FDA, Pantheris. No single customer accounted for more than 10% of our revenues during the three and six months ended June 30, 2015 and 2014.

We expect our revenues to fluctuate from quarter-to-quarter due to a variety of factors including capital equipment purchasing patterns that are typically heavier towards the calendar year-end and lightest 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 Profit

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. 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. Cost of revenues also includes depreciation expense for production equipment, depreciation and related maintenance expense for leased equipment held by customers and certain direct costs such as those incurred for shipping our products. We expect cost of revenues to increase in absolute dollars to the extent our revenues grow.

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 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 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. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. However, 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

We have a direct sales organization that is divided into two distinct roles - sales of capital equipment, such as our Lightbox, and sales of disposable products, such as our catheters. Our current sales efforts focus on establishing new lumivascular platform sites by marketing our products to physicians and hospital administrators. Additionally, we seek to increase the use of our lumivascular platform products by our current customers through case coverage, clinical training and other programs.

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses,

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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, a 2.3% tax on U.S. sales of medical devices, general corporate expenses and allocated facilities-related expenses. We expect to grow our sales force in preparation for the commercial launch of Pantheris in order to increase the base of customers using our lumivascular platform products. We believe that expanding our U.S. sales infrastructure and establishing distributor relationships in select regions outside the United States will drive further adoption of our lumivascular platform. We expect SG&A expenses to continue to increase in absolute dollars and as a percentage of revenues through at least 2015 as we expand our infrastructure to both drive and support anticipated growth in revenues and due to additional legal, accounting, insurance and other expenses associated with being a public company.

Interest Income (Expense), net

Interest income (expense), net consists primarily of interest incurred on our outstanding indebtedness, our royalty obligation to PDL and non-cash interest related to the amortization of debt discount and issuance costs associated with our various debt agreements. Due to the conversion of $7.8 million and $3.8 million in principal amount of the notes and related accrued interest into shares of our Series E preferred stock in September and November 2014, respectively, we expect that for 2015 our interest expense will decrease. During 2015 we may consider refinancing or restructuring existing debt arrangements or entering into a credit facility in order to replace our outstanding indebtedness, which we expect will decrease our interest expense.

Other Income (Expense), net

Other income (expense), net primarily consists of gains and losses resulting from the remeasurement of the fair value of our common stock warrant liability and the compound embedded derivative instrument associated with the notes. We continued to record adjustments to the estimated fair value of the common stock warrants until the Series E preferred stock issuance in September 2014, upon which the common stock warrant exercise price was fixed at $12.60 per share. At this time we re-evaluated the terms of the common stock warrants and determined that the common stock warrants issued with the convertible notes met the requirements for equity classification and the fair value of the warrant liability was reclassified to additional paid-in capital. We will continue to record adjustments to the estimated fair value of the compound embedded derivative instrument associated with the notes until the notes are repaid.

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Results of Operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(unaudited) (in thousands, except percentages)		(unaudited) (in thousands, except percentages)	
Revenues	$ 3,047	$ 3,389	$ 5,135	$ 5,508
Cost of revenues	1,634	1,968	2,922	3,470
Gross profit	1,413	1,421	2,213	2,038
Gross margin	46%	42%	43%	37%
Operating expenses:				
Research and development	3,951	2,763	7,812	5,618
Selling, general and administrative	6,545	4,186	12,910	8,326
Total operating expenses	10,496	6,949	20,722	13,944
Loss from operations	(9,083)	(5,528)	(18,509)	(11,906)
Interest income (expense), net	(1,335)	(1,620)	(2,655)	(3,192)
Other income (expense), net	204	83	534	84
Loss before provision for income taxes	(10,214)	(7,065)	(20,630)	(15,014)
Provision for income taxes	6	13	7	35
Net loss and comprehensive loss	$ (10,220)	$ (7,078)	$ (20,637)	$ (15,049)

Comparison of Three Months Ended June 30, 2015 and 2014

Revenues. Revenues decreased $0.4 million, or 10%, to $3.0 million during the three months ended June 30, 2015, compared to $3.4 million during the three months ended June 30, 2014. For the three months ended June 30, 2015, sales of our Lightbox imaging console increased by 11% to $1.4 million while sales of our disposable catheters decreased by 22% to $1.6 million. The decrease in disposable catheter revenues in 2015 and changes in revenue mix related to the Company s continuing commercial focus on its lumivascular programs to broaden physician exposure to optical coherence tomography (OCT) image interpretation and build the installed base of the Lightbox imaging console prior to availability of Pantheris.

Cost of Revenues and Gross Margin. Cost of revenues decreased $0.4 million, or 17%, to $1.6 million during the three months ended June 30, 2015, compared to $2.0 million during the three months ended June 30, 2014. This decrease was attributable to the decrease in revenues from sales of our disposable catheters. Gross margin for the three months ended June 30, 2015 was 46%, up from 42% compared to the three months ended June 30, 2014. This increase was primarily attributable to operational efficiencies achieved in our lumivascular manufacturing processes and the increasing proportion of revenue coming from our lumivascular products.

Research and Development Expenses. R&D expenses increased $1.2 million, or 43%, to $4.0 million during the three months ended June 30, 2015, compared to $2.8 million during the three months ended June 30, 2014. This increase

was primarily due to a $0.9 million increase in personnel-related expenses and an increase of $0.4 million in outside services. These increases were partially offset by a $0.1 million decrease in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $0.6 million compared to $23,000 for the three months ended June 30, 2015 and 2014, respectively. The remaining increase in personnel-related expenses and increase in outside services were attributable to our VISION clinical trial.

Selling, General and Administrative Expenses. SG&A expenses increased $2.3 million, or 56%, to $6.5 million during the three months ended June 30, 2015, compared to $4.2 million during the three months ended June 30, 2014. This increase was primarily due to a $1.8 million increase in personnel-related expenses and an increase of $0.4 million in consulting, legal and professional fees. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of $0.6 million compared to $0.1 million for the three months ended June 30, 2015 and 2014, respectively. Increases in our consulting, legal and professional fees were associated with the review of our financial statements and other costs associated with operating as a public company.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.3 million, or 18%, to an expense of $1.3 million during the three months ended June 30, 2015, compared to an expense of $1.6 million during the three months ended June 30, 2014. This decreased expense was attributable to the conversion of our convertible notes into shares of Series E preferred stock during the third and fourth quarter of 2014.

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Other Income (Expense), Net. Other income (expense), net increased to an income of $0.2 million during the three months ended June 30, 2015, compared to income of $0.1 million during the three months ended June 30, 2014. The increase in other income was primarily attributable to the remeasurement of the fair value of the derivative instruments associated with our notes which are accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

Comparison of Six Months Ended June 30, 2015 and 2014

Revenues. Revenues decreased $0.4 million, or 7%, to $5.1 million during the six months ended June 30, 2015, compared to $5.5 million during the six months ended June 30, 2014. For the six months ended June 30, 2015, sales of our Lightbox imaging console increased by 24% to $2.0 million while sales of our disposable catheters decreased by 19% to $3.1 million. The decrease in disposable catheter revenues in 2015 and changes in revenue mix related to the Company s continuing commercial focus on its lumivascular programs to broaden physician exposure to optical coherence tomography (OCT) image interpretation and build the installed base of the Lightbox imaging console prior to availability of Pantheris.

Cost of Revenues and Gross Margin. Cost of revenues decreased $0.6 million, or 16%, to $2.9 million during the six months ended June 30, 2015, compared to $3.5 million during the six months ended June 30, 2014. This decrease was attributable to the decrease in revenues from sales of our disposable catheters. Gross margin for the six months ended June 30, 2015 was 43%, up from 37% compared to the six months ended June 30, 2014. This increase was primarily attributable to operational efficiencies achieved in our lumivascular manufacturing processes and the increasing proportion of revenue coming from our lumivascular products.

Research and Development Expenses. R&D expenses increased $2.2 million, or 39%, to $7.8 million during the six months ended June 30, 2015, compared to $5.6 million during the six months ended June 30, 2014. This increase was primarily due to a $1.7 million increase in personnel-related expenses and an increase of $0.6 million in outside services. These increases were partially offset by a $0.1 million decrease in product development materials and related costs. Personnel-related expenses included stock-based compensation expense of $1.1 million compared to $0.1 million for the six months ended June 30, 2015 and 2014, respectively. The remaining increase in personnel-related expenses and increase in outside services were attributable to our VISION clinical trial.

Selling, General and Administrative Expenses. SG&A expenses increased $4.6 million, or 55%, to $12.9 million during the six months ended June 30, 2015, compared to $8.3 million during the six months ended June 30, 2014. This increase was primarily due to a $3.1 million increase in personnel-related expenses and an increase of $1.3 million in consulting, legal and professional fees. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of $1.3 million compared to $0.2 million for the six months ended June 30, 2015 and 2014, respectively. Increases in our

consulting, legal and professional fees were associated with the audit and review of our financial statements and other costs associated with operating as a public company.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.5 million, or 17%, to an expense of $2.7 million during the six months ended June 30, 2015, compared to an expense of $3.2 million during the six months ended June 30, 2014. This decreased expense was attributable to the conversion of our convertible notes into shares of Series E preferred stock during the third and fourth quarter of 2014.

Other Income (Expense), Net. Other income (expense), net increased to an income of $0.5 million during the six months ended June 30, 2015, compared to income of $0.1 million during the six months ended June 30, 2014. The increase in other income was primarily attributable to the remeasurement of the fair value of the derivative instruments associated with our notes which are accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date.

Liquidity and Capital Resources

As of June 30, 2015, we had cash and cash equivalents of $60.7 million and an accumulated deficit of $169.6 million, compared to cash and cash equivalents of $12.3 million and an accumulated deficit of $146.5 million as of December 31, 2014. We currently believe our existing cash and cash equivalents and expected revenues, will be sufficient to meet our capital requirements and fund our operations for at least 15 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or obtain an additional credit facility. Prior to our initial public offering in January 2015, our primary sources of capital have been private placements of preferred stock and debt financing agreements. In April 2013, we entered into a credit agreement with PDL, under which we could borrow up to $40.0 million, of which $20.0 million was immediately available and drawn by us. The remaining $20.0 million would have been available based upon the achievement of certain net revenue milestones prior to June 30, 2014. We did not achieve the net revenue milestones and, accordingly, cannot borrow additional funds under the credit agreement. As of June 30, 2015, we had $20.5 million outstanding under the credit agreement. See section titled Contractual Obligations PDL Credit and Security Agreements.

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If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any 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 scale back our business and operations.

Cash Flows

	Six Months Ended June 30,	
	2015	2014
	(unaudited) (in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (16,986)	$ (10,646)
Investing activities	148	(8)
Financing activities	65,219	4,200
Net (decrease) increase in cash and cash equivalents	$ 48,381	$ (6,454)

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2015 was $17.0 million, consisting primarily of a net loss of $20.6 million, partially offset by non-cash charges of $3.6 million. The non-cash charges primarily consisted of depreciation, stock-based compensation, and non-cash interest expense related to our credit agreement with PDL, partially offset by the change in fair value of the embedded compound derivative associated with the notes.

During the six months ended June 30, 2014, net cash used in operating activities was $10.6 million, consisting primarily of a net loss of $15.0 million, partially offset by a decrease in net operating assets of $1.4 million and by non-cash charges of $3.0 million. The decrease in net operating assets was primarily due to decreases in accounts receivable and inventory, reflecting a decline in our revenues, and an increase in accrued expenses and other current liabilities related to interest payable to PDL. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense related to our credit agreement with PDL, partially offset by the change in fair value of common stock warrants and the embedded compound derivative associated with the notes.

Net Cash Used in Investing Activities

Net cash provided by investing activities in the six months ended June 30, 2015 was $0.1 million consisting of $255,000 from the release of a restriction against our cash, offset by purchases of property and equipment of $107,000.

Net cash used in investing activities in the six months ended June 30, 2014 was $8,000 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, 2015 was $65.2 million, consisting of net proceeds of $58.7 million from the issuance of common stock related to our IPO and net proceeds of $6.2 million from the issuance of our Series E preferred stock. As of December 31, 2014, cash paid for deferred IPO costs was $1.8 million.

During the six months ended June 30, 2014, net cash provided by financing activities was $4.2 million, consisting of net proceeds of $4.2 million from the issuance of convertible notes.

Off-Balance Sheet Arrangements

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

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Contractual Obligations

Our principal obligations consist of the operating lease for our facilities, capital leases related to office equipment, the credit agreement with PDL, the notes and non-cancellable purchase commitments. There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 27, 2015, except for our entering into four additional capital lease agreements in 2015. As of June 30, 2015, under these capital lease agreements, we are obligated to pay approximately $55,000 in lease payments through January 2018 over the term of the agreements.

Convertible Promissory Notes

On October 29, 2013, we entered into a Note and Warrant Purchase Agreement, or the Convertible Note Agreement, with certain existing preferred stockholders, third-parties and employees for the issuance of convertible notes up to an aggregate principal amount of $25.0 million. Under the terms of the Convertible Note Agreement, we issued convertible notes, or the notes, in October and November 2013 for total proceeds of $13.5 million and in May and July 2014 for total proceeds of $4.7 million. The notes bear interest equal to 30-day LIBOR, plus 6% per annum subject to a minimum internal rate of return of 20% per annum. The principal and accrued interest thereon will mature on the earlier of: (i) October 29, 2018, (ii) an event of default or (iii) a change of control event.

The principal and the accrued interest on the notes was convertible, at the option of the holder, upon a future issuance of our preferred stock or common stock into that same stock at a conversion price equal to 85% of the price paid by other investors in the financing event. For holders who elected not to convert their notes upon the closing of our Series E financing or upon our IPO, we may repay the notes at the greater of (i) 125% of the outstanding principal and accrued and unpaid interest or (ii) the amount providing the investor with an annual 20% minimum internal rate of return. Upon a change of control, at the election of the holder, we are obligated to make a payment to such holder equal to the greater of (i) 125% of the outstanding principal and accrued and unpaid interest, (ii) an amount equal to the return the holders of Series D preferred stock would be entitled to receive in such change of control, or (iii) the amount providing the investor with an annual 20% minimum internal rate of return, provided that in the event that the change of control includes any contingent payments based on future performance, the amount due and payable under clause (ii) will be recalculated at the time each installment or contingent payment is made. In September 2014, in connection with the issuance of the Series E preferred stock, $7.8 million of principal and accrued interest outstanding under the notes was converted into shares of Series E preferred stock. In November 2014, an additional $3.8 million of principal and accrued interest outstanding under the notes was converted into shares of Series E preferred stock. As of June 30, 2015, $9.5 million in principal and accrued interest remained outstanding under the notes.

We may, at our sole election, prepay such outstanding principal and accrued and unpaid interest under the notes by paying each holder an amount equal to the greater of (i) 125% of the principal and accrued and unpaid interest under the notes or (ii) the amount providing the investor with an annual 20% minimum internal rate of return at any time prior to their maturity date.

Lease Agreement

We lease our headquarters in Redwood City, California pursuant to a lease agreement with HCP LS Redwood City dated July 30, 2010, or the 2010 Lease, as amended by the First Amendment to Lease dated September 30, 2011 and together with the 2010 Lease, the Amended Lease. The Amended Lease has a rental commencement date of December 1, 2011 and a term of five years and expires in November 2016. We have two options to extend the lease term for a period of three years each. Each option must be exercised no more than 12 months and no less than nine months prior to the expiration of the applicable term. The Amended Lease is for an aggregate of approximately 44,200 rentable square feet.

PDL Credit and Security Agreements

On April 18, 2013, we, as borrower, entered into a credit agreement with PDL, as lender and agent. The credit agreement provided for an aggregate term loan facility of up to $40.0 million, available in two tranches of up to $20.0 million each. We borrowed $20.0 million as a term loan under tranche one of the credit agreement on April 18, 2013. We also paid closing fees to PDL of approximately $200,000, which were deducted from the tranche one funds we received, plus legal and brokerage fees. Tranche two of the credit agreement, the availability of which was conditioned on our satisfaction of certain milestones, never became available to us as we did not reach those milestones. The proceeds from tranche one were used for working capital, capital expenditures and general corporate purposes.

The tranche one term loan bears interest at a rate equal to 12.0% per annum. Interest on the tranche one term loan is due and payable quarterly in arrears, provided that we may elect to add up to 1.5% percent of interest per annum to increase the outstanding principal balance of such loan for the first eight interest payment dates after the closing date with respect to the tranche one loan. Pursuant to this provision, we converted $0.6 million of the interest on the tranche one loan amount into principal and, as of June 30,

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2015, there was $20.5 million outstanding under the credit agreement. Principal is payable in equal quarterly installments beginning December 2015. All outstanding amounts under the tranche one term loan must be repaid on April 18, 2018.

At maturity of the tranche one term loan, or upon its full prepayment, we are obligated to pay an exit fee equal to 1.0% of the original principal amount borrowed. Additionally, until April 18, 2018, even if the term loan is prepaid, we are obligated to pay to PDL a certain percentage of our net revenue each quarter. Until the end of the quarter in which prepayment occurs, we are required to pay to PDL a quarterly amount equal to 1.8% of our net revenues for such quarter. If we prepay the loan, we are still required to pay to PDL a quarterly amount equal to the greater of 0.9% of our net revenues for each calendar month during such quarter and certain minimum amounts, starting at $65,000 per quarter in 2013 and increasing annually to $310,000 per quarter in 2018. On April 18, 2013, we entered into a security agreement with PDL, as agent, pursuant to which we secured our obligations under the tranche one term loan by granting to PDL a security interest on substantially all of our assets.

The credit agreement and the security agreement contain customary affirmative covenants and customary negative covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate with affiliates, make acquisitions, incur debt, incur liens, pay dividends, enter into restrictive agreements, repurchase stock and make investments, in each case subject to certain exceptions. Additionally, even if the term loan is prepaid, until there are no further obligations to periodically pay to lender 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 credit agreement and the security agreement also contain customary events of default including, among others, payment defaults, breaches of covenants, bankruptcy and insolvency events, cross defaults with certain material indebtedness, judgment defaults, and breaches of representations and warranties. Upon an event of default, PDL may declare all or a portion of our outstanding obligations payable to be immediately due and payable and exercise other rights and remedies provided for under the credit agreement, the security agreement and any guaranty. Additionally, upon an event of default, the interest rate would likely be increased to a default rate of 14.0% per annum. We were in compliance with the covenants under the credit agreement and the security agreement as of June 30, 2015.

Indemnification

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification of the counterparty. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future, but have not yet been made. To date, we have not been subject to any claims or been required to defend any action related to our indemnification obligations. However, we may incur significant expense in the future as a result of these indemnification obligations.

In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, we have indemnification obligations to our officers and directors, subject to some limits, with respect to their service in such capacities. We have also entered into indemnification agreements with our directors and certain of our officers. To date, we have not been subject to any claims, and we have director and officer insurance that may enable us to recover a portion of any amounts paid for future potential claims. However, we may incur significant expense in the future as a result of these indemnification obligations.

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. 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 and six months ended June 30, 2015, 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 27, 2015.

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.

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We are also exposed to market risk related to fluctuations in interest rates indexed to LIBOR, which determines the variable interest payments we make on the notes, as they bear interest equal to 30-day LIBOR, plus 6% per annum. However, we do not believe we are subject to any material market risk exposure as the notes are subject to, and interest is accrued at, a minimum internal rate of return of 20%.

Credit Risk

As of June 30, 2015 and December 31, 2014, 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. Three and no customers represented more than 10% of our accounts receivable as of June 30, 2015 and December 31, 2014, respectively.

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.

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, 2015. Based on such evaluation,

our principal executive officer and principal financial officer have concluded that, as of June 30, 2015, 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 2015 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. From time to time we may be involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. 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.

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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, particularly our Pantheris atherectomy device, which has not yet been approved for marketing;

- market acceptance of our lumivascular platform;

- 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, particularly our VISION trial for Pantheris;

- 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, industry and market conditions;
- the regulatory environment;
- the hiring, training and retention of key employees, including our ability to expand our sales team;
- litigation or other claims against us;
- 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, including net losses of $39.9 million and $32.0 million in for the years ended December 31, 2013 and 2014, respectively, and $20.6 million for the six months ended June 30, 2015. As of June 30, 2015, we had an accumulated deficit of approximately $169.6 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 costs and expenses to increase in the future due to anticipated increases in cost of revenues, sales and marketing expenses, research and development expenses and general and administrative expenses and, therefore, 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 incur significant legal, accounting and other expenses that we did not incur as a private company. 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.

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

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. 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 and increasing and unforeseen expenses as we continue to attempt to grow our business.

Our short commercialization experience and limited number of approved products also make it difficult for us to forecast our future financial performance and growth and such forecasts are limited and subject to a number of uncertainties, including our ability to successfully complete our VISION clinical trial and obtain FDA clearance for, and successfully commercialize, Pantheris 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 our ability to obtain FDA clearance for, and successfully commercialize, Pantheris. This device is still in clinical trials, has been used in only a limited number of procedures and there is no long-term data on its safety and efficacy.

The long-term viability of our company is largely dependent on the successful development and commercialization of Pantheris. In March 2015, we completed enrollment of patients in a clinical study called VISION that will be used to support regulatory clearance of Pantheris, and we do not have significant long-term data on Pantheris safety and efficacy. While we expect to successfully complete the on-going study and file our 510(k) submission for Pantheris in the second half of 2015 with FDA, there can be no guarantee that the FDA will conclude that our primary endpoints have been achieved based on our clinical results or that we will receive regulatory clearance for the sale and marketing of Pantheris in the United States. A number of companies in the medical device field have suffered significant setbacks during clinical trials notwithstanding promising early results. During the review of our 510(k) submission, the FDA may conclude that we need to gather additional clinical data to support the approval of Pantheris. Because we are depending heavily on sales of Pantheris to achieve our revenue goals, delays related to the need to collect additional clinical data or the failure to successfully receive FDA clearance, in a timely manner or at all, will harm our financial results and ability to become profitable. Even if we obtain regulatory clearance, our ability to successfully market this product will be limited due to a number of factors including regulatory restrictions in our labeling. In addition, there can be no guarantee that Pantheris will be accepted by the medical community as a valid alternative to currently available devices. If we cannot sell Pantheris as planned, our financial results will be harmed.

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.

We believe that our cash and cash equivalents at June 30, 2015 and expected revenues from operations will be sufficient to satisfy our capital requirements and fund our operations for at least 15 months following the date of this Quarterly Report on Form 10-Q. We will likely need additional funds to meet our operational needs and capital requirements for product development, clinical trials and commercialization.

Prior to our initial public offering, we have financed our operations primarily through sales of our products, net proceeds from the issuance of our preferred stock and debt financings. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. 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 business technology 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 costs, timing and outcomes of clinical trials and regulatory reviews associated with our future products, including Pantheris;

- the costs and expenses of 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;

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- the degree of success we experience in commercializing our lumivascular platform products, particularly Pantheris;

- 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 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, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. 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, 2015, we had $20.5 million in principal and interest outstanding under our credit facility, or the credit agreement, with PDL Biopharma, or PDL, and $9.5 million in principal plus interest outstanding under convertible promissory notes, or the notes. We must make significant annual debt payments under the credit agreement, which diverts resources from other activities. Our debt with PDL is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. In addition to the interest and principal payments due under the credit agreement, we are obligated to pay PDL a royalty at the rate of 1.8% of our quarterly revenues through the maturity date of April 18, 2018. To the extent that we prepay the borrowings under the credit agreement, our royalty obligations will continue and will be payable through the maturity date at the higher of a reduced rate of 0.9% of our quarterly revenues or certain minimum amounts. During this period, we must continue to comply with covenants limiting our ability to, among other things, undergo a change in control and dispose of assets, in each case subject to certain exceptions. These covenants may make it difficult to operate our business. We are also subject to standard event of default provisions both under the credit agreement and the notes that, if triggered, would allow the debt to be accelerated,

which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. The existing collateral pledged under the credit agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even after the PDL debt is 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, as of June 30, 2015, we were obligated to pay our former financial advisor a transaction fee of $320,000.

We depend on a limited number of products, which we only recently introduced in the United States. If these products fail to gain, or lose, market acceptance, our business will suffer.

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat and Kittycat 2 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. We expect that sales of our current and future lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Because of their recent commercial introduction, our lumivascular platform products have limited product and brand recognition. We do not know if our lumivascular platform products will be successful over the long term and 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

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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 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, the current model of Pantheris may require two physicians to operate the catheter and a technician to operate the Lightbox, making it less financially attractive for physicians. 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.

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 less costly than the alternatives offered by our competitors. If we are unable to convince physicians that our lumivascular platform leads to significantly lower restenosis, or narrowing of the artery, rates and fewer adverse events during surgery than those using competing technologies, our business will suffer. In order to use our Ocelot family of catheters or, if cleared, Pantheris, 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 up to two physicians 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 disruption of the black line when physicians are using our products is lower than with competing products. If minimizing disruption to the black line does not significantly impact patient outcomes, meaning either (i) that restenosis is often triggered without disrupting the black line, or (ii) the black line can often be disrupted 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 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 device, 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 not FDA-cleared or approved 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

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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 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.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could harm sales of our products. Our products could be rendered obsolete because of future innovations in the treatment of PAD. In order to remain competitive, we must continue to develop new product offerings and enhancements to our existing lumivascular platform products. 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, Bard, Boston Scientific, Cook Medical, Johnson & Johnson 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.

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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. 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:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time consuming;

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

- FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;

- FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;

- there may be delays or failure in obtaining approval of our clinical trial protocols from FDA or other regulatory authorities;

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

- FDA or similar foreign regulatory authorities may find our or our suppliers manufacturing processes or facilities unsatisfactory;

- FDA or similar foreign regulatory authorities may change their review policies or adopt 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;

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- we may have trouble in managing multiple clinical sites;

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

- we, or regulators, may suspend or terminate 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 no long-term data regarding the safety and efficacy of our lumivascular platform products. 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 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 are not known.

The results of short-term clinical experience of our lumivascular platform products 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 our VISION trial or 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 in addition to VISION to support expanded use, which would be expensive, time-consuming and may not be successful.

Our current products are cleared in the United States solely for crossing sub-total and chronic total occlusions in the peripheral vasculature. This clearance prohibits 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

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and FDA does not regulate physicians choice of treatments, 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 FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action by 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 coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from 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 cafnnot 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 Health and Human Services 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.

If we fail to grow our sales and marketing capabilities and develop widespread brand awareness cost effectively, our growth will be impeded and our business may suffer.

We plan to continue to expand and optimize our sales infrastructure in order to grow our customer base and our business. Identifying and recruiting qualified personnel and training them in the use of our lumivascular platform, and on applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. It can take several months before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenues. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenues.

John Borrell, our former Vice President of Sales, left our company in July 2015. We intend to initiate a search for a new Vice President of Sales. This search may take time and we can provide no estimate as to how long it will take and no assurance that we will find a qualified candidate to replace him.

Our ability to increase our customer base and achieve broader market acceptance of our lumivascular platform will depend to a significant extent on our ability to expand our marketing operations. We plan to dedicate significant financial and other resources to our marketing programs. Our business will be harmed if our marketing efforts and expenditures do not generate an increase in revenue.

In addition, we believe that developing and maintaining widespread awareness of our brand in a cost-effective manner is critical to achieving widespread acceptance of our lumivascular platform and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenues, and even if they do, any increase in revenues may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our lumivascular platform.

If we are unable to manage the anticipated growth of our business, our future revenues and operating results may be harmed.

Any growth that we experience in the future could provide challenges to our organization, requiring us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. We expect to grow our sales force in anticipation of obtaining marketing clearance for Pantheris. Rapid expansion in personnel could mean that less experienced people produce and sell our products, which could result in inefficiencies and unanticipated costs and disruptions to our operations.

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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:

- we intend to significantly expand our manufacturing capacity, and our production processes may have to change to accommodate this growth;

- 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;

- we have limited experience in complying with FDA s Quality System Regulation, which applies to the manufacture of our lumivascular platform products; and

- to increase our manufacturing output significantly, we will have to attract and retain qualified employees, who are in short supply, for our manufacturing operations.

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 Quality System regulations. 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, 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. Any of these may render it difficult or impossible for us to manufacture products 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;

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- 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 Quality System regulations 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 a single vendor for our data acquisition card in 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 intend to 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, including the recent addition of our chief executive officer, could disrupt our business. In particular, our founder, Dr. John 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

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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.

To execute our growth plan, 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 executives. 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 and future growth prospects 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 European 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 carryovers may be limited.

As of December 31, 2014, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $133.9 million and $134.2 million, respectively, which if not utilized will begin to expire in 2027 for federal purposes and 2015 for state purposes. We may use these NOLs to offset against 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. This offering or 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, 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.

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Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of June 30, 2015, we held five issued U.S. patents and had 17 U.S. utility patent applications and 5 PCT applications pending. As of June 30, 2015, we also had one issued patent from the Japan Patent Office, one issued patent from the Chinese patent office, and one European patent which has been nationalized in Germany, France, Great Britain, Italy and Ireland. As of June 30, 2015, we had 37 pending patent applications outside of the United States, including in Australia, Canada, 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;

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- 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 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. To market Pantheris in the United States, we must successfully complete a clinical trial, submit an application to FDA for 510(k) clearance and obtain such clearance. Therefore, even if we believe we have successfully developed Pantheris, we may not be permitted to market Pantheris in the United States if we do not obtain FDA regulatory clearance to market the product. 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 medical device reporting regulations, or 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. For example, we have submitted to the FDA five MDRs regarding our Ocelot family of catheters, which included four perforations and one related to removal of the guidewire coating.

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 publically 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 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, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

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

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

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Material modifications to our lumivascular platform products may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our lumivascular platform products until clearances 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 FDA published guidelines, 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, 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 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 have made minor modifications and may make further modifications to the design of Pantheris prior to widespread commercialization, which could require regulatory clearances or approvals.

If we or our suppliers fail to comply with FDA s Quality System Regulation, 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 FDA s Quality System Regulation, 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 FDA, state authorities and comparable agencies in other countries. If we fail a Quality System inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse Quality System 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 product and cause our revenues to decline.

We have registered with FDA as a medical device manufacturer and have obtained a manufacturing license from the California Department of Health Services, or CDHS. FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by 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 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 2013 and in 2015 and found zero non-conformances. We can provide no assurance that we will continue to remain in compliance with the QSR. If 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

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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, imposes 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.

It remains unclear whether changes will be made to the Affordable Care Act. We cannot assure you that the Affordable Care Act, as currently enacted or as amended in the future, will not harm our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. 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 federal Physician Payment 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

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under Medicare, Medicaid, or the Children s Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or 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 Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and 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 part 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.

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 since our initial public offering 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:

- the results of our clinical trials, including our VISION trial;

- changes in analysts estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts estimates;

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

- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;

- 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.

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. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition, reputation and cash flows. These factors may materially and adversely affect the market price of our common stock.

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. If one or more of the 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 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 recently completed our initial public offering and a substantial number of shares became available for sale on July 29, 2015. We are unable to predict the effect that these sales and others may have on the prevailing market price of our common stock.

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

As of August 3, 2015, our directors, officers and each stockholder holding more than 5% of our common stock collectively control approximately 43.5% 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

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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.

We previously identified and remediated a material weakness in our internal control over financial reporting. We may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with US generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Prior to the completion of our initial public offering, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for our initial public offering, we determined that we had a material weakness in our internal control over financial reporting as of December 31, 2013 and 2012. The material weakness we identified related to not maintaining sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

For a discussion of our remediation and the actions that we have executed during 2014 to remediate the material weakness see our most recent Annual Report on Form 10-K, as filed with the SEC on March 27, 2015. We believe the measures described remediated the material weakness we previously identified and strengthened our internal control over financial reporting. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have remediated this weakness, we cannot assure you that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness or significant deficiency could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

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 The NASDAQ Stock Market 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

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

We are an emerging growth company and a smaller reporting 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 will remain eligible for these exemptions, other than with respect to stockholder approval of golden parachute payments, after we are no longer an emerging growth company for as long as we remain a smaller reporting company. 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 initial public offering, (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.

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;

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- 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 credit agreement 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.

An active trading market for our common stock may not be maintained.

Our stock is currently approved for quotation on the NASDAQ Stock Market, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active market for our common stock is not maintained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all.

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

Unregistered Sales of Equity Securities

We have issued and sold the following securities from April 1, 2015 to June 30, 2015:

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1. In April 2015 we granted options to purchase 113,800 shares of our common stock with an exercise price of $10.98 per share. From April 1 through June 30, 2015, no options were exercised.

The sales of the above securities were deemed to be exempt from registration under the Securities Act with respect to items 2 and 3 above in reliance on Section 4(2) of the Securities Act, or Regulation D promulgated thereunder, with respect to item 4 above in reliance on Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving a public offering or transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under such Rule 701 and with respect to item 1 above in reliance on both section 4(2) of the Securities Act and Rule 701 promulgated under section 3(b) of the Securities Act. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and warrants issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

Use of Proceeds from Public Offering of Common Stock

Our initial public offering of 5,000,000 shares of common stock was effected through a registration statement on Form S-1 (File No. 333-201322), which was declared effective on January 29, 2015. Our initial public offering closed on February 4, 2015 and resulted in net proceeds of approximately $56.9 million, after deducting underwriting discounts and commissions of approximately $4.5 million and other expenses of approximately $3.6 million. No payments for such expenses were made directly or indirectly to any of our officers or directors.

Canaccord Genuity Inc., Cowen and Company, LLC, Oppenheimer & Co. Inc., BTIG, LLC and Stephens Inc. acted as the underwriters. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on January 30, 2015 pursuant to Rule 424(b) of the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Avinger, Inc.
(Registrant)

Date: August 12, 2015

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

Date: August 12, 2015

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

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EXHIBIT INDEX

Exhibit Number	Exhibit Title
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.
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.
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