UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 August 1, 2016, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 12,842,491.

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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, expe 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;
- our ability to obtain additional financing through our at-the-market program and follow-on public offering that we intend to conduct;
- 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.

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

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

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AVINGER, INC.

AS OF AND FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2016

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Avinger, Pantheris, and Lumivascular are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are our property. Other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q appear without the symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and trade names.

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

AVINGER, INC.

CONDENSED BALANCE SHEETS

(unaudited)

(In thousands, except share and per share data)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 22,439	$ 43,059
Accounts receivable, net of allowance for doubtful accounts of $20 at June 30, 2016 and December 31, 2015	3,404	2,060
Inventories	6,927	5,405
Prepaid expenses and other current assets	1,081	533
Total current assets	33,851	51,057
Property and equipment, net	3,918	2,822
Other assets	422	225
Total assets	$ 38,191	$ 54,104
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 703	$ 1,113
Accrued compensation	2,265	3,083
Accrued expenses and other current liabilities	2,760	3,285
Total current liabilities	5,728	7,481
Borrowings	40,141	29,565
Other long-term liablities	1,057	1,469
Total liabilities	46,926	38,515
Commitments and contingencies (Note 8)		
Stockholders equity (deficit):		
Preferred stock issuable in series, par value of $0.001 Shares authorized: 5,000,000 at June 30, 2016 and December 31, 2015 Shares issued and outstanding: none at June 30, 2016 and December 31, 2015		
Common stock, par value of $0.001 Shares authorized: 100,000,000 at June 30, 2016 and December 31, 2015 Shares issued and outstanding: 12,836,144 at June 30, 2016 and 12,643,538 at December 31, 2015	13	13
Additional paid-in capital	217,175	211,837

Accumulated deficit		(225,923)		(196,261)
Total stockholders equity (deficit)		(8,735)		15,589
Total liabilities and stockholders equity (deficit)	$	38,191	$	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 June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Revenues	$ 4,680	$ 3,047	$ 9,219	$ 5,135
Cost of revenues	3,645	1,634	7,005	2,922
Gross profit	1,035	1,413	2,214	2,213
Operating expenses:				
Research and development	3,867	3,951	7,914	7,812
Selling, general and administrative	9,461	6,545	21,622	12,910
Total operating expenses	13,328	10,496	29,536	20,722
Loss from operations	(12,293)	(9,083)	(27,322)	(18,509)
Interest income	28	9	61	12
Interest expense	(1,235)	(1,344)	(2,406)	(2,667)
Other income (expense), net	4	204	5	534
Loss before provision for income taxes	(13,496)	(10,214)	(29,662)	(20,630)
Provision for income taxes		6		7
Net loss and comprehensive loss	(13,496)	(10,220)	(29,662)	(20,637)
Adjustment to net loss resulting from convertible preferred stock modification				(2,384)
Net loss and comprehensive loss attributable to common stockholders	$ (13,496)	$ (10,220)	$ (29,662)	$ (23,021)
Net loss attributable to common stockholders per share, basic and diluted	$ (1.06)	$ (0.83)	$ (2.34)	$ (2.23)
Weighted average common shares used to compute net loss per share, basic and diluted	12,734	12,240	12,702	10,317

See accompanying notes.

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AVINGER, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Six Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Cash flows from operating activities				
Net loss	$	(29,662)	$	(20,637)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		692		639
Amortization of debt issuance costs and debt discount		98		101
Stock-based compensation		3,588		2,480
Remeasurement of embedded derivatives				(547)
Noncash interest expense and other charges		767		907
Provision for excess and obsolete inventories		465		(7)
Changes in operating assets and liabilities:				
Accounts receivable		(1,343)		417
Inventories		(3,033)		126
Prepaid expenses and other current assets		(549)		(810)
Other assets		(34)		(8)
Accounts payable		(422)		(25)
Accrued compensation		(818)		980
Accrued expenses and other current liabilities		(510)		(448)
Other long-term liabilities and accrued interest		(426)		(154)
Net cash used in operating activities		(31,187)		(16,986)
Cash flows from investing activities				
Purchase of property and equipment		(729)		(107)
Restricted cash				255
Net cash provided by (used in) investing activities		(729)		148
Cash flows from financing activities				
Principal paydown of capital lease obligations		(15)		(10)
Payments on deferred offering costs		(163)		
Proceeds from borrowings, net of issuance costs		9,725		
Proceeds from the issuance of convertible preferred stock, net of issuance costs				6,176
Proceeds from public offerings, net of issuance costs		1,252		58,745
Proceeds from the exercise of common stock warrants				308
Proceeds from the issuance of common stock		497		
Net cash provided by financing activities		11,296		65,219
Net change in cash and cash equivalents		(20,620)		48,381
Cash and cash equivalents, beginning of period		43,059		12,316
Cash and cash equivalents, end of period	$	22,439	$	60,697
Supplemental disclosure of cash flow information				
Cash paid for interest	$	1,956	$	1,257
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	13	
Modification of convertible preferred stock		2,384
Vesting of common stock subject to repurchase		16
Issuance of common stock warrants		804
Transfer between inventory and property and equipment	1,046	113

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 June 30, 2016, the Company had an accumulated deficit of $225,923,000. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of $22,439,000 at June 30, 2016, expected revenues and the net proceeds from its at-the-market program and 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 March 31, 2017. Consistent with its 2016 operating plan, the Company will need to obtain additional funding in the form of debt financing or additional equity issuances to make strategic investments in, and continue to operate, 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 significantly 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 (deficit) to additional paid-in capital.

2. Summary of Significant Accounting Policies

Basis of Presentation

On January 14, 2015, the Company s Board of Directors (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 the Company s financial information. The results for the three and six months ended June 30, 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 June 30, 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 June 30, 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 (deficit). There were no unrealized gains and losses as of June 30, 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 June 30, 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 June 30, 2016 and December 31, 2015, there were none and one customers that represented 10% or more of the Company s accounts receivable, respectively. For the three and six months ended June 30, 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 June 30, 2016, $217,000 of deferred offering costs were capitalized in other assets on the balance sheet, of which $163,000 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 an at-the-market program pursuant to a Sales Agreement with Cowen and Company (Cowen), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG Partners III L.P. and certain of its affiliated funds (collectively CRG) in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the three months ended June 30, 2016, the Company sold 125,214 shares of common stock under the at-the-market program at an average price of $11.20 and raised net proceeds of $1,252,000, after payment of $42,000 in commissions and fees to Cowen.

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

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.

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Revenue Recognition

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

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

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

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

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

The Company offers its customers the ability to purchase or lease its Lightbox. 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.

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

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

Cost of Revenues

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

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Product Warranty Costs

The Company typically offers a one-year warranty for parts and labor on its products commencing upon the transfer of title and risk of loss to the customer. The Company accrues for the estimated cost of product warranties upon invoicing its customers, based on historical results. 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	463
Usage/Release	(274)
Balance at June 30, 2016	$ 259

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 June 30, 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.

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

	Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Net loss	$ (13,496)	$ (10,220)	$ (29,662)	$ (20,637)
Adjustment to net loss resulting from convertible preferred stock modification				(2,384)
Net loss attributable to common stockholders	$ (13,496)	$ (10,220)	$ (29,662)	$ (23,021)
Weighted average common stock outstanding	12,734	12,240	12,702	10,317
Net loss attributable to common stockholders per share, basic and diluted	$ (1.06)	$ (0.83)	$ (2.34)	$ (2.23)

In addition to the convertible notes outstanding as of June 30, 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:

	June 30, 2016	June 30, 2015
Common stock options	3,801,543	3,104,358
Unvested restricted stock units	267,558	
Common stock warrants	2,152,117	2,213,395
	6,221,218	5,317,753

Comprehensive Loss

For the three and six months ended June 30, 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 June 30, 2016 and 2015, 93.8% and 100.0% of the Company s revenues were in the United States, respectively, based on the shipping location of the external customer. For the six months ended June 30, 2016 and 2015, 96.8% and 99.7% of the Company s revenues were in the United States, respectively, 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).

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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.

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 June 30, 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 and six months ended June 30, 2016 and 2015.

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4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Raw materials	$ 3,529	$ 2,662
Work-in-process	454	372
Finished products	2,944	2,371
Total inventories	$ 6,927	$ 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 March 29, 2017. The Company borrowed $30,000,000 on September 22, 2015. The Company borrowed an additional $10,000,000 on June 15, 2016 under the Loan Agreement. The Company may borrow an additional $10,000,000, 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 has elected the PIK interest option to the extent available and has made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. All unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021.

The Company may voluntarily prepay the 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 amounts 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 had to achieve minimum revenue of $7,000,000 in 2015, and must achieve minimum revenue of $23,000,000 in 2016, $40,000,000 in 2017, $50,000,000 in 2018, $60,000,000 in 2019 and $70,000,000 in 2020 and in each year thereafter, as applicable. If the Company fails to meet the applicable minimum revenue target in any calendar year, the Loan Agreement provides the Company with a cure right if it prepays a portion of the outstanding principal equal to 2.0 times the revenue shortfall. In addition, the Loan Agreement prohibits the payment of cash dividends on the Company s capital stock and also places restrictions on mergers, sales of assets, investments, incurrence of liens, incurrence of indebtedness and transactions with affiliates. CRG may accelerate the payment terms of the Loan Agreement upon the occurrence of certain events of default set forth therein, which include the failure of the Company to make timely payments of amounts due under the Loan Agreement, the failure of the Company to adhere to the covenants set forth in the Loan Agreement, the insolvency of the Company or upon the occurrence of a material adverse change. The Company is in compliance with all applicable covenants. As of June 30, 2016, principal and PIK payments under the Loan Agreement follows (in thousands):

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Period Ending December 31,		Principal and PIK Loan Repayments
2016	$	
2017		
2018		
2019		10,000
2020 and thereafter		30,000
		40,000
Add: Accretion of closing fees		199
Add: PIK		967
		41,166
Less: Amount representing debt financing costs		(1,025)
Borrowings, net of current portion	$	40,141

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

In connection with the initial drawdown under the Loan Agreement, the Company recorded a debt discount of $876,000. The debt discount comprised financing fees of $450,000, paid directly to CRG, and an allocation of the other costs directly attributable to the Loan Agreement and Securities Purchase Agreement with CRG of $541,000 net of the common stock premium of $115,000 based on the relative fair values of each security. In connection with the June 2016 drawdown under the Loan Agreement, the Company recorded a debt discount of $275,000 which comprised financing fees of $150,000, paid directly to CRG, and other costs directly attributable to the Loan Agreement with CRG of $125,000. The debt discount is being amortized as non-cash interest expense using the effective interest method over the term of the Loan Agreement. As of June 30, 2016, the aggregate balance of the debt discount was $1,025,000.

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).

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.

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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 $1,902,000 and $2,303,000, representing the net present value of the future minimum royalty obligation as of June 30, 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 June 30, 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.

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

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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 June 30, 2016 and December 31, 2015, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $52,000 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.