Avinger Inc
Form 10-Q
May 09, 2016
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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 March 31, 2016

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 x	Smaller reporting company o

(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 May 2, 2016, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 12,693,485.

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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 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 510(k) submission to FDA, and associated marketing clearances by FDA, for enhanced versions of Pantheris;
- the expected growth in our business and our organization;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;
- our ability to obtain and maintain intellectual property protection for our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;

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

- our financial performance;

- our ability to remain in compliance with laws and regulations that currently apply or become applicable to our business, both in the United States and internationally; 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 MARCH 31, 2016

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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)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 26,882	$ 43,059
Accounts receivable, net of allowance for doubtful accounts of $20 at March 31, 2016 and December 31, 2015	4,036	2,060
Inventories	6,540	5,405
Prepaid expenses and other current assets	1,048	533
Total current assets	38,506	51,057
Property and equipment, net	3,207	2,822
Other assets	453	225
Total assets	$ 42,166	$ 54,104
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 2,312	$ 1,113
Accrued compensation	3,349	3,083
Accrued expenses and other current liabilities	3,413	3,285
Total current liabilities	9,074	7,481
Borrowings, net of current portion	29,976	29,565
Other long-term liablities	1,298	1,469
Total liabilities	40,348	38,515
Commitments and contingencies (Note 8)		
Stockholders equity:		
Preferred stock issuable in series, par value of $0.001 Shares authorized: 5,000,000 at March 31, 2016 and December 31, 2015 Shares issued and outstanding: none at March 31, 2016 and December 31, 2015		
Common stock, par value of $0.001 Shares authorized: 100,000,000 at March 31, 2016 and December 31, 2015 Shares issued and outstanding: 12,693,485 at March 31, 2016 and 12,643,538 at December 31, 2015	13	13
Additional paid-in capital	214,233	211,837

Accumulated deficit		(212,428)		(196,261)
Total stockholders equity		1,818		15,589
Total liabilities and stockholders equity	$	42,166	$	54,104

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 March 31,	
	2016	**2015**
Revenues	$ 4,539	$ 2,088
Cost of revenues	3,360	1,288
Gross profit	1,179	800
Operating expenses:		
Research and development	4,047	3,860
Selling, general and administrative	12,161	6,365
Total operating expenses	16,208	10,225
Loss from operations	(15,029)	(9,425)
Interest income	33	3
Interest expense	(1,172)	(1,323)
Other income (expense), net	1	329
Loss before provision for income taxes	(16,167)	(10,416)
Provision for income taxes		1
Net loss and comprehensive loss	(16,167)	(10,417)
Adjustment to net loss resulting from convertible preferred stock modification		(2,384)
Net loss and comprehensive loss attributable to common stockholders	$ (16,167)	$ (12,801)
Net loss attributable to common stockholders per share, basic and diluted	$ (1.28)	$ (1.53)
Weighted average common shares used to compute net loss per share, basic and diluted	12,669	8,373

See accompanying notes.

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AVINGER, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	**2015**
Cash flows from operating activities		
Net loss	$ (16,167)	$ (10,417)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	336	317
Amortization of debt issuance costs and debt discount	47	50
Stock-based compensation	1,978	1,232
Remeasurement of warrant liability and embedded derivatives		(344)
Noncash interest expense and other charges	371	487
Provision for excess and obsolete inventories	294	(8)
Changes in operating assets and liabilities:		
Accounts receivable	(1,976)	775
Inventories	(1,794)	(133)
Prepaid expenses and other current assets	(516)	(1,058)
Other assets	(135)	
Accounts payable	1,145	642
Accrued compensation	267	212
Accrued expenses and other current liabilities	136	388
Other long-term liabilities and accrued interest	(179)	(64)
Net cash used in operating activities	(16,193)	(7,921)
Cash flows from investing activities		
Purchase of property and equipment	(301)	(208)
Net cash used in investing activities	(301)	(208)
Cash flows from financing activities		
Principal paydown of capital lease obligations	(9)	(4)
Payments on deferred offering costs	(93)	
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		300
Proceeds from the issuance of common stock	419	
Net cash provided by financing activities	317	65,217
Net change in cash and cash equivalents	(16,177)	57,088
Cash and cash equivalents, beginning of period	43,059	12,316
Cash and cash equivalents, end of period	$ 26,882	$ 69,404
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 957	$ 55
Noncash investing and financing activities:		
Conversion of convertible preferred stock to common stock upon initial public offering	$	$ 137,632
Accounts payable for purchases of property and equipment	54	37

Modification of convertible preferred stock		2,384
Vesting of common stock subject to repurchase		2
Issuance of common stock warrants		804
Transfer between inventory and property and equipment	365	87

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 artery disease (PAD). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. The Company manufactures and sells a suite of products in the United States (U.S.) and in select 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). In March 2016, the Company also received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for commercialization of Pantheris, the Company s image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company commenced sales of Pantheris in the U.S. and select European markets promptly thereafter. The Company is located in Redwood City, California.

Liquidity Matters

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of March 31, 2016, the Company had an accumulated deficit of $212,428,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $26,882,000 at March 31, 2016, expected revenues, the additional $10,000,000 available under the loan agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively CRG) and the net proceeds from the follow-on public offering the Company intends to conduct whereby it may issue and sell shares of common stock will be sufficient to allow the Company to fund its current operations until at least December 31, 2016. The Company is eligible to borrow the additional $10,000,000 in principal amount from CRG, on or prior to June 30, 2016. Consistent with its 2016 operating plan, the Company will need to acquire additional funding in the form of debt financing or additional equity issuances to make strategic investments in its business, however, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be favorable. If the Company s revenue levels from its products are not sufficient or if the Company is unable to secure additional funding when desired, the Company may need to delay the development, commercialization and marketing of its products and scale back its business and operations. The Company s ultimate success will largely depend on its ability to successfully commercialize its products and its ability to raise additional funding.

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 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.

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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 months ended March 31, 2016, are not necessarily indicative of results to be expected for the year ending December 31, 2016, or for any other interim period or for any future year. The December 31, 2015 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, 2015, which was filed with the SEC on March 7, 2016. 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, 2015.

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 compound embedded derivatives, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of March 31, 2016 and December 31, 2015. Financial instruments consist of cash and cash equivalents, accounts receivable and payable, and other current liabilities and borrowings. The carrying amounts of cash and cash equivalents, accounts receivable and payable, and other current liabilities approximate their respective fair values because of the short-term nature of those instruments. Based upon the borrowing terms and conditions currently available to the Company, the carrying values of its borrowings approximate fair value.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, using level 1 inputs, based on quoted market prices. As of March 31, 2016 and December 31, 2015, the Company s cash equivalents are entirely comprised of investments

in money market funds. Any related unrealized gains and losses are recorded in other comprehensive income (loss) and included as a separate component of stockholders equity. There were no unrealized gains and losses as of March 31, 2016 and December 31, 2015. Any realized gains and losses and interest and dividends on available-for-sale securities are included in interest income or expense and computed using the specific identification cost method.

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 March 31, 2016 and December 31, 2015.

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The Company s accounts receivable are due from a variety of health-care organizations in the United States and select European markets. At March 31, 2016 and December 31, 2015, there were no customers that represented 10% or more of the Company s accounts receivable. For the three months ended March 31, 2016 and 2015, there were no customers that represented 10% or more of revenues. Disruption of sales orders or a deterioration of financial condition of its customers would have a negative impact on the Company s financial position and results of operations.

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

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

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

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to an offering of equity securities, were capitalized. As of March 31, 2016, $248,000 of deferred offering costs were capitalized in other assets on the balance sheet, of which $93,000 had been paid. Deferred offering costs of $29,000 were capitalized as of December 31, 2015.

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to $150,000,000 of its securities and entered into a Sales Agreement with Cowen and Company (Cowen), pursuant to which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016, no shares of common stock have been sold under the Sales Agreement with Cowen to date.

Convertible Preferred Stock

Prior to its IPO the Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs and classified the convertible preferred stock outside of stockholders equity 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 to additional paid-in capital.

Embedded Derivative Instruments

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

Revenue Recognition

The Company s revenues are derived from (1) sale of its Lightbox (2) sale of disposables, which consist of catheters and accessories, and (3) sale of customer service contracts. The Company 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.

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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.

Product Warranty Costs

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

	Amount
Balance at December 31, 2015	$ 70
Warranty provision	288
Usage/Release	(21)
Balance at March 31, 2016	$ 337

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Common Stock Valuation and Stock-Based Compensation

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

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. As applicable, 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, there were no common stock shares subject to repurchase excluded from the calculations as of March 31, 2016 and December 31, 2015. 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.

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

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

	Three Months Ended March 31,	
	2016	2015
Net loss	$ (16,167)	$ (10,417)
Adjustment to net loss resulting from convertible preferred stock modification		(2,384)
Net loss attributable to common stockholders	$ (16,167)	$ (12,801)

Weighted average common stock outstanding	12,669	8,373
Net loss attributable to common stockholders per share, basic and diluted	$ (1.28)	$ (1.53)

In addition to the convertible notes outstanding as of March 31, 2015 (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:

	March 31,	
	2016	**2015**
Common stock options	3,840,226	3,035,348
Unvested restricted stock units	276,608	
Common stock warrants	2,152,117	2,213,395
	6,268,951	5,248,743

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Comprehensive Loss

For the three months ended March 31, 2016 and 2015, there was no difference between comprehensive loss and the Company s net loss.

Segment and Geographical Information

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB), jointly with the International Accounting Standards Board, issued a comprehensive new standard on recognition from contracts with customers. The standard s core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. On July 9, 2015, FASB voted to delay the effective date of the new standard by one year. As such the standard will become effective for the Company beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company is currently evaluating the impact of its adoption and transition approach of this standard on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15 Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern under Accounting Standards Codification Subtopic 205-40, Presentation of Financial Statements Going Concern. ASU No. 2014-15 provides guidance about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for the Company s annual reporting period ending December 31, 2016 and all annual and interim reporting periods thereafter, with early adoption permitted. The Company has not elected to early adopt this standard. When adopted, ASU 2014-15 will require Management s evaluation to be based on relevant conditions and events that are known or reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Under ASU 2014-15 substantial doubt about an entity s ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued).

In July 2015, the FASB issued an accounting standard which applies to all inventory that is measured using methods other than last-in, first-out or the retail inventory method, including inventory that is measured using first-in, first-out or average cost. The standard requires entities to

measure inventory at the lower of cost and net realizable value, defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public entities for fiscal years beginning after December 15, 2016, and interim periods with fiscal years beginning after December 15, 2017. The amendments in the standard should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

In February 2016, the FASB issued an ASU that requires a lessee to recognize a right-of-use asset and lease liability on the balance sheet for all leases with terms of more than 12 months. Recognition, measurement and presentation of expenses will depend on the classification as a finance or operating lease. This ASU is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the effect that the ASU will have on its financial statements and related footnote disclosures.

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In March 2016, the FASB issued ASU No. 2016-09, Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which simplifies several aspects of the accounting for employee share-based payments, including income tax consequences, application of award forfeitures to expense, classification on the statement of cash flows, and classification of awards as either equity or liabilities. This guidance is effective for annual reporting periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the effect that this guidance will have on its financial statements and related footnote disclosures.

3. Fair Value Measurements

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

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

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

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

As of March 31, 2016 and December 31, 2015, cash equivalents were all categorized as Level 1 and consisted of money market funds. In 2013 and 2014 the Company issued convertible notes containing redemption features which were determined to be a compound embedded derivative which, prior to their extinguishment in September 2015, required fair value accounting (Note 6). The 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. Upon the extinguishment of the convertible notes in September 2015, the fair value of the compound embedded derivatives at the date of extinguishment was expensed to other income (expense), net. Subsequent to September 2015, there were no changes in fair value.

There were no transfers between fair value hierarchy levels during the three months ended March 31, 2016 and 2015.

4. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Raw materials	$ 3,726	$ 2,662
Work-in-process	194	372
Finished products	2,620	2,371
Total inventories	$ 6,540	$ 5,405

5. Borrowings

CRG

On September 22, 2015, the Company entered into a Term Loan Agreement (the Loan Agreement) with CRG under which, subject to certain conditions, the Company may borrow up to $50,000,000 in principal amount from CRG on or before December 31, 2016. The Company borrowed $30,000,000 on September 22, 2015. Upon FDA approval of the 510(k) for Pantheris the Company became eligible to borrow an additional $10,000,000 in principal amount, on or prior to June 30, 2016. The Company may borrow an additional $10,000,000 in principal amount, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions. Under the Loan Agreement, the first sixteen quarterly payments are interest only payments, and the last eight quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 12.5% per annum. The Company makes quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, the Company may elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind (PIK) for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the loan. To date the Company have elected the PIK interest option to the extent available and have made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

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The Company may voluntarily prepay the loan in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the borrowed loan principal, which is recorded as a discount to the debt. In addition, a facility fee equal to 7.0% of the amount borrowed plus any PIK is payable at the end of the term or when the loan is repaid in full. A long-term liability is being accreted using the effective interest method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The term loan is collateralized by a security interest in substantially all of the Company s assets. The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that the Company maintains a minimum of $5,000,000 of cash and certain cash equivalents, and the Company must achieve minimum revenue of $7,000,000 in 2015, with the target minimum revenue increasing in each year thereafter until reaching $70,000,000 in 2020 and in each year thereafter, as applicable. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company s capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. As of March 31, 2016, the Company was in compliance with all applicable covenants. As of March 31, 2016, principal and PIK payments under the Loan Agreement follows (in thousands):

Period Ending December 31,		**Principal and PIK Loan Repayments**
2016	$	
2017		
2018		
2019		7,500
2020 and thereafter		22,500
		30,000
Add: Accretion of closing fees		130
Add: PIK		640
		30,770
Less: Amount representing debt financing costs		(794)
Borrowings, net of current portion	$	29,976

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

In connection with the Loan Agreement, the Company recorded a debt discount of $876,000. The debt discount comprised financing fees of $450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and Security Purchase Agreement with CRG of $541,000 net of the common stock premium of $115,000 based on the relative fair values of each security. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of March 31, 2016, the balance of the debt discount was $794,000.

PDL BioPharma

On April 18, 2013, the Company entered into a Credit Agreement (Agreement) with PDL BioPharma, Inc. (PDL) whereby PDL agreed to loan up to $40,000,000. Contemporaneous with the execution of the Agreement the Company borrowed an initial $20,000,000 (Term Note). 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 was scheduled to mature April 18, 2018, had a stated interest rate of 12.0% per annum and could be prepaid by the Company at any time. The Company paid interest-only through the first ten quarters and, thereafter, repayment of principal in equal installments including accrued and unpaid interest, payable each quarter. As provided under the terms of the Agreement, for the first eight quarterly interest payments, or through 2015, on the Term Note the Company elected to convert an amount of interest, up to 1.5% per annum, into additional loans, referred to as PIK loans. The PIK loans accrued interest and were added to the aggregate principal balance of the Term Note.

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

In addition to the interest and principal payments, the Company also paid a royalty, referred to as Assigned Interests, equal to 1.8% of the Company s quarterly net revenues. Upon the prepayment of the Term Note, the Company s obligations relating to Assigned Interests continue, and are payable through the maturity date at a reduced rate of 0.9% of the quarterly net revenues, subject to certain quarterly minimum mandatory amounts, which are payable monthly. The ongoing obligation was determined to be an embedded element of the Agreement and cannot be bifurcated from the Term Note for accounting purposes. Accordingly, the Company continued to account for the Assigned Interest obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the

retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2015, is used to adjust the carrying amount to the present value of the revised estimated cash flows, discounted at the new effective interest rate. At the time of the repayment the resulting increase in the carrying value of the Assigned Interests, of $942,000, was recognized as a component of other income (expense), net, on the statements of operations and comprehensive loss. The Company has an aggregate accrual for its Assigned Interests obligations of $2,107,000 and $2,303,000, representing the net present value of the future minimum royalty obligation as of March 31, 2016 and December 31, 2015, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities and within other long-term liabilities as of March 31, 2016 and December 31, 2015, on the balance sheet. Prior to the repayment of the Term Note, the Assigned Interests liability was included within borrowings and borrowings, net of current portion, on the balance sheet.

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Additionally, until there are no further obligations to periodically pay PDL a percentage of our net revenue, the Company must comply with certain affirmative covenants and negative covenants limiting its ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The Company was in compliance with the covenants under the Agreement as of March 31, 2016.

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

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

7. Capital Leases

Capital lease obligations consist of leased office equipment. As of March 31, 2016 and December 31, 2015, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $56,000 and $39,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of March 31, 2016, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2016	$ 19
2017	26
2018	13
2019	1
Total minimum payments	59
Less: Amount representing future interest	3
Present value of minimum lease payments	$ 56

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 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In 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 original term of the Company s operating lease. Rent expense was $230,000 for the three months ended March 31, 2016 and 2015.

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The future minimum lease payments as of March 31, 2016, are as follows (in thousands):

Year ending December 31,	Future Minimum Lease Payments
2016	$ 853
2017	113
2018	117
2019	110
Total minimum lease payments	$ 1,193

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 $4,568,000 and $4,347,000 as of March 31, 2016 and December 31, 2015, respectively.

Indemnification

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

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 March 31, 2016 and December 31, 2015. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable.

9. Stockholders Equity

Preferred Stock

At March 31, 2016, the Company s certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At March 31, 2016, the Company s certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 12,693,485 shares were issued and outstanding.

Common Stock Warrants

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

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

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.

As of March 31, 2016 and December 31, 2015, warrants to purchase an aggregate of 2,152,117 and 2,193,507 shares of common stock were outstanding, respectively.

The Company determined that the amendment to the Series E Convertible Preferred Stock Purchase agreement should be accounted for as a modification. Accordingly, the incremental fair value from the modification, the additional warrants to purchase 632,381 shares of common stock warrants, of $2,384,000, was recorded as an increase to stockholders equity and as an adjustment to net loss attributable to common stockholders in the Company s statement of operations and comprehensive loss for the three months ended March 31, 2015. This amount represents a return to the preferred stockholders and is treated in a manner similar to the treatment of dividends paid to holders of preferred stock in the computation of earnings per share. As a result, the deemed dividend is subtracted from net loss available to common stockholders in reconciling net loss to net loss available for common stockholders.

Stock Plans

In January 2015, the 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, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 1,320,000 shares of common stock were reserved for issuance pursuant to the 2015 Plan. The shares reserved for issuance under the 2015 Plan included shares reserved but not issued under the 2009 Plan, plus any share awards granted under the 2009 Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2015 Plan includes an automatic annual increase on the first day of each fiscal year beginning in fiscal 2016, equal to the lesser of 1,690,000 shares, 5.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year or an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the 2015 Plan was increased by 632,176 shares of common stock. As of March 31, 2016, 1,037,487 shares were available for grant under the 2015 Plan.

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

Stock option activity under the Plans is set forth below:

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2015	3,356,981	$ 7.53	$ 50,970
Options granted	527,212	$ 13.00	
Options exercised	(1,944)	$ 4.50	
Options cancelled	(42,023)	$ 13.05	
Balance at March 31, 2016	3,840,226	$ 8.22	$ 12,890

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The weighted-average grant date fair value of stock options granted during the three months ended March 31, 2016 and 2015 was $6.18 and $5.83 per share, respectively. As of March 31, 2016, the aggregate intrinsic value of options outstanding and vested was $4,123,000. The aggregate intrinsic value of options exercised was $13,000 and none during the three months ended March 31, 2016 and 2015, respectively. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company s net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the three months ended March 31, 2016 and 2015.

At March 31, 2016 and at December 31, 2015, there were 1,063,654 and 878,948 shares, respectively, vested with a weighted-average exercise price of $7.26 and $7.46 per share, respectively, and a weighted average contractual life of 8.12 and 8.24 years, respectively.

The Company s RSUs vest annually over four years in equal increments. No RSUs vested during the three months ended March 31, 2016. A summary of all RSU activity for the three months ended March 31, 2016 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Awards outstanding at December 31, 2015	92,946	$ 19.61		
Awarded	185,500	$ 12.98		
Forfeited	(1,838)	$ 19.61		
Awards outstanding at March 31, 2016	276,608	$ 15.16	3.81 years	$ 2,650

As of March 31, 2016, $4,045,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 3.79 years. The Company used the closing market price of $9.58 per share at March 31, 2016, to determine the aggregate intrinsic value.

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. Initially 500,000 shares of common stock were reserved for issuance, which is subject to an automatic increase on the first day of each fiscal year, commencing in 2016, by an amount equal to the lesser of (i) 493,000 shares (ii) 1.5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. For fiscal 2016, the common stock available for issuance under the ESPP was increased by 189,653 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of March 31, 2016, approximately 625,000 shares of common stock remained reserved for issuance under the ESPP. The Company incurred $93,000 and $23,000 in stock-based compensation expense related to the ESPP for the three months ended March 31, 2016 and 2015, respectively.

10. Stock-Based Compensation

Stock-based compensation for the Company includes amortization related to all stock options, RSUs and shares issued under the ESPP, based on the grant-date estimated fair value. The Company estimates the fair value of stock options and shares issued under the ESPP on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model determines the fair value of stock-based payment awards based on the fair market value of the Company s common stock on the date of grant and is affected by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the fair value of the Company s common stock, and the volatility over the expected term of the awards. The Company has opted to use the simplified method for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. Prior to the Company s IPO in January 2015, due to the Company s limited operating history and a lack of company specific historical and implied volatility data, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, stage of development, risk profile, and position within the industry as well as selecting companies with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies shares during the equivalent period of the calculated expected term of the share-based payments. Following the closing of the Company s IPO, the Company supplements its own available company specific historical volatility with the volatility of the previously selected peer group of publicly traded companies. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company s common stock becomes available. The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company s stock options. The expected dividend assumption is based on the Company s history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

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As noncash stock-based compensation expense recognized in the financial statements is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The Company estimates a forfeiture rate for its stock options and RSUs based on an analysis of its actual forfeitures based on actual forfeiture experience and other factors. Forfeitures are estimated at the time of grant and revised, if necessary, over the service period to the extent that actual forfeitures differ, or are expected to differ, from prior estimates. Forfeitures are estimated based on estimated future employee turnover and historical experience.

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

	Three Months Ended March 31,	
	2016	2015
Expected term (years)	6.0	6.3
Expected volatility	49.0%	55.0%
Risk-free interest rate	1.5%	1.7%
Dividend rate		

As of March 31, 2016 and December 31, 2015, the total unamortized compensation expense related to stock-based awards granted to employees and directors was $18,249,000 and $16,871,000, which is expected to be amortized over the next 3.0 and 3.2 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 months ended March 31, 2016 and 2015:

	Three Months Ended March 31,	
	2016	2015
Expected term (years)	0.5	0.5
Expected volatility	61.4%	47.2%
Risk-free interest rate	0.38%	0.07%
Dividend rate		

Total stock-based compensation expense recognized during the three months ended March 31, 2016 and 2015, is as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Cost of revenues	$ 132	$ 60
Research and development expenses	681	552
Selling, general and administrative expenses	1,165	620
	$ 1,978	$ 1,232

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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 artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to dramatically improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select 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, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. In October 2015, we received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris, and we received an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the U.S. and select European countries promptly thereafter. We believe that Pantheris 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 our August 2015 510(k) filing with the FDA for our Pantheris atherectomy device. VISION was designed to evaluate the safety and efficacy of Pantheris to perform atherectomy using intravascular imaging and successfully achieved all primary and secondary safety and efficacy endpoints. We believe the data from VISION will also allow us to demonstrate that avoiding damage to healthy arterial structures, and in particular disruption of the external elastic lamina, which is the membrane between the outermost layers of the artery, reduces the likelihood of restenosis, or re-narrowing, of the diseased artery. We have recently commenced commercialization of Pantheris as part of our Lumivascular platform in the United States and in select European countries, after obtaining the required marketing authorizations.

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

for hospitals to invest in our technology. We also believe that Pantheris will qualify for existing reimbursement codes currently utilized by other atherectomy products, further facilitating adoption of our products.

Prior to the introduction of our Lumivascular platform our non-imaging catheter products were manufactured by third parties. All of our products are now manufactured in-house at our facilities in Redwood City, California using components and sub-assemblies manufactured both in-house and by outside vendors. We expect our current manufacturing facility will be sufficient to meet our anticipated growth through at least 2017. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors.

We began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $4.5 million in the three months ended March 31, 2016 and $2.1 million in the three months ended March 31, 2015. During the three months ended March 31, 2016 and 2015, our net loss was $16.2 million and $12.8 million, respectively. We have not been profitable since inception and as of March 31, 2016, our accumulated deficit was $212.4 million. Since inception, we have financed our operations primarily through private placements of our preferred securities and, to a lesser extent, debt financing arrangements. In January 2015, we completed an initial public offering, or IPO, of 5.0 million shares. As a result of our IPO, which closed in February 2015, we received net proceeds of approximately $56.9 million, after underwriting discounts and commissions of approximately $4.5 million and other expenses associated with our IPO of approximately $3.6 million.

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In September 2015, we entered into a Term Loan Agreement, or Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds, collectively CRG, under which we may borrow up to $50.0 million on or before March 29, 2017. We borrowed $30.0 million on September 22, 2015. Upon FDA approval of our 510(k) for Pantheris we became eligible to borrow an additional $10.0 million, on or prior to June 30, 2016. We may also borrow an additional $10.0 million, on or prior to March 29, 2017, contingent on achieving certain revenue milestones, among other conditions. Contemporaneous with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 348,262 shares of common stock on September 22, 2015 at a price of $14.357 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the securities purchase agreement, we were obligated to file a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into a Sales Agreement with Cowen and Company, or Cowen, pursuant to which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016, and no shares of common stock have been sold under the Sales Agreement with Cowen to date.

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 Pantheris. No single customer accounted for more than 10% of our revenues during the three months ended March 31, 2016 and 2015.

We expect our revenues to increase in 2016 as we expand the commercial launch of Pantheris in the United States. However, revenues may fluctuate from quarter to quarter due to a variety of factors including customer capital equipment purchasing patterns that are typically heavier towards the end of the calendar year and lighter in the first quarter. In addition, during the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. In the third quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients.

Cost of Revenues and Gross Profit

Cost of revenues consists primarily of costs related to manufacturing overhead, materials and direct labor. We expense all warranty costs and inventory provisions as cost of revenues. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. A significant portion of our cost of revenues currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. We expect overhead costs as a percentage of revenues to become less significant as our production volume increases. 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 and as we continue to invest in our operational infrastructure to support anticipated growth.

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 due, among other things, to the mix of products sold, manufacturing levels and manufacturing yields and as we continue to introduce new products and sales channels, and as we adopt new manufacturing processes and technologies.

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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

Our sales organization is divided into two primary roles, one focused on sale and use of our disposable catheters and the other focused on sale and service of our Lightbox console. 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, educational and promotional activities, devices used for demonstration purposes by our sales and marketing personnel, 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. Effective January 1, 2016, the excise tax of 2.3% on U.S sales of medical devices has been suspended for two years. We expect to continue to grow our sales force in order to support current customers and attract new users of 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 decrease in absolute dollars and as a percentage of revenues through at least the remainder of 2016, as certain expenses related to the commercial launch of Pantheris are not continued and as revenues are anticipated to increase.

Interest Income (Expense), net

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

Other Income (Expense), net

Other income (expense), net primarily consisted of gains and losses resulting from the remeasurement of the fair value of the compound embedded derivative instrument associated with our convertible promissory notes, or the notes, which were repaid in full in September 2015, and the loss on the extinguishment of the notes. We continued to record adjustments to the estimated fair value of the compound embedded derivative instrument associated with the notes until the notes were repaid in September 2015. Upon extinguishment of the notes, the associated current fair value of the embedded derivative asset was expensed to other income (expense), net.

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Results of Operations:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Revenues	$ 4,539	$ 2,088
Cost of revenues	3,360	1,288
Gross profit	1,179	800
Gross margin	26%	38%
Operating expenses:		
Research and development	4,047	3,860
Selling, general and administrative	12,161	6,365
Total operating expenses	16,208	10,225
Loss from operations	(15,029)	(9,425)
Interest income (expense), net	(1,139)	(1,320)
Other income (expense), net	1	329
Loss before provision for income taxes	(16,167)	(10,416)
Provision for income taxes		1
Net loss and comprehensive loss	$ (16,167)	$ (10,417)

Comparison of Three Months Ended March 31, 2016 and 2015

Revenues. Revenues increased $2.4 million, or 117%, to $4.5 million during the three months ended March 31, 2016, compared to $2.1 million during the three months ended March 31, 2015. For the three months ended March 31, 2016, revenues related to our Lightbox imaging console increased by 100% to $1.2 million and sales of our disposable catheters increased by 125% to $3.3 million. The increased revenues in 2016 reflects the commercial launch of Pantheris in March 2016 and our continuing commercial focus on our Lumivascular programs to broaden physician exposure to optical coherence tomography, or OCT, image interpretation and building the installed base of the Lightbox imaging console.

Cost of Revenues and Gross Margin. Cost of revenues increased $2.1 million, or 161%, to $3.4 million during the three months ended March 31, 2016, compared to $1.3 million during the three months ended March 31, 2015. This increase was attributable to our increased sales and increases in manufacturing overhead costs as we invest in operational infrastructure to support anticipated growth and the commercial launch of Pantheris. Gross margin for the three months ended March 31, 2016 was 26%, compared to 38% in the three months ended March 31, 2015. This decrease was primarily attributable to increases in manufacturing overhead costs as we invested in operational infrastructure to support anticipated growth and the commercial launch of Pantheris. Gross margin was also negatively impacted by an increase of $0.3 million related to warranty expense and a $0.3 million charge in the three months ended March 31, 2016 for excess and obsolescence predominantly related to our Pantheris inventories.

Research and Development Expenses. R&D expenses increased $0.1 million, or 5%, to $4.0 million during the three months ended March 31, 2016, compared to $3.9 million during the three months ended March 31, 2015. This increase was primarily due to a $0.2 million increase in personnel-related expenses and an increase of $0.1 million increase in product development materials and related costs, partially offset by a $0.2 million decrease in outside services and depreciation. Personnel-related expenses included stock-based compensation expense of $0.7 million compared to $0.6 million for the three months ended March 31, 2016 and 2015, respectively.

Selling, General and Administrative Expenses. SG&A expenses increased $5.8 million, or 91%, to $12.2 million during the three months ended March 31, 2016, compared to $6.4 million during the three months ended March 31, 2015. This increase was primarily due to a $4.3 million increase in personnel-related expenses and an increase of $1.3 million in marketing costs. Personnel-related expenses increased due to an increase in headcount and stock-based compensation expense. Personnel-related expenses included stock-based compensation expense of $1.2 million compared to $0.6 million for the three months ended March 31, 2016 and 2015, respectively. Increases in our marketing costs were associated with pre-commercial preparation expenses primarily relating to $1.1 million of Pantheris devices being designated as training and demonstration units for use by our sales and marketing personnel.

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Interest Income (Expense), Net. Interest expense, net decreased $0.2 million, or 14%, to an expense of $1.1 million during the three months ended March 31, 2016, compared to an expense of $1.3 million during the three months ended March 31, 2015. This decreased expense was attributable to the retirement of our outstanding principal and accrued interest with PDL, and extinguishment of the principal and accrued interest underlying our notes using the proceeds from the CRG borrowing and securities purchase in September 2015.

Other Income (Expense), Net. Other income, net decreased $0.3 million to an income of $1,000, during the three months ended March 31, 2016, compared to an income of $0.3 million during the three months ended March 31, 2015. Other income for the three months ended March 31, 2015, was primarily attributable to the remeasurement of the fair value of the derivative instruments associated with our notes which were accounted for as a compound embedded derivative instrument and marked-to-market at each reporting date through the date of their repayment in September 2015.

Liquidity and Capital Resources

As of March 31, 2016, we had cash and cash equivalents of $26.9 million and an accumulated deficit of $212.4 million, compared to cash and cash equivalents of $43.1 million and an accumulated deficit of $196.3 million as of December 31, 2015. We currently believe our existing cash and cash equivalents, expected revenues, debt financing currently available under our Loan Agreement with CRG and the net proceeds from the follow-on public offering we intend to conduct whereby we may issue and sell shares of common stock, will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity, through one or more additional follow-on public offerings or in separate financings, or sell additional debt securities or obtain an additional credit facility. Further, because of the risk and uncertainties associated with the commercialization of our existing products as well as products in development, we may need additional funds to meet our needs sooner than planned. To date, our primary sources of capital were private placements of preferred stock, debt financing agreements and our IPO. In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to $50.0 million, of which $30.0 million was immediately available and drawn down by us. Of the remaining $20.0 million, $10.0 million is currently available to us until June 30, 2016 and the remaining $10.0 million is contingent on the achievement of certain net revenue milestones prior to December 31, 2016, and if such milestones are achieved, the remaining amount may be drawn down until March 29, 2017. As of March 31, 2016, we had $30.0 million outstanding under the Loan Agreement. See section titled Contractual Obligations.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into a Sales Agreement with Cowen, as sales agent, pursuant to which we may, from time to time, issue and sell common stock with an aggregate value of up to $50.0 million in an at-the-market, or ATM, offering. The shelf registration statement was declared effective by the Securities and Exchange Commission, or SEC, on March 8, 2016. Cowen is acting as sole sales agent for any sales made under the Sales Agreement for a 3% commission on gross proceeds. Common stock sold in the ATM offering would be sold at prevailing market prices at the time of the sale, and, as a result, prices may vary. Unless otherwise terminated earlier, the Sales Agreement continues until all shares available under the Sales Agreement have been sold. No shares of common stock have been sold under the Sales Agreement with Cowen to date.

If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which diverts resources from other activities. Additional financing may not be available at all, or in amounts or on terms acceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our products and scale back our business and operations.

Cash Flows

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (16,193)	$ (7,921)
Investing activities	(301)	(208)
Financing activities	317	65,217
Net (decrease) increase in cash and cash equivalents	$ (16,177)	$ 57,088

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Net Cash Used in Operating Activities

Net cash used in operating activities for the three months ended March 31, 2016 was $16.2 million, consisting primarily of a net loss of $16.2 million and an increase in net operating assets of $3.0 million, offset by non-cash charges of $3.0 million. The increase in net operating assets was primarily due to the commercial launch of Pantheris in March 2016 resulting in an increase in accounts receivable and inventories. The increase in net operating assets was also due to an increase in prepaids and other current assets, partially offset by an increase in accounts payable, due to timing of payments, and an increase in accrued compensation. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to our credit agreement with CRG and increased reserve for excess and obsolescence in inventories.

Net cash used in operating activities for the three months ended March 31, 2015 was $7.9 million, consisting primarily of a net loss of $10.4 million, partially offset by a decrease in net operating assets of $0.8 million and by non-cash charges of $1.7 million. The decrease in net operating assets was primarily due to a decrease in accounts receivable and an increase in accounts payable and accrued expenses and other current liabilities related to timing of payments and interest payable to PDL, partially offset by increases in our prepaid expenses and other current assets and inventories. The non-cash charges primarily consisted of depreciation, stock-based compensation, and non-cash interest expense related to our credit agreement with PDL.

Net Cash Used in Investing Activities

Net cash used in investing activities in the three months ended March 31, 2016 and 2015 was $0.3 million and $0.2 million, respectively, consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the three months ended March 31, 2016 of $0.3 million primarily relates to $0.4 million proceeds from purchases under our employee stock purchase plan and proceeds from the exercise of stock options, partially offset by the cash paid for deferred offering costs of $0.1 million as of March 31, 2016.

Net cash provided by financing activities in the three months ended March 31, 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 offering costs was $1.8 million.

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 7, 2016, except for the amendment to our facility operating lease in March 2016 to extend the lease term for a period of three years, from December 1, 2016, until November 30, 2019. Under the terms of the amended facility lease agreement, we are obligated to pay approximately $5.7 million in lease payments through November 2019 over the term of the amended agreement.

CRG

In September 2015, we entered into a Loan Agreement with CRG, under which we may borrow up to $50.0 million in principal amount from CRG on or before December 31, 2016. We borrowed $30.0 million on September 22, 2015. Upon FDA approval of our 510(k) for Pantheris, we became eligible to borrow an additional $10.0 million in principal amount, on or prior to June 30, 2016. We may borrow the final $10.0 million, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions. Under the Loan Agreement, the first sixteen quarterly payments are interest only payments, and the last eight quarterly payments will be equal installments in which interest and principal amounts are paid. Interest is calculated at a fixed rate of 12.5% per annum. We make quarterly payments of interest only in arrears commencing on September 30, 2015. During the interest only period, we may elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind, or PIK, for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the loan. To date we have elected the PIK option to the extent available and have made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

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We may voluntarily prepay the loan in full, with a prepayment premium beginning at 5% and declining by 1% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing requires the payment, on the borrowing date, of a financing fee equal to 1.5% of the principal amount borrowed. In addition, a facility fee equal to 7.0% of loan principal borrowed plus any PIK is payable at the end of the term or when the loan is repaid in full. The term loan is collateralized by a security interest in substantially all of our assets.

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents, and we must achieve minimum revenue of $7.0 million in 2015, with the target minimum revenue increasing in each year thereafter until reaching $70,000,000 in 2020 and in each year thereafter, as applicable. If we fail to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides a cure right if we prepay a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on our capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include our failure to make timely payments of amounts due under the Loan Agreement, the failure to adhere to the covenants set forth in the Loan Agreement, our insolvency or upon the occurrence of a material adverse change. We were in compliance with the covenants under the Loan Agreement as of March 31, 2016.

We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding debt with PDL and to retire the principal and accrued interest underlying our outstanding notes, which are described below.

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. We are required to pay interest under the notes at a rate 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 was to mature on the earlier of: (i) October 29, 2018, (ii) an event of default or (iii) a change of control event.

In September 2015, in connection with the consummation of the Loan Agreement, we repaid all principal and accrued interest outstanding under the notes.

Lease Agreement

We lease our headquarters in Redwood City, California pursuant to a lease agreement with HCP LS Redwood City dated July 30, 2010, as amended by the First Amendment to Lease dated September 30, 2011 and the Second Amendment to Lease dated March 4, 2016, collectively, the Amended Lease. The Amended Lease has a rental commencement date of December 1, 2011, a term of eight years and expires in

November 2019. We have an additional option to extend the lease term for a period of three years. The 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 the borrower, entered into a credit agreement with PDL, as the 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.

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In September 2015, in connection with the consummation of the Loan Agreement with CRG, we repaid all amounts outstanding under the credit agreement with PDL. The payoff amount of $21.4 million included accrued interest through the repayment date of $0.6 million and $0.2 million as an end-of-term final payment fee.

Following the retirement of the PDL debt, our royalty obligations under the PDL credit agreement continue and are payable through the maturity date at the higher of a reduced rate of 0.9% of our quarterly revenues or certain minimum amounts, starting at $65,000 per quarter in 2013 and increasing annually to $310,000 per quarter in 2018. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. We were in compliance with the covenants under the credit agreement as of March 31, 2016.

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 months ended March 31, 2016, 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 7, 2016.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

Credit Risk

As of March 31, 2016 and December 31, 2015, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenues from the sale of our Lumivascular platform products to hospitals and medical centers in the United States. None of our customer represented more than 10% of our accounts receivable as of March 31, 2016 and December 31, 2015.

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.

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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 March 31, 2016. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2016, 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 first quarter of 2016 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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.

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 Pantheris, which we commenced commercialization in March 2016;

- market acceptance of our Lumivascular platform and products, including Pantheris;

- the availability of reimbursement for our Lumivascular platform products;

- our ability to attract new customers and grow our business with existing customers;

- results of our clinical trials;

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

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

- changes in our pricing policies or those of our competitors;

- general economic, 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.

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

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $39.9 million in 2013, $32.0 million in 2014, $47.3 million in 2015, and $16.2 million for the three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of approximately $212.4 million. These losses and our accumulated deficit reflect the substantial investments we have made to develop our Lumivascular platform and acquire customers.

We expect our 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.

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

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

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 obtain FDA clearance for new versions of Pantheris and other Lumivascular platform products we intend to commercialize in the United States. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of Pantheris and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA approval to market an enhanced version of Pantheris in March 2016. As such, increased acceptance among physicians of these products may not occur. Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. If demand for Pantheris and our other Lumivascular platform products do not increase as we anticipate and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

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

We 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 the net proceeds from the follow-on public offering we intend to conduct whereby we may issue and sell shares of common stock and, together with our cash and cash equivalents at March 31, 2016 and expected revenues from operations and debt financing currently available under our Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds, or CRG, will be sufficient to satisfy our capital requirements and fund our operations for at least the next 12 months. We can provide no assurance that we will be successful in raising funds pursuant to a follow-on public offering or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. We will likely need additional funds through one or more additional follow-on public offerings or in separate financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization.

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

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

- 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;

- 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.

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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 March 31, 2016, we had $30.0 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG. Our debt with CRG is collateralized by substantially all of our assets and contains customary financial and operating covenants limiting our ability to, among other things, incur debt, grant liens, make investments, make acquisitions, make certain restricted payments and sell assets, in each case subject to certain exceptions. We are also subject to standard event of default provisions under the Loan Agreement that, if triggered, would allow the debt to be accelerated, which could significantly deplete our cash resources, cause us to raise additional capital at unfavorable terms, require us to sell portions of our business or result in us becoming insolvent. We used the initial net proceeds under the Loan Agreement to repay and terminate our credit facility with PDL Biopharma, Inc., or PDL, however, our obligation to continue to make royalty payments to PDL out of our quarterly revenues through April 18, 2018 remain in effect. Additionally, until there are no further obligations to periodically pay to PDL a percentage of our net revenue, we must comply with certain affirmative covenants and negative covenants limiting our ability to, among other things, undergo a change in control or dispose of assets, in each case subject to certain exceptions. The existing collateral pledged under the Loan Agreement, the covenants to which we are bound and the obligation to pay a certain percentage of our future revenues to PDL, even though the PDL debt has been repaid, may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions.

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- trouble in managing multiple clinical sites;

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

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

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

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

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

We have no long-term data regarding the safety and efficacy of our Lumivascular platform products, including Pantheris. Any long-term data that is generated by clinical trials involving our Lumivascular platform may not be positive or consistent with our short-term data, which would harm our ability to obtain clearance to market and sell our products.

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

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

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

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

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

The development, marketing, and sale of our products, including Pantheris, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry s relationship with physicians is under increasing scrutiny by the 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 could take several months before any new 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.

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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 continue to grow our sales force and manufacturing infrastructure. 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.

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

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

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

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

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

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

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

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

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber and drive cables that are key components of our catheters, and we rely on 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.

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

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

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

As of December 31, 2015, we had federal and state net operating loss carryforwards, or NOLs, due to prior period losses of $171.2 million and $161.2 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.

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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.

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 March 31, 2016, we held eight issued U.S. patents and had 20 U.S. utility patent applications and 2 PCT applications pending. As of March 31, 2016, we also had 12 issued patents outside of the United States. As of March 31, 2016, we had 37 pending patent applications outside of the United States, including in Australia, Canada, China, Europe, India and Japan. Our patents and patent applications include claims covering key aspects of the design, manufacture and therapeutic use of OCT imaging catheters, occlusion-crossing catheters, atherectomy devices and our imaging console. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Any patents issued to us may be challenged by third parties as being invalid, or third parties may independently develop similar or competing technology that avoids our patents. Should such challenges be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property protection is incomplete, we are exposed to a greater risk of direct competition. In addition, competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our Lumivascular platform, brand and business.

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

Risks Related to Government Regulation

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

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

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

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

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

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

In addition, we are required to timely file various reports with the FDA, including reports required by the MDRs that require that we report to the regulatory authorities if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose

sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. For example, to date we have submitted to the FDA 1) five MDRs regarding our Ocelot family of catheters, which included incidents of perforations and the removal of the guidewire coating and 2) one MDR regarding our Pantheris product, which was based on an interaction between the catheter and sheath as the catheter was being removed from the sheath.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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;

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- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children s Health Insurance Program to report annually to the HHS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- HIPAA, as amended by the HITECH Act, which 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 party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

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

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

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

- market acceptance of our Lumivascular platform and products, including Pantheris;
- the results of our clinical trials;
- changes in analysts estimates, investors perceptions, recommendations by securities analysts or our failure to achieve analysts estimates;
- actual or anticipated fluctuations in our financial condition and operating results;
- 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.

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

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

We maintain a shelf registration statement on Form S-3, or the Registration Statement, with the SEC pursuant to which we may, from time to time, sell up to an aggregate of $150.0 million of our common stock, preferred stock, depositary shares, warrants, units, subscription rights or debt securities. We have also established, and may in the future establish, at-the-market offerings pursuant to which we may offer and sell shares of our common stock pursuant to the Registration Statement. The Registration Statement was declared effective by the SEC on March 8, 2016. In addition, pursuant to our Securities Purchase Agreement with CRG, the Registration Statement also registers for resale 348,262 shares of common stock held by CRG. Upon the effectiveness of the Registration Statement by the SEC, shares held by CRG may be sold freely in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Sales of newly issued securities under the Registration Statement will result in dilution of our stockholders and could cause our stock price to fall.

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

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

As of May 2, 2016, our directors, officers and their affiliates collectively control approximately 31.8% of our outstanding common stock, assuming the exercise of all options and warrants held by such persons. As a result, these stockholders, if they act together, would be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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 IPO, 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 IPO, 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 a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements.

The actions we have taken to remediate the material weakness 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.

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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 Global 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 activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

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

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

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

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

- a classified board of directors;

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

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

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

- allowing stockholders to remove directors only for cause;

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

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

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

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

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

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

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

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

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

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

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

Unregistered Sales of Equity Securities

There were no sales of unregistered securities during the three months ended March 31, 2016.

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: May 9, 2016

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

Date: May 9, 2016

/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
10.1	Second Amendment to Lease Agreement dated March 4, 2016 by and between registrant and HCP LS Redwood City, LLC (*incorporated by reference to Exhibit 10.12 filed with the Registrant s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2016*).
10.2	Sales Agreement dated as of February 3, 2016, between the Registrant and Cowen and Company, LLC (i*ncorporated by reference to Exhibit 1.2 filed with the Registrant s Registration Statement on Form S-3 (File No. 333-209368) filed with the Securities and Exchange Commission on February 3, 2016).*
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