Avinger Inc
Form 10-Q
August 13, 2018
Table of Contents

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, 2018

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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer o

Non-accelerated filer o | Smaller reporting company x

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

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 9, 2018, the number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 11,552,052.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as anticipate, assume, believe, contemplate, continue, could, due, estimate, 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 and expectations regarding our clinical studies, including our INSIGHT trial 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 future equity or debt financings;

- the expected timing of 510(k) clearances by FDA for enhanced versions of Pantheris;

- the expected timing of 510(k) submission to FDA, and associated marketing clearances by FDA, for additional versions of Pantheris designed for use in smaller vessels;

- the expected growth in our business and our organization;

- our expectations regarding government and third-party payor coverage and reimbursement, including the ability of Pantheris to qualify for reimbursement codes used by other atherectomy products;

- our ability to continue as a going concern;

- our ability to retain and recruit key personnel, including the continued development of our sales and marketing infrastructure;

- our ability to obtain and maintain intellectual property protection for our products;

- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;

- our expectations regarding revenue, cost of revenue, gross margins, and expenses, including research and development and selling, general and administrative expenses;

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

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

- our financial performance;

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

- developments and projections relating to our competitors or our industry.

Table of Contents

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management s beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. We urge you to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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

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

Table of Contents

AVINGER, INC.

AS OF AND FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2018

TABLE OF CONTENTS

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

AVINGER, INC.

CONDENSED BALANCE SHEETS

(unaudited)

(In thousands, except share and per share data)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 10,144	$ 5,389
Accounts receivable, net of allowance for doubtful accounts of $191 and $146 at June 30, 2018 and December 31, 2017, respectively	1,675	1,127
Inventories	3,651	4,295
Prepaid expenses and other current assets	1,079	640
Total current assets	16,549	11,451
Property and equipment, net	2,098	2,950
Other assets	584	687
Total assets	$ 19,231	$ 15,088
Liabilities and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,373	$ 1,273
Accrued compensation	1,197	863
Accrued expenses and other current liabilities	812	3,597
Borrowings	7,823	44,744
Preferred stock dividends payable	1,246	
Total current liabilities	12,451	50,477
Other long-term liabilities	188	301
Total liabilities	12,639	50,778
Commitments and contingencies (Note 7)		
Stockholders equity (deficit):		
Preferred stock issuable in series, par value of $0.001		
Shares authorized: 5,000,000 at June 30, 2018 and December 31, 2017		
Shares issued and outstanding: 43,501 and none at June 30, 2018 and December 31, 2017, respectively		
Common stock, par value of $0.001		
Shares authorized: 100,000,000 at June 30, 2018 and December 31, 2017		
Shares issued and outstanding: 9,305,872 and 833,597 at June 30, 2018 and December 31, 2017, respectively	8	1

Additional paid-in capital		323,991		265,636
Accumulated deficit		(317,407)		(301,327)
Total stockholders equity (deficit)		6,592		(35,690)
Total liabilities and stockholders equity (deficit)	$	19,231	$	15,088

See accompanying notes.

Table of Contents

AVINGER, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenues	$ 2,058	$ 2,459	$ 3,867	$ 5,950
Cost of revenues	2,169	3,919	3,584	7,994
Gross profit (loss)	(111)	(1,460)	283	(2,044)
Operating expenses:				
Research and development	1,159	3,097	2,936	7,020
Selling, general and administrative	4,204	6,189	8,464	15,507
Restructuring charges		519		519
Total operating expenses	5,363	9,805	11,400	23,046
Loss from operations	(5,474)	(11,265)	(11,117)	(25,090)
Interest income	50	31	83	63
Interest expense	(362)	(1,571)	(5,034)	(3,121)
Other income (expense), net	(13)	6	(12)	9
Net loss and comprehensive loss	(5,799)	(12,799)	(16,080)	(28,139)
Accretion of preferred stock dividends	(836)		(1,246)	
Deemed dividend arising from beneficial conversion feature of convertible preferred stock			(5,216)	
Net loss applicable to common stockholders	$ (6,635)	$ (12,799)	$ (22,542)	$ (28,139)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.98)	$ (21.40)	$ (5.18)	$ (47.13)
Weighted average common shares used to compute net loss per share, basic and diluted	6,755	598	4,354	597

See accompanying notes.

Table of Contents

AVINGER, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited)

(In thousands)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (16,080)	(28,139)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	518	854
Amortization of debt issuance costs and debt discount	57	124
Stock-based compensation	1,260	2,877
Noncash interest expense and other charges	5,037	1,083
Common stock to be issued for services	106	
Provision for doubtful accounts receivable	45	99
Provision for excess and obsolete inventories	528	3,577
Changes in operating assets and liabilities:		
Accounts receivable	(593)	1,981
Inventories	575	(1,925)
Prepaid expenses and other current assets	(439)	(468)
Other assets	104	(39)
Accounts payable	(301)	(457)
Accrued compensation	334	(898)
Accrued expenses and other current liabilities	(2,383)	(640)
Other long-term liabilities and accrued interest	(114)	(340)
Net cash used in operating activities	(11,346)	(22,311)
Cash flows from investing activities		
Purchase of property and equipment	(125)	(45)
Net cash used in investing activities	(125)	(45)
Cash flows from financing activities		
Principal paydown of capital lease obligations		(12)
Proceeds from the issuance of convertible preferred stock, net of issuance costs	15,534	
Proceeds from the issuance of common stock related to warrant exercises	581	
Proceeds from the issuance of common stock		236
Proceeds from public offerings, net of issuance costs	326	
Payment of debt discount in connection with loan amendment	(155)	
Payment of accrued interest included in borrowings	(60)	
Net cash provided by financing activities	16,226	224
Net change in cash	4,755	(22,132)
Cash and cash equivalents, beginning of period	5,389	36,096
Cash and cash equivalents, end of period	$ 10,144	$ 13,964
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 60	$ 2,406
Noncash operating and financing activities:		

Conversion of CRG loan principal into Series A preferred stock	$	38,000	$	
Series A preferred stock accrued dividends	$	1,246	$	
Deemed dividend arising from beneficial conversion feature of convertible preferred stock	$	5,216	$	

See accompanying notes.

Table of Contents

AVINGER, INC.

Notes to Condensed Financial Statements

1. Organization

Organization, Nature of Business

Avinger, Inc. (the Company), a Delaware corporation, was incorporated in March 2007. The Company designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease (PAD). Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. The Company manufactures and sells a suite of products in the United States (U.S.) and in select international markets. The Company has developed its Lumivascular platform, which integrates optical coherence tomography (OCT) visualization with interventional catheters and is the industry s only system that provides real-time intravascular imaging during the treatment portion of PAD procedures. The Company s Lumivascular platform consists of a capital component, Lightbox, as well as a variety of disposable catheter products. The Company s current products include its non-imaging catheters, Wildcat and Kittycat, as well as its Lumivascular platform products, Ocelot, Ocelot PIXL and Ocelot MVRX, all of which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion (CTO). In March 2016, the Company also received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for commercialization of Pantheris, the Company s image-guided atherectomy system, designed to allow physicians to precisely remove arterial plaque in PAD patients. The Company commenced sales of Pantheris in the U.S. and select international markets promptly thereafter. The Company is located in Redwood City, California. In May 2018, the Company also received 510(k) clearance from the FDA for its next generation of Pantheris, Pantheris 3.0.

Liquidity Matters

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company adopted Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15*, Presentation of Financial Statements - Going Concern (Subtopic 205-40),* effective December 31, 2016, which requires the Company to make certain disclosures if it concludes that there is substantial doubt about the entity s ability to continue as a going concern within one year from the date of the issuance of these financial statements. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

In the course of its activities, the Company has incurred losses and negative cash flows from operations since its inception. As of June 30, 2018, the Company had an accumulated deficit of approximately $317.4 million. The Company expects to incur losses for the foreseeable future. The Company believes that its cash and cash equivalents of approximately $10.1 million at June 30, 2018 and expected revenues will be sufficient to allow the Company to fund its current operations through approximately December 2018. The Company will seek additional sources of funding in the form of debt financing or equity issuances, however, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations. These conditions raise substantial doubt about the Company s ability to continue as a going

concern. If the Company is unable to raise additional capital in sufficient amounts or on terms acceptable to it, the Company may have to significantly reduce its operations or delay, scale back or discontinue the development of one or more of its products. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company s ultimate success will largely depend on its continued development of innovative medical technologies, its ability to successfully commercialize its products and its ability to raise significant additional funding. Additionally, due to the substantial doubt about the Company s ability to continue operating as a going concern and the material adverse change clause in the Loan Agreement with CRG Partners III L.P. and certain of its affiliated funds (collectively CRG), the entire amount of borrowings at June 30, 2018 and December 31, 2017 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause. On November 3, 2017, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC (Lincoln Park), pursuant to which Lincoln Park is obligated to purchase, at the Company s request, up to $15,000,000 of the Company s common stock over a 30-month period, subject to certain limitations set forth in the agreement (the Lincoln Park Purchase Agreement). As a fee for Lincoln Park s commitment to purchase such shares, the Company issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Purchase Agreement, the Company filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 17, 2017. On July 12, 2018, the Company filed a prospectus supplement to offer 2,166,180 shares of its common stock at an offering price of $1.6425 per share, for net proceeds of approximately $3,100,000 after deducting placement agent fees of approximately $285,000 and expenses of approximately $160,000.

Table of Contents

Public Offerings

On February 3, 2016, the Company filed a universal shelf registration statement to offer up to $150,0000 of its securities and entered into an at-the-market program pursuant to a Sales Agreement with Cowen and Company (Cowen), through which it may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50,000,000. The shelf registration statement also covers the resale of the shares sold to CRG in September 2015. The registration statement was declared effective by the SEC on March 8, 2016. During the three and six months ended June 30, 2018 and 2017, the Company sold no shares of common stock through the at-the-market program. Due to the SEC s baby shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, the Company is unable to issue more shares in its at-the-market program at this time.

On February 16, 2018, the Company completed a public offering of 17,979 shares of Series B convertible preferred stock (the Series B preferred stock). As a result, the Company received net proceeds of approximately $16.0 million after underwriting discounts, commissions, legal and accounting fees of approximately $1.9 million (Note 8).

Since November 2017, we have sold an aggregate of 65,000 shares of our common stock under the Lincoln Park Purchase Agreement for approximately $0.5 million of gross proceeds. In February 2018, we sold $18.0 million in Series B preferred stock and warrants to purchase our common stock in a registered offering. In July 2018, the Company sold a further 2,166,180 shares of our common stock (excluding warrants to purchase an additional 1,083,091 shares of our common stock issued in a concurrent private placement) pursuant to the Shelf Registration Statement for gross proceeds of approximately $3.5 million.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) and pursuant to the rules and regulations of the 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, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, or for any other interim period or for any future year. The December 31, 2017 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, 2017, which was filed with the SEC on March 30, 2018. The Company s significant accounting policies are more fully described in Note 2 of the Notes to Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

On January 30, 2018, the Company s Board of Directors approved an amendment to the Company s amended and restated certificate of incorporation to effect a 1-for-40 reverse stock split of the Company s common 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, stock options, restricted stock units 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 30, 2018.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses significant judgment when making estimates related to its common stock valuation and related stock-based compensation, the valuation of the common stock warrants, the valuation of compound embedded derivatives, provisions for doubtful accounts receivable and excess and obsolete inventories, clinical trial accruals, and its reserves for sales returns and warranty costs. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. 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.

Table of Contents

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of June 30, 2018 and December 31, 2017. 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 the borrowings approximate their 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, 2018 and December 31, 2017, 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, 2018 and December 31, 2017. 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, 2018 and December 31, 2017.

The Company s accounts receivable are due from a variety of healthcare organizations in the United States and select international markets. At June 30, 2018 and December 31, 2017, there were no customers that represented 10% or more of the Company s accounts receivable. For the three and six months ended June 30, 2018 and 2017, 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.

Table of Contents

Revenue Recognition

The Company s revenues are derived from (1) sale of Lightboxes, (2) sale of disposables, which consist of catheters and accessories, and (3) service revenue. The Company sells its products directly to hospitals and medical centers as well as through distributors. The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and the customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. The Company s revenues are measured based on consideration specified in the contract with each customer, net of any sales incentives and taxes collected from customers that are remitted to government authorities. 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 contract revenue is recognized ratably over the term of the service period and maintenance contract revenue is recognized as work is performed. To date, service revenue has been insignificant.

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

The Company evaluates its lease and commercial evaluation program agreements and accounts for these contracts under the guidance in Accounting Standards Codification (ASC) 840, *Leases* and ASU No. 2014 09, *Revenue from Contracts with Customers (Topic 606)*. 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.

Table of Contents

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, 2017	$	(390)
Warranty provision		(54)
Usage/Release		8
Balance at June 30, 2018	$	(436)

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. Any common stock shares subject to repurchase are excluded from the calculations as the continued vesting of such shares is contingent upon the holders continued service to the Company. As of June 30, 2018 and 2017, there were no shares subject to repurchase. 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 potentially dilutive common shares would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017

Net loss attributable to common stockholders	$ (6,635)	$ (12,799)	$ (22,542)	$ (28,139)
Weighted average common stock outstanding	6,755	598	4,354	597
Net loss per share attributable to common stockholders, basic and diluted	$ (0.98)	$ (21.40)	$ (5.18)	$ (47.13)

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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Common stock warrants	18,032,715	53,803	17,742,215	53,803
Common stock options	55,862	112,259	84,842	101,601
Preferred stock	52,762		43,501	
Unvested restricted stock units	3,457	11,115	3,306	8,799
	18,144,796	177,177	17,873,864	164,203

Table of Contents

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, 2018 and 2017, 95% and 96%, respectively, of the Company s revenues were in the United States based on the shipping location of the external customer. For the six months ended June 30, 2018 and 2017, 93% and 96%, respectively, of the Company s revenues were in the United States based on the shipping location of the external customer.

Recent Accounting Pronouncements

Adopted:

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which effectively delayed the adoption date by one year, to an effective date for public entities for annual and interim periods beginning after December 15, 2017.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606) : Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net), to clarify certain aspects of the principal-versus-agent guidance in its new revenue recognition standard.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606) : Identifying Performance Obligations and Licensing to clarify how to identify the performance obligations and the licensing implementation guidance in its new revenue recognition standard.

In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606) : Narrow-Scope Improvements and Practical Expedients, to address certain issues identified by the Transition Resource Group, (the TRG) in the guidance on assessing collectability, presentation of sales tax, noncash consideration, and completed contracts and contracts modifications at transition.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation Stock Compensation (Topic 718): Scope of Modification Accounting* which provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply

modification accounting under Topic 718. The amendments in this ASU should be applied prospectively to an award modified on or after the adoption date. The Company adopted this guidance on January 1, 2018 and such adoption did not have a material impact on the Company s condensed financial statements.

During the three months ended March 31, 2018, the Company adopted ASC 606, using the modified retrospective approach. The adoption did not have a material impact on the Company s financial statements

Pending Adoption:

In February 2016, the FASB issued ASU No. 2016-02 *Leases* (Topic 842). Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. In July, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10 *Codification Improvements to Topic 842,* Leases and ASU 2018-11 *Leases (Topic 842): Targeted Improvements*. The guidance will become effective for us beginning in the first quarter of 2019 and is required to be adopted using a modified retrospective approach. Early adoption is permitted.

As we continue to evaluate the impact of the adoption of these standards, we anticipate recognition of additional assets and corresponding liabilities related to leases on our Condensed Balance Sheets with no material impact to our Condensed Statements of Income. We plan to adopt these standards using the modified retrospective approach with the cumulative effect of adoption recognized to retained earnings on January 1, 2019. We plan to elect the practical expedients upon transition that will retain the lease classification and initial direct costs for any leases that existed prior to the adoption of these new standards. We will not reassess whether any contracts entered into prior to the adoption are leases.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* , which expands the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor s own operations by issuing share-based payment awards. Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity s adoption date of Topic 606. The Company is evaluating the effect that this update will have on its condensed financial statements and related 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

Table of Contents

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, 2018 and December 31, 2017, cash equivalents were all categorized as Level 1 and consisted of money market funds. As of June 30, 2018 and December 31, 2017, there were no financial assets and liabilities categorized as Level 2 or 3. There were no transfers between fair value hierarchy levels during the three and six months ended June 30, 2018 and 2017.

4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2018	December 31, 2017
Raw materials	$ 76	$ 1,286
Work-in-process	300	
Finished products	3,275	3,009
Total inventories	$ 3,651	$ 4,295

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 had the right to borrow up to $50,000,000 in principal amount from CRG on or before March 29, 2017. The Company borrowed $30,000,000 on September 22, 2015. The Company borrowed

an additional $10,000,000 on June 15, 2016 under the Loan Agreement. The Company would have been eligible to borrow an additional $10,000,000, on or prior to March 29, 2017, upon achievement of certain revenue milestones, among other conditions, but those milestones were not achieved.

On October 28, 2016, the Company and CRG amended the Loan Agreement to reduce the minimum revenue that the Company was required to achieve in 2016 to $18,000,000. On February 14, 2018, the Company and CRG further amended the Loan Agreement concurrent with the conversion of $38,000,000 of the principal amount of the senior secured term loan (plus $3,800,000 in back-end fees and prepayment premium applicable thereto) into a newly authorized Series A convertible preferred stock (see Note 8, below). For the six months ended June 30, 2018, the $3,800,000 was accounted for in the condensed statement of operations and comprehensive loss as interest expense.

Under the Loan Agreement, as in effect prior to amendment, the first sixteen quarterly payments were to be interest only payments, and the last eight quarterly payments were to be equal installments in which interest and principal amounts would be 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 had the right to elect to make the 12.5% interest payment by making a cash payment for 8.5% per annum of interest and making a payment-in-kind (PIK) for the remaining amount, for which the 4.0% per annum of interest would be added to the outstanding principal amount of the borrowings. To date, the Company has elected the PIK interest option to the extent available and has made a cash payment for the remaining amount. Principal is repayable in eight equal quarterly installments during the final two years of the term. Under the original Loan Agreement, all unpaid principal, and accrued and unpaid interest, was to be due and payable in full on September 30, 2021.

The Company may voluntarily prepay the borrowings in full, with a prepayment premium beginning at 5.0% and declining by 1.0% annually thereafter, with no premium being payable if prepayment occurs after the fifth year of the loan. Each tranche of borrowing required 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 was to be payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest

Table of Contents

method for the facility fee over the term of the Loan Agreement with a corresponding discount to the debt. The borrowings are collateralized by a security interest in substantially all of the Company s assets. The Loan Agreement requires that the Company adheres to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the original Loan Agreement included a covenant that the Company maintain a minimum of $5,000,000 of cash and certain cash equivalents, and the Company had to achieve minimum revenue of $7,000,000 in 2015, $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. On October 28, 2016, the Company amended the terms of the Loan Agreement, to reduce the minimum revenue that the Company must achieve in 2016 to $18,000,000. 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.

On December 14, 2017, the Company entered into a waiver and consent agreement (the Waiver and Consent) with CRG. The Waiver and Consent provided for the waiver of the minimum required revenue financial covenant for the twelve-month period beginning January 1, 2017, as required under the terms of the Loan Agreement. Pursuant to the Waiver and Consent, CRG also consented to the Company s payment of the cash interest payment due on December 31, 2017 in the form of a PIK loan instead. On January 24, 2018, we entered into a waiver agreement (the Waiver) with CRG. The Waiver provided for the waiver of the $5,000,0000 minimum liquidity financial covenant and reduced it to $2,500,000 for the period beginning January 1, 2018 through February 28, 2018, as required under the terms of the Loan Agreement and waived any event of default resulting from non-compliance with the $5,000,000 minimum liquidity financial covenant.

On February 14, 2018, the Company entered into Amendment No. 2 to the Loan Agreement to, among other things:

- extend the interest only payment period and the period during which the Company may elect to pay a portion of the interest in PIK interest payments through June 30, 2021;
- provide for a 15% facility fee to be paid on the maturity date;
- permit the Company to make the entire interest payment for payment dates in 2018 and 2019 in PIK interest payments, provided no default has occurred and is continuing;
- extend the maturity date to June 30, 2023;
- modify certain of the covenants, including the indebtedness covenant, lien covenant and restricted payments covenant, to eliminate or modify permitted exceptions to the restrictions in those covenants;
- modify the financial covenants to reduce the minimum liquidity requirement to $3,500,000 at all times, to eliminate the minimum revenue requirements for 2018 and 2019, and to reduce the minimum revenue requirements to

$15,000,000 million for 2020, $20,000,000 for 2021 and $25,000,000 for 2022; and

- provide CRG with board observer rights.

As of June 30, 2018, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of June 30, 2018, principal and PIK payments under the Loan Agreement were as follows (in thousands):

Period Ending June 30,		**Principal and PIK Loan Repayments**
2018	$	
2019		
2020		
2021		
2022 and after		2,000
		2,000
Add: Accretion of closing fees		994
Add: PIK		5,645
		8,639
Less: Amount representing debt financing costs		(816)
Borrowings, as of June 30, 2018	$	7,823

Table of Contents

Contemporaneously with the execution of the Loan Agreement in September 2015, the Company entered into a Securities Purchase Agreement (the CRG Purchase Agreement) with CRG which allowed it to purchase up to $5,000,000 of the Company s common stock. CRG purchased 8,705 shares of common stock on September 22, 2015 at a price of $559.64 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 $558.80 yielding a $0.84 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 CRG 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 CRG 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 as contra-debt. 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 CRG Securities Purchase Agreement 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. Concurrent with the Amendment No.2 to the Loan Agreement, the Company recorded an additional debt discount of $154,000 of issuance costs. 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, 2018 and December 31, 2017, the balance of the aggregate debt discount was $816,000 and $716,000, respectively. The Company s interest expense associated with the debt discount amounted to $30,000 and $57,000 during the three months ended June 30, 2018 and 2017, respectively. The Company s interest expense associated with the debt discount amounted to $56,000 and $115,000 during the six months ended June 30, 2018 and 2017, respectively.

As noted in Note 1 to these financial statements, due to the substantial doubt about the Company s ability to continue operating as a going concern and the material adverse change clause in the CRG Loan Agreement, the entire amount of borrowings at June 30, 2018 and December 31, 2017 has been classified as current in these financial statements. CRG has not invoked the material adverse change clause.

PDL BioPharma

On April 18, 2013, the Company entered into a Credit Agreement (Agreement) with PDL BioPharma, Inc. (PDL) whereby PDL agreed to loan up to $40,000,000. 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 recorded in other income (expense), net on the statement of loss and comprehensive loss. For the three months ended June 30, 2018 and 2017, the Company incurred interest expense of $61,000 and $251,000,

respectively. For the six months ended June 30, 2018 and 2017, the Company incurred interest expense of $364,000 and $492,000, respectively.

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 Interests obligation relating to future royalties as a debt instrument by applying the retrospective approach and reviews its estimate of forecasted Assigned Interests payable annually. Under the retrospective method, the Company computes a new effective interest rate based on the original carrying amount, actual cash flows to date, and remaining estimated cash flows over the maturity date. The new effective interest rate, 20.4% as of December 31, 2016, was 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 had an aggregate accrual for its Assigned Interests obligations of $364,000, representing the net present value of the future minimum royalty obligation as of

Table of Contents

December 31, 2017, respectively. The Assigned Interest liability was included within accrued expenses and other current liabilities as of December 31, 2017. This amount was fully paid during the six months ended June 30, 2018.

Additionally, until April 2018, the Company was required to pay on a periodic basis PDL a percentage of its net revenue and 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.

6. Capital Leases

Capital lease obligations consist of leased office equipment. As of June 30, 2018 and December 31, 2017, the aggregate amount of capital leases recorded within property and equipment, net, on the accompanying balance sheet is $5,000 and $14,000, respectively. The current portion of the capital lease obligations is included in accrued liabilities and the balance included within other long-term liabilities represents the long-term portion.

The future minimum lease payments as of June 30, 2018, are as follows (in thousands):

Period ending December 31,	Future Minimum Lease Payments
2018	$ 4
2019	1
Total minimum payments	5
Less: Amount representing future interest	
Present value of minimum lease payments	$ 5

7. Commitments and Contingencies

Lease Commitments

The Company s operating lease obligations primarily consist of leased office, laboratory, and manufacturing space under a non-cancelable operating lease that expires in November 2019. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of three years. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments. In connection with the facility lease, the landlord also provided incentives of $369,000 to the Company in the form of leasehold improvements. These amounts were reflected as deferred rent and were amortized as a reduction to rent expense over the original term of the Company s operating lease. In February 2016, the Company entered into an additional non-cancelable operating lease for

warehouse and storage space that expires in November 2019. Rent expense was $240,000 and $506,000 for the three months ended June 30, 2018 and 2017, respectively. Rent expense was $480,000 and $1,013,000 for the six months ended June 30, 2018 and 2017, respectively.

On October 19, 2017, the Company entered into an agreement to sublease one of its facilities (Note 10). The sublease agreement commenced on approximately December 1, 2017 and is scheduled to expire on November 15, 2019 (which is 15 days prior to the expiration of the facility lease). The sublessee pays a base rent of $3.25 per rentable square foot, for a total of $79,950 per month, increasing to $3.35 per rentable square foot, for a total of $82,410 per month as of December 1, 2017. In addition to the base rent, the sublessee pays the Landlord s operating expenses and property taxes due and payable with respect to the subleased facility.

The future aggregate minimum lease payments, net of sublease income, as of June 30, 2018, are as follows (in thousands):

Year ending December 31,		Future Minimum Lease Payments
2018	$	537
2019		1,009
Total minimum lease payments	$	1,546

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. The Company had non-cancellable commitments to suppliers for purchases totaling approximately $2,050,000 as of June 30, 2018.

Table of Contents

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.

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

Legal Proceedings

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

Between May 22, 2017 and May 25, 2017, three purported class action lawsuits were filed in the Superior Court of the State of California, County of San Mateo (State Court), against the Company, certain of its officers and directors and the underwriters of the Company s January 2015 IPO. The actions were captioned Grotewiel v. Avinger, Inc., et al., No. 17-CIV-02240, Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, and Olberding v. Avinger, Inc., et al., No. 17-CIV-02307. These lawsuits allege that the registration statement for the Company s IPO made false and misleading statements and omissions in violation of the Securities Act of 1933. Plaintiffs seek to represent a class of purchasers of our common stock in and/or traceable to our IPO. Plaintiffs seek, among other things, unspecified compensatory damages, interest, costs, recission, and attorneys fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California (Federal Court).

On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted the motions to remand the Olberding and Gonzalez actions to the State Court. On August 9, 2017, the State Court consolidated the Olberding and Grotewiel actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284 (State Action). On September 22, 2017, an amended complaint was filed in the State Action. On October 31, 2017, the parties in the State Action stipulated to a stay of proceedings until judgment is entered in the Federal Action.

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Grotewiel action (Federal Action). On November 2, 2017, pursuant to stipulation of the parties, the State Court entered an order staying

proceedings in the State Action until judgment is entered in the Federal Action. On June 20, 2018, the State Court dismissed the State Action pursuant to the proposed settlement described below. On November 21, 2017, an amended complaint was filed in the Federal Action. Defendants filed a motion to dismiss that complaint on January 26, 2018. On March 19, 2018, plaintiff in the Federal Action filed a further amended complaint, on behalf of a class of purchasers of our common stock in and/or traceable to our IPO, as well as purchasers of our common stock during the period January 30, 2015, to April 10, 2017.

The Company and its directors believe that the foregoing lawsuits were entirely without merit; however, in the interest of avoiding the cost and disruption of continuing to defend against these lawsuits, the Company entered into a settlement of the securities class actions pending against the Company and several of its officers and directors. The settlement is for a total of $5 million and, if approved by the court, will result in a full release of claims against all defendants. The settlement is subject to approval by the court. A court hearing regarding final settlement approval is set for October 23, 2018. The Company s total contribution to the settlement fund is $1.76 million, which amount was included within accrued expenses and other current liabilities as of December 31, 2017. In March 2018, the Company paid out the $1.76 million.

Table of Contents

8. Stockholders Equity (Deficit)

Preferred Stock

As of June 30, 2018, 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 43,501 shares were issued and outstanding.

Series A Preferred Stock

On February 14, 2018, the Company entered into a Series A Purchase Agreement with CRG, pursuant to which it agreed to convert $38,000,000 of the outstanding principal amount of its senior secured term loan (plus $3,800,000 in back-end fees and prepayment premium applicable thereto), totaling $41,800,000, into a newly authorized Series A preferred stock. The Series A preferred stock is initially convertible into 20,900,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement. Under the terms of the Series A Purchase Agreement, the holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at the Company s option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company s equity in terms of repayment and certain other rights. The Series A preferred stock and any of the Company s common stock issued upon conversion of the Series A preferred stock are subject to a lockup agreement through February 14, 2019. As of June 30, 2018, 41,800 shares of Series A preferred stock were outstanding. The Series A preferred stock accrued dividends through June 30, 2018 of approximately $1.2 million which is included within current liabilities.

Series B Preferred Stock

On February 16, 2018, the Company completed a public offering of 17,979 shares of Series B convertible preferred stock (the Series B preferred stock). As a result, the Company received net proceeds of approximately $16.0 million after underwriting discounts, commissions, legal and accounting fees of approximately $1.9 million. The Series B preferred stock has a liquidation preference of $0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. As of March 31, 2018, 10,962 shares of Series B preferred stock were outstanding. During the months of April, May and June 2018 certain investors exercised their conversion rights and converted 9,261 shares of preferred stock into 4,631,148 shares of the Company s common stock. As of June 30, 2018, 1,701 shares of Series B preferred stock were outstanding.

The Company evaluated the Series B convertible preferred stock issuance in accordance with the provisions of ASC 815, *Derivatives and Hedging*, including consideration of embedded derivatives requiring bifurcation. The issuance of the convertible preferred stock could generate a beneficial conversion feature (BCF), which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor or in the money at inception because the conversion option has an effective conversion price that is less than the market price of

the underlying stock at the commitment date. The Company recognized the BCF by allocating the intrinsic value of the conversion option, which is the number of shares of common stock available upon conversion multiplied by the difference between the effective conversion price per share and the fair value of common stock per share on the commitment date, to additional paid-in capital, resulting in a discount on the convertible preferred stock. As the Series B convertible preferred stock may be converted immediately, the Company recognized a BCF of $5.2 million as a deemed dividend in the condensed consolidated statements of operations as of February 16, 2018. This one-time, non-cash charge impacted net loss attributable to common stockholders and net loss per share attributable to common stockholders for the six months ended June 30, 2018.

Common Stock

As of June 30, 2018, 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 9,305,872 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 warrants to purchase an aggregate of 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 by such investor. As of June 30, 2018, there were 53,803 warrants outstanding with an exercise price of $504.00 per share. These warrants expire upon the earlier of September 2, 2019 or upon consummation of a change in control of the Company.

Table of Contents

On February 16, 2018, in connection with the Company s completed public offering of Series B preferred stock, the Company issued two series of warrants that together provide for the purchase, by the investors in the Series B Offering, of an aggregate of 17,979,000 shares of common stock (the Series B Warrants). Each share of Series B preferred stock is accompanied by one warrant that expires on the seventh anniversary of the date of issuance to purchase up to 500 shares of common stock and one warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of the Company s Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 500 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date. The Company assessed the Series B Warrants under ASC 480 and determined that the Series B Warrants were outside the scope of ASC 480. The Company next assessed the Series B Warrants under ASC 815. Under the related guidance, a reporting entity shall not consider a contract to be a derivative instrument if the contract is both (1) indexed to the entity s own stock and (2) classified in stockholders equity. The Company determined that the Series B Warrants were indexed to the Company s stock, as the agreements do not contain any exercise contingencies and the Series B Warrants settlement amount equals the difference between the fair value of the Company s common stock price and the Series B Warrant strike price. The Company also assessed the classification as stockholders equity and determined the Series B Warrants met all of the criteria for classification as equity under ASC 815. Based on this analysis, the Company determined that the Series B Warrants should be classified as equity. During the three months ended June 30, certain of the Series B Warrants were exercised and 290,500 shares of the Company s common stock were issued to the warrant holders in return. As of June 30, 2018, Series B Warrants to purchase an aggregate of 17,688,500 shares of common stock were outstanding.

As of June 30, 2018 and December 31, 2017, warrants to purchase an aggregate of 17,742,215 and 53,715 shares of common stock were outstanding, respectively.

Stock Plans

In January 2015, the Board of Directors adopted and the Company s stockholders approved the 2015 Equity Incentive Plan (2015 Plan). The 2015 Plan replaced the 2009 Stock Plan (the 2009 Plan) which was terminated immediately prior to consummation of the Company s IPO, collectively the Plans. The 2015 Plan provides for the grant of incentive stock options (ISOs) to employees and for the grant of nonstatutory stock options (NSOs), restricted stock, RSUs, stock appreciation rights, performance units and performance shares to employees, directors and consultants. Initially a total of 33,000 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 42,250 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 2018, the common stock available for issuance under the 2015 Plan was increased by 41,674 shares of common stock. During the three and six months ended June 30, 2018, the common stock available for issuance under the 2015 Plan was increased by an additional 3,000,000 shares of common stock. As of June 30, 2018, 3,090,775 shares were available for grant under the 2015 Plan.

Table of Contents

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, 2017	76,645	$ 291.73	$
Options granted	31,000	$ 1.67	
Options exercised		$	
Options cancelled	(22,803)	$ 258.35	
Balance at June 30, 2018	84,842	$ 194.72	$

As of June 30, 2018, the aggregate intrinsic value of options outstanding and vested was zero. There were no options exercised during the six months ended June 30, 2018. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the closing market price of the common stock on the date of exercise. Because of the Company s net operating losses, the Company did not realize any tax benefits from share-based payment arrangements for the three and six months ended June 30, 2018 and 2017.

The Company s RSUs vest annually over four years in equal increments. A summary of all RSU activity 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, 2017	5,089	$ 237.78	2.87	$ 37
Awarded		$		
Released	(1,166)	$ 225.52		
Forfeited	(617)	$ 237.96		
Awards outstanding at June 30, 2018	3,306	$ 242.07	2.00	$ 6

As of June 30, 2018, approximately $651,000 of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.0 years. The Company used the closing market price of $1.67 per share at June 29, 2018, to determine the aggregate intrinsic value.

2015 Employee Stock Purchase Plan

In January 2015, the Board of Directors adopted and the Company s stockholders approved the 2015 Employee Stock Purchase Plan (ESPP) under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. Initially 12,500 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) 12,325 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 2018, the common stock available for issuance under the ESPP was increased by 12,325 shares of common stock. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended. The first offering under the ESPP began in February 2015. As of June 30, 2018, approximately 27,515 shares of common stock remained reserved for issuance under the ESPP. The Company incurred $0 and $25,000 in stock-based compensation expense related to the ESPP for the three months ended June 30, 2018 and 2017, respectively. The Company incurred $1,000 and $90,000 in stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2018 and 2017, respectively.

Table of Contents

9. Stock-Based Compensation

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

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. During the year ended December 31, 2017, the Company estimated 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. Effective January 1, 2017, the Company adopted ASU 2016-09 and elected to recognize forfeitures when they occur using a modified retrospective approach. The fair value for the Company s employee stock options was estimated at the date of grant using the Black-Scholes valuation model with the following average assumptions:

	Three Months Ended June 30, 2017	Six Months Ended June 30, 2017
Expected term (years)	5.5	5.9
Expected volatility	63.3%	57.1%
Risk-free interest rate	1.8%	2.2%
Dividend rate		

As of June 30, 2018 and December 31, 2017, the total unamortized compensation expense related to stock option awards granted to employees and directors was approximately $1,566,000 and $2,979,000, which is expected to be amortized over the next 1.04 and 1.45 years, respectively.

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

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

Table of Contents

10. Restructuring Charges and Expenses

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

In September 2017, the Company effected a cost reduction plan, which included a company-wide reduction in force, lowering its total headcount by 24 employees. The Company recorded a restructuring charge of approximately $416,000, relating to severance costs at that time. In October 2017, the Company subleased one of its facilities and ceased to use the facility as part of the cost reduction plan. The Company recorded a restructuring charge of approximately $388,000 relating to the cost to exit the facility. As of December 31, 2017, all of the severance costs related to the termination of 24 employees had been paid. As of June 30, 2018 and December 31, 2017, $99,000 and $98,000, respectively, of the total costs to exit the facility was included within accrued expenses and other current liabilities.

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

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

Overview

We are a commercial-stage medical device company that designs, manufactures and sells image-guided, catheter-based systems that are used by physicians to treat patients with peripheral artery disease, or PAD. Patients with PAD have a build-up of plaque in the arteries that supply blood to areas away from the heart, particularly the pelvis and legs. Our mission is to significantly improve the treatment of vascular disease through the introduction of products based on our Lumivascular platform, the only intravascular image-guided system available in this market. We manufacture and sell a suite of products in the United States and select international markets. Our current products include our Lightbox imaging console, the Ocelot family of catheters, which are designed to allow physicians to penetrate a total blockage in an artery, known as a chronic total occlusion, or CTO, and Pantheris, our image-guided atherectomy device which is designed to allow physicians to precisely remove arterial plaque in PAD patients. We received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for commercialization of Pantheris in October 2015. We received an additional 510(k) clearance for enhanced versions of Pantheris in March 2016 and May 2018, and those versions of Pantheris became commercially available in the United States and select international markets promptly thereafter. We also offer the

Wildcat and Kittycat 2 catheters, which are used for crossing CTOs but do not contain on-board imaging technology.

Table of Contents

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

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

Prior to the introduction of our Lumivascular platform our non-imaging catheter products were manufactured by third parties. All of our products are now manufactured in-house at our facilities in Redwood City, California using components and sub-assemblies manufactured both in-house and by outside vendors. We assemble all of our products at our manufacturing facility, but certain critical processes such as coating and sterilization are done by outside vendors. We expect our current manufacturing facility will be sufficient through at least 2019.

In addition to commercialization of Pantheris in the United States and select international markets in March 2016, we began commercializing our initial non-Lumivascular platform products in 2009 and introduced our Lumivascular platform products in the United States in late 2012. We generated revenues of $3.9 million and $6.0 million in the six months ended June 30, 2018 and 2017, respectively. During the six months ended June 30, 2018 and 2017, our net loss was $16.1 million and $28.1 million, respectively. We have not been profitable since inception, and as of June 30, 2018, our accumulated deficit was approximately $317.4 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.

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 were able to borrow up to $50.0 million on or before March 29, 2017, subject to certain terms and conditions. We borrowed $30.0 million on September 22, 2015 and an additional $10.0 million on June 15, 2016 under the Loan Agreement. Contingent on achievement of certain revenue milestones, among other conditions, we would have been eligible to borrow an additional $10.0 million, on or prior to March 29,

2017; however, we did not achieve the level of revenues required to borrow the final $10.0 million. Contemporaneously with the execution of the Loan Agreement, we entered into a Securities Purchase Agreement with CRG, pursuant to which CRG purchased 8,705 shares of our common stock on September 22, 2015 at a price of $559.64 per share, which represents the 10-day average of closing prices of our common stock ending on September 21, 2015. Pursuant to the Securities Purchase Agreement, we filed a registration statement covering the resale of the shares sold to CRG and must comply with certain affirmative covenants during the time that such registration statement remains in effect. We used the proceeds from the CRG borrowing and securities purchase to retire our outstanding principal and accrued interest with PDL Biopharma, or PDL, and to retire the principal and accrued interest underlying our outstanding promissory notes, or the notes.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into an at-the-market program pursuant to a Sales Agreement with Cowen and Company, or Cowen, through which we may, from time to time, issue and sell shares of common stock having an aggregate offering value of up to $50.0 million. The shelf registration statement also covers the resale of the shares sold to CRG. The registration statement was declared effective by the SEC on March 8, 2016. During the year ended December 31, 2016, we sold 27,374 shares of common stock through the at-the-market program at an average price of $194.74 and raised net proceeds of $5.2 million, after payment of $0.2 million in commissions and fees to Cowen. During the three and six months ended June 30, 2018 and 2017, we sold no shares of common stock through the at-the-market program. Due to the SEC s baby shelf rules, which prohibit companies with a public float of less than $75 million from

Table of Contents

issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, at this time we are unable to issue more shares through our at-the-market program. In addition, in August 2016 we completed a follow-on public offering of 246,445 shares of our common stock for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 246,445 shares include the exercise in full by the underwriters of their option to purchase an additional 32,145 shares of our common stock.

In April 2017, we undertook an organizational realignment which included a reduction in force, that lowered our total headcount by approximately 33% compared to December 31, 2016. The organizational realignment was designed to focus our commercial efforts on driving catheter utilization in our strongest markets, around our most productive sales professionals. Our field sales personnel headcount was reduced to 32, down from 60 as of December 31, 2016. This workforce reduction was designed to reduce operating expenses while continuing to support major product development and clinical initiatives. The strategic reduction in the field sales force was designed to maintain robust engagement with higher volume users of our Lumivascular technology and position us to increase utilization of our catheters within our installed base of accounts in 2018 following the launch of our next generation products. In September 2017, we effected a cost reduction plan, which also included a company-wide reduction in force, lowering our total headcount by an additional 24 employees. Our field sales personnel headcount was further reduced to a total of 20 people. In addition, as part of the cost reduction plan, in October 2017, we subleased a portion of the Company s facilities and consolidated our operations primarily into one building.

On November 3, 2017, we entered the Lincoln Park Purchase Agreement, pursuant to which Lincoln Park is obligated to purchase, at our request, up to $15.0 million of our common stock over a 30-month period, subject to certain limitations set forth in the Lincoln Park Purchase Agreement. As a fee for Lincoln Park s commitment to purchase such shares, we issued 23,584 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection with the Lincoln Park Purchase Agreement, we filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 17, 2017.

On February 14, 2018, we entered into Amendment No. 2 to the Term Loan Agreement (the Amendment No. 2 Loan Agreement) with CRG. Under its terms, the Amendment No. 2 Loan Agreement, among other things: (1) extended the interest-only period through June 30, 2021; (2) extended the period during which the Company may elect to pay a portion of interest in payment-in-kind, or PIK, interest payments through June 30, 2021, so long as no default has occurred and is continuing; (3) permitted the Company to make its entire interest payments in PIK interest payments for through December 31, 2019, so long as no default has occurred and is continuing; (4) extended the maturity date to June 30, 2023; (5) reduced the minimum liquidity requirement to $3.5 million at all times; (6) eliminated the minimum revenue covenant for 2018 and 2019; (7) reduced the minimum revenue covenant to $15 million for 2020, $20 million for 2021 and $25 million for 2022; and (8) provided CRG with board observer rights.

In addition, on February 14, 2018, we entered into a Series A preferred stock Purchase Agreement (the Series A Purchase Agreement) with CRG, pursuant to which it agreed to convert $38.0 million of the outstanding principal amount of its senior secured term loan (plus $3.8 million in back-end fees and prepayment premium applicable thereto), totaling $41.8 million, into a newly authorized Series A preferred stock. The Series A preferred stock is initially convertible into 20,900,000 shares of common stock subject to certain limitations contained in the Series A Purchase Agreement. The holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at our option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company s equity in terms of repayment and certain other rights. The Series A preferred stock and any of

the Company s common stock issued upon conversion of the Series A preferred stock is subject to a lockup agreement through February 14, 2019.

On February 16, 2018, we completed a public offering of 17,979 shares of Series B preferred stock and warrants to purchase 17,979,000 shares of common stock. As a result, we received net proceeds of approximately $16.0 million after underwriting discounts, commissions, legal and accounting fees of approximately $1.9 million. Each share of Series B preferred stock is accompanied by one warrant that expires on the seventh anniversary of the date of issuance to purchase up to 500 shares of common stock (the Series 1 warrants) and one warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris below-the-knee device (or the same or similar product with a different name) to purchase up to 500 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date (the Series 2 warrants).

In July 2018, we sold a further 2,166,180 shares of our common stock (excluding warrants to purchase an additional 1,083,091 shares of our common stock issued in a concurrent private placement) pursuant to the Shelf Registration Statement for gross proceeds of approximately $3.5 million.

Table of Contents

We are developing two next-generation versions of our Pantheris atherectomy device, Pantheris 3.0 and a lower profile Pantheris (Pantheris 6F), that we believe represent significant improvements over our existing product. Pantheris 3.0 includes new features and design improvements to the handle, shaft, balloon and nose cone that we believe will improve usability and reliability, while the Pantheris 6F has a smaller diameter and longer length that we believe will optimize it for use in smaller vessels and below-the-knee applications. We obtained FDA clearance for Pantheris 3.0 in May 2018 and we plan to file a 510(k) submission for Pantheris 6F in the third quarter of 2018. We received a CE Mark for Pantheris 3.0 in December 2017.

Critical Accounting Policies and Estimates

Management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures of contingent assets and liabilities. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. There have been no significant and material changes in our critical accounting policies during the six months ended June 30, 2018, 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 30, 2018.

Components of Our Results of Operations

Revenues

All of our revenues are currently derived from sales and rentals of our Lightbox console and sales of our various PAD catheters, as well as related services in the United States and select international markets. Our revenues were adversely affected by the product performance issues we have experienced with the previous version of Pantheris as well as our strategic decision to reduce the size of our sales force in April 2017 and September 2017. However, we expect our revenues to increase in 2018 as we introduce two next-generation versions of Pantheris. No single customer accounted for more than 10% of our revenues during the three and six months ended June 30, 2018 and 2017.

Revenues may fluctuate from quarter to quarter due to a variety of factors including capital equipment purchasing patterns that are typically increased towards the end of the calendar year and decreased in the first quarter. In addition, 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 second quarter, the number of elective procedures nationwide is historically lower than other quarters throughout the year, which we believe is primarily attributable to the summer vacations of physicians and their patients.

Cost of Revenues and Gross Margin

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

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

Table of Contents

Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, business development, finance, information technology and human resource functions. Other SG&A expenses include commissions, training, travel expenses, educational and promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to remain lower in the near term compared to recent prior years due to our reductions in force in April and September 2017.

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 consists of gains and losses resulting from the remeasurement of foreign exchange transactions.

Results of Operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except percentages)			
Revenues	$ 2,058	$ 2,459	$ 3,867	$ 5,950

Cost of revenues	2,169	3,919	3,584	7,994
Gross profit (loss)	(111)	(1,460)	283	(2,044)
Gross margin	-5%	-59%	7%	-34%
Operating expenses:				
Research and development	1,159	3,097	2,936	7,020
Selling, general and administrative	4,204	6,189	8,464	15,507
Restructuring charges		519		519
Total operating expenses	5,363	9,805	11,400	23,046
Loss from operations	(5,474)	(11,265)	(11,117)	(25,090)
Interest income (expense), net	(312)	(1,540)	(4,951)	(3,058)
Other income (expense), net	(13)	6	(12)	9
Net loss and comprehensive loss	$ (5,799)	$ (12,799)	$ (16,080)	$ (28,139)

Comparison of Three Months Ended June 30, 2018 and 2017

Revenues. For the three months ended June 30, 2018, revenue decreased 16% compared to the three months ended June 2017. The decrease primarily reflects the impact of the reduced size of our field sales force in 2017 and the efforts we made to refocus our sales force on driving the utilization at our current installed base rather than on expanding the installed base of Lightbox imaging consoles.

Cost of Revenues and Gross Margin.

Cost of revenues decreased $1.8 million, or 45%, to $2.2 million during the three months ended June 30, 2018, compared to $3.9

Table of Contents

million during the three months ended June 30, 2017. This decrease was primarily attributable to lower charges for inventory excess and obsolescence in the three months ended June 30, 2018 compared to the prior year period.

Gross margin for the three months ended June 30, 2018 increased to (5%), compared to (59%) in the three months ended June 30, 2017. The increase in gross margin was primarily due to the decreased charges for inventory excess and obsolescence compared to the prior year period.

Research and Development Expenses (R&D).

R&D expense for the three months ended June 30, 2018 was lower than the amounts reported during the three months ended June 30, 2017 primarily due to a decrease in personnel-related expenses as a result of having fewer employees and project spending.

Stock-based compensation expense within R&D totaled approximately $0.1 million and $0.5 million during the three months ended June 30, 2018 and 2017, respectively.

Selling, General and Administrative Expenses (*SG&A*).

SG&A expense for the three months ended June 30, 2018 was lower than the amount reported during the three months ended June 30, 2017 primarily due to a decrease in personnel-related expenses including compensation expense and professional services expenses.

Stock-based compensation expense within SG&A totaled approximately $0.5 million and $0.7 million during the three months ended June 30, 2018 and 2017, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $1.2 million, to an expense of $0.3 million during the three months ended June 30, 2018, compared to an expense of $1.5 million during the three months ended June 30, 2017 due to the CRG note conversion and payoff of the PDL loan.

Other Income (Expense), Net. Other income (expense), net decreased $19,000 to an expense of $13,000, during the three months ended June 30, 2018, compared to income of $6,000 during the three months ended June 30, 2017. Other income for the three months ended June 30, 2018 and 2017, was primarily attributable to the remeasurement of foreign exchange transactions.

Comparison of Six Months Ended June 30, 2018 and 2017

Revenues. For the six months ended June 30, 2018, revenue decreased 35% compared to the six months ended June 2017. The decrease primarily reflects the impact of the reduced size of our field sales force in the first and third quarters of 2017 and the efforts we made to refocus our sales force on driving the utilization at our current installed base rather than on expanding the installed base of Lightbox imaging consoles.

Cost of Revenues and Gross Margin.

Cost of revenues decreased $4.4 million, or 55%, to $3.6 million during the six months ended June 30, 2018, compared to $8.0 million during the six months ended June 30, 2017. This decrease was primarily attributable to lower charges for inventory excess and obsolescence in the six months ended June 30, 2018 and the reduced costs related to lower revenue due to a significantly reduced sales force.

Gross margin for the six months ended June 30, 2018 increased to 7%, compared to (34%) in the six months ended June 30, 2017. The increase in gross margin was primarily due to the lower charges for inventory excess and obsolescence compared to the prior year period.

Research and Development Expenses (R&D).

R&D expense for the six months ended June 30, 2018 was lower than the amounts reported during the six months ended June 30, 2017 primarily due to a decrease in personnel-related expenses as a result of fewer employees and project spending.

Stock-based compensation expense within R&D totaled approximately $0.2 million and $1.0 million during the six months ended June 30, 2018 and 2017, respectively.

Selling, General and Administrative Expenses (SG&A).

SG&A expense for the six months ended June 30, 2018 was lower than the amount reported in the same period in 2017 primarily due to a decrease in personnel-related expenses including compensation expense and professional services expenses as a result of having fewer employees.

Table of Contents

Stock-based compensation expense within SG&A totaled approximately $1.0 million and $1.6 million during the six months ended June 30, 2018 and 2017, respectively.

Interest Income (Expense), Net. Interest income (expense), net increased $1.9 million, to an expense of $4.9 million during the six months ended June 30, 2018, compared to an expense of $3.1 million during the six months ended June 30, 2017 due to $3.8 million in back-end charges from the CRG note conversion, offset by decreased interest expense of $1.2 million related to the payoff of the PDL loan.

Other Income (Expense), Net. Other income (expense), net decreased $21,000 to an expense of $12,000, during the six months ended June 30, 2018, compared to income of $9,000 during the six months ended June 30, 2017. Other income for the six months ended June 30, 2018 and 2017 was primarily attributable to the remeasurement of foreign exchange transactions.

Liquidity and Capital Resources

As of June 30, 2018, we had cash and cash equivalents of $10.1 million and an accumulated deficit of $317.4 million, compared to cash and cash equivalents of $5.4 million and an accumulated deficit of $301.3 million as of December 31, 2017. We believe that the net proceeds we received from our Series B Offering on February 16, 2018, net proceeds from the sale of our common stock to Lincoln Park pursuant to the Lincoln Park Purchase Agreement entered into on November 3, 2017, net proceeds from the February 2018 Series B Offering, together with our cash and cash equivalents at December 31, 2017, and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations through at least December 31, 2018. We will need to raise additional funds through future equity or debt financings within the next five months to meet our operational needs and capital requirements for product development, clinical trials and commercialization. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the foreseeable future could cause substantial dilution to our existing stockholders. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders and require significant debt service payments, which divert resources from other activities. Additional financing may not be available at all, or if available, may not be 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 we may be required to significantly scale back our business and operations.

To date, our primary sources of capital have been private placements of preferred stock, debt financing agreements, our at-the-market program, our IPO and our follow-on public offerings. As previously disclosed, on April 20, May 24, and October 24, 2017 we received letters from the Listing Qualifications Department of The Nasdaq Stock Market, LLC (Nasdaq) notifying us that we were not in compliance with applicable listing rules. On March 1, 2018, Nasdaq informed us that we had regained compliance with the applicable requirements

for listing on the Nasdaq Capital Market. For more information on this risk, see Part II, Item 1A *Risk Factors*.

In September 2015, we entered into a Loan Agreement with CRG, under which we could borrow up to $50.0 million, of which $30.0 million was immediately available and borrowed by us. Of the remaining $20.0 million, we borrowed $10.0 million on June 15, 2016 and the availability of the remaining $10.0 million was contingent on the achievement of certain net revenue milestones prior to December 31, 2016, which were not achieved. Under the original terms of 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% per annum interest payment by making a cash payment for 8.5% per annum of interest and making a 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. Under the original terms of the Loan Agreement, all unpaid principal, and accrued and unpaid interest, is due and payable in full on September 30, 2021. As of June 30, 2018, we had $7.8 million outstanding under the Loan Agreement. For more information, see Part I, Item 2 *Contractual Obligations.*

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. 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.

Table of Contents

The Loan Agreement requires that we adhere to certain affirmative and negative covenants, including financial reporting requirements, certain minimum financial covenants for pre-specified liquidity and revenue requirements and a prohibition against the incurrence of indebtedness, or creation of additional liens, other than as specifically permitted by the terms of the Loan Agreement. In particular, the covenants of the Loan Agreement, as amended as of December 31, 2017, include a covenant that we maintain a minimum of $5.0 million of cash and certain cash equivalents. On December 14, 2017, we entered into a waiver and consent agreement (the Waiver and Consent) with CRG. The Waiver and Consent provided for the waiver of the minimum required revenue financial covenant for the twelve-month period beginning January 1, 2017, as required under the terms of the Loan Agreement. Pursuant to the Waiver and Consent, CRG also consented to our payment of the cash interest payment due on December 31, 2017 in the form of a PIK loan instead. On January 24, 2018, we entered into a Waiver with CRG. The Waiver provided for the waiver of the $5,000,0000 minimum liquidity financial covenant and reduced it to $2,500,000 for the period beginning January 1, 2018 through February 28, 2018, as required under the terms of the Loan Agreement and waived any event of default resulting from non-compliance with the $5,000,000 minimum liquidity financial covenant.

On February 14, 2018, we entered into Amendment No. 2 to the Term Loan Agreement (the Amendment No. 2 Loan Agreement) with CRG. Under its terms, the Amendment No. 2 Loan Agreement, among other things: (1) extended the interest-only period through June 30, 2021; (2) extended the period during which the Company may elect to pay a portion of interest in PIK interest payments through June 30, 2021 so long as no default has occurred and is continuing; (3) permitted the Company to make its entire interest payments in PIK interest payments for through December 31, 2019 so long as no default has occurred and is continuing; (4) extended the maturity date to June 30, 2023; (5) reduced the minimum liquidity requirement to $3.5 million at all times; (6) eliminated the minimum revenue covenant for 2018 and 2019; (7) reduced the minimum revenue covenant to $15 million for 2020, $20 million for 2021 and $25 million for 2022; and (8) provided CRG with board observer rights. 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 are currently in compliance with the covenants under the Loan Agreement, but if we default on any such covenants we will need, and may not be able to obtain, relief in the form of waivers or amendments to the applicable debt agreement.

In addition, on February 14, 2018, we entered into the Series A Purchase Agreement with CRG, pursuant to which it agreed to convert $38.0 million of the outstanding principal amount of its senior secured term loan (plus the back-end fee and prepayment premium applicable thereto) under the Loan Agreement into a newly authorized Series A preferred stock. Under the terms of the Series A Purchase Agreement, the holders of Series A preferred stock are entitled to receive annual accruing dividends at a rate of 8%, payable in additional shares of Series A preferred stock or cash, at our option. The shares of Series A preferred stock have no voting rights and rank senior to all other classes and series of the Company s equity in terms of repayment and certain other rights. The Series A preferred stock and any of the Company s common stock issued upon conversion of the Series A preferred stock is subject to a lockup agreement through February 14, 2019.

On February 3, 2016, we filed a universal shelf registration statement to offer up to $150.0 million of our securities and entered into an at-the-market program pursuant to a Sales Agreement with Cowen, as sales agent, through which we issued and sold common stock with an aggregate value of approximately $8.7 million between the registration statement s effectiveness on March 8, 2016 and September 2017. During the year ended December 31, 2016, we sold 27,374 shares of common stock through the at-the-market program at an average price of $194.74 and raised net proceeds of $5.2 million, after payment of $0.2 million in commissions and fees to Cowen. During the three and six months ended June 30, 2018 and 2017, we sold no shares of common stock through the at-the-market program. Due to the SEC s

baby shelf rules, which prohibit companies with a public float of less than $75 million from issuing securities under a shelf registration statement in excess of one-third of such company s public float in a twelve-month period, we are unable to issue more shares through our at-the-market program at this time. In addition, in August 2016, we issued and sold 246,445 shares of our common stock in a follow-on public offering at a public offering price of $140.00 per share, for net proceeds of approximately $31.5 million after deducting underwriting discounts and commissions of approximately $2.4 million and other expenses of approximately $0.6 million. The 246,445 shares include the exercise in full by the underwriters of their option to purchase an additional 32,145 shares of our common stock.

On November 3, 2017, we entered into the Lincoln Park Purchase Agreement pursuant to which Lincoln Park is obligated to purchase, at our request, up to $15.0 million of our common stock over a 30-month period, subject to certain limitations set forth in the purchase agreement. As a fee for Lincoln Park s commitment to purchase such shares, we issued 943,396 shares of common stock to Lincoln Park on November 3, 2017. As obligated under a registration rights agreement entered into with Lincoln Park in connection

Table of Contents

with the Purchase Agreement, we filed a registration statement on Form S-1 on November 6, 2017 for up to 248,750 of such shares, which registration statement was declared effective by the SEC on November 17, 2017.

On February 16, 2018, we completed a public offering of 17,979 shares of Series B preferred stock and warrants to purchase 17,979,000 shares of common stock. As a result, we received net proceeds of approximately $16.0 million after underwriting discounts, commissions, legal and accounting fees of approximately $1.9 million. The Series B preferred stock has a liquidation preference of $0.001 per share, full ratchet price based anti-dilution protection, has no voting rights and is subject to certain ownership limitations. The Series B preferred stock is immediately convertible at the option of the holder, has no stated maturity, and does not pay regularly stated dividends or interest. Each share of Series B preferred stock is accompanied by one Series 1 warrant that expires on the seventh anniversary of the date of issuance to purchase up to 500 shares of common stock and one Series 2 warrant that expires on the earlier of (i) the seventh anniversary of the date of issuance or (ii) the 60th calendar day following the receipt and announcement of FDA clearance of our Pantheris small vessel device (or the same or similar product with a different name) to purchase up to 500 shares of common stock; provided, however, if at any time during such 60-day period the volume weighted average price for any trading day is less than the then effective exercise price, the termination date shall be extended to the seven year anniversary of the initial exercise date.

In July 2018, we sold a further 2,166,180 shares of our common stock (excluding warrants to purchase an additional 1,083,091 shares of our common stock issued in a concurrent private placement) pursuant to the Shelf Registration Statement for gross proceeds of approximately $3.5 million.

Cash Flows

	Six Months Ended June 30,	
	2018	**2017**
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (11,346)	$ (22,311)
Investing activities	(125)	(45)
Financing activities	16,226	224
Net increase (decrease) in cash and cash equivalents	$ 4,755	$ (22,132)

Table of Contents

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2018 was $11.3 million, consisting primarily of a net loss of $16.1 million and a decrease in net operating assets of $2.8 million, offset by non-cash charges of $7.6 million. The decrease in net operating assets was due to a decrease in other liabilities related to the payment of litigation settlement expense, assigned interest to PDL, partially offset by fluctuations in inventories, accounts receivable, prepaid expenses and accounts payable, due to timing of payments. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and an increased reserve for excess and obsolete inventories.

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

Net Cash Used in Investing Activities

Net cash used in investing activities in the six months ended June 30, 2018 was $0.1 million consisting of purchases of property and equipment.

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2018 of $16.2 million primarily relates to proceeds from issuances of convertible preferred stock and common stock.

Net cash provided by financing activities in the six months ended June 30, 2017 of $0.2 million primarily relates to proceeds from issuances of common stock.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements and we currently do not use any structured finance, special purpose entities, or variable interest entities.

Contractual Obligations

There have been no other material changes to our contractual obligations from those described in our Annual Report on Form 10-K, as filed with the SEC on March 30, 2018.

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.

Table of Contents

Credit Risk

As of June 30, 2018 and December 31, 2017, 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 relates to revenues from the sale and rental of our Lumivascular platform products to hospitals and medical centers in the United States. None of our customers represented more than 10% of our accounts receivable as of June 30, 2018 and December 31, 2017.

Foreign Currency Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2018. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2018, 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 2018 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

Between May 22, 2017 and May 25, 2017, three class actions were filed in the Superior Court of the State of California, County of San Mateo (State Court), against us and certain of our officers and directors. The underwriters of our IPO in January 2015 are also named as defendants. The actions were captioned Grotewiel v. Avinger, Inc., et al., No. 17-CIV-02240, Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284, and Olberding v. Avinger, Inc., et al., No. 17-CIV-02307. These lawsuits allege that the registration statement for our IPO made false and misleading statements and omissions in violation of the Securities Act of 1933. Plaintiffs seek to represent a class of purchasers of our common stock in and/or traceable to our IPO. Plaintiffs seek, among other things, unspecified compensatory damages, interest, costs, recission, and attorneys fees. On June 12, 2017, defendants removed these actions to the United States District Court for the Northern District of California (Federal Court).

Table of Contents

On June 22, 2017, and June 23, 2017, plaintiffs Olberding and Gonzalez moved to remand their cases to the State Court. Defendants opposed these motions. On July 21, 2017, the Federal Court granted the motions to remand the Olberding and Gonzalez actions to the State Court. On August 9, 2017, the State Court consolidated the Olberding and Gonzalez actions under the caption Gonzalez v. Avinger, Inc., et al., No. 17-CIV-02284 (State Action). On September 22, 2017, an amended complaint was filed in the State Action. On October 31, 2017, the parties in the State Action stipulated to a stay of proceedings until judgment is entered in the federal Grotewiel action (Federal Action). On June 20, 2018, the State Court dismissed the State Action pursuant to the proposed settlement described below.

On October 11, 2017, the Federal Court appointed a lead plaintiff and approved the selection of a lead counsel in the Federal Action. In order to allow the parties to pursue mandatory alternative dispute resolution, the parties have stipulated and the Federal Court ordered that defendants motion to dismiss the Federal Action will be due on January 17, 2018, with a hearing set for May 1, 2018. On November 21, 2017, an amended complaint was filed in the Federal Action. Defendants filed a motion to dismiss that complaint on January 26, 2018. On March 19, 2018, plaintiff in the Federal Action filed a further amended complaint, on behalf of a class of purchasers of our common stock in and/or traceable to our IPO, as well as purchasers of our common stock during the period January 30, 2015, to April 10, 2017.

The Company and its directors believe that the foregoing lawsuits were entirely without merit however, in the interest of avoiding the cost and disruption of continuing to defend against these lawsuits, the Company entered into a settlement of the securities class actions pending against the Company and several of its officers and directors. The settlement is for a total of $5 million and, if approved by the court, will result in a full release of claims against all defendants. The settlement is subject to final approval by the court. A court hearing regarding the final settlement approval is set for October 23, 2018. The Company s total contribution to the settlement fund is $1.76 million. The Company paid this amount in March 2018.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. *We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, 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. If any of the risks actually occur, our business, financial condition, results of operations, cash flows and prospects could be materially and adversely affected. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes. Please also see Cautionary Notes Regarding Forward-Looking Statements.*

Risks Related to Our Business

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

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

- our ability to obtain and maintain FDA clearance and approval from foreign regulatory authorities for our products, and the timing of such clearances and approvals, particularly with respect to current and future generations of Pantheris;

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

- the availability of reimbursement for our Lumivascular platform products;

- our ability to attract new customers and increase the amount of business we generate from existing customers;

- results of our clinical trials;

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

Table of Contents

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

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

- general economic, political, industry and market conditions, including economic and political uncertainty caused by the recent U.S. presidential election;

- the regulatory environment;

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

- the cost and potential outcomes of existing and future litigation;

- our ability to obtain additional financing; and

- advances and trends in new technologies and industry standards.

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

We have incurred significant losses in each period since our inception in 2007. We incurred net losses of $16.1 million for the six months ended June 30, 2018, $48.7 million in 2017, $56.1 million in 2016 and $47.3 million in 2015. As of June 30, 2018, we had an accumulated deficit of approximately $317.4 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 losses to continue for the foreseeable future as we continue to make significant future expenditures to develop and expand our business. In addition, as a public company, we will continue to incur significant legal, accounting and other expenses. Accordingly, we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

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

We believe that the net proceeds from the recently completed offerings of our Series B preferred stock and common stock, together with our cash and cash equivalents at June 30, 2018 and expected revenues from operations, will be sufficient to satisfy our capital requirements and fund our operations for at least the next five months. Even though we sold $18.0 million in Series B preferred stock and warrants in our February 2018 offering, and $3.5 million of common stock and warrants in our July 2018 offering, we will need to raise additional funds through future equity or debt financings within the next five months to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. We can provide no assurance that we will be successful in raising funds pursuant to additional equity or debt financings or that such funds will be raised at prices that do not create substantial dilution for our existing stockholders. Given the recent decline in our stock price, any financing that we undertake in the next five months could cause substantial dilution to our existing stockholders.

To date, we have financed our operations primarily through sales of our products and net proceeds from the issuance of our preferred stock and debt financings, our at-the-market program, our initial public offering, or IPO, and our follow-on public offerings. The warrants issued pursuant to the Series B Purchase Agreement entered into in connection with the Series B preferred stock follow-on in February 2018 (the Series B Offering) prohibit us from entering into certain transactions involving the issuance of securities for a price determined by reference to the trading price of our common stock or otherwise subject to modification following the date of issuance, in each case for a period of three years from the closing date of the Series B Offering (and excluding purchases pursuant to the Series B Purchase Agreement, which may be made on the 120 day anniversary of the closing date of the offering). This prohibition may be waived by holders of two-thirds of the outstanding Series 1 and Series 2 warrants at any time. We do not know when or if our operations will generate sufficient cash to fund our ongoing operations. We cannot be certain that additional capital will be available as needed on acceptable terms, or at all. In the future, we may require additional capital in order to (i) continue to conduct research and development activities, (ii) conduct post-market clinical studies, as well as clinical trials to obtain regulatory clearances and approvals necessary to commercialize our Lumivascular platform products, (iii) expand our sales and marketing infrastructure and (iv) acquire complementary businesses technologies or products; or (v) respond to business opportunities,

Table of Contents

challenges, a decline in sales, increased regulatory obligations or unforeseen circumstances. Our future capital requirements will depend on many factors, including:

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

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

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

- the costs and timing of developing variations of our Lumivascular platform products, especially Pantheris and, if necessary, obtaining FDA clearance of such variations;

- the extent to which our Lumivascular platform is adopted by hospitals for use by interventional cardiologists, vascular surgeons and interventional radiologists in the treatment of PAD;

- the number and types of future products we develop and commercialize;

- the costs of defending ourselves against existing and future litigation;

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

- the extent and scope of our general and administrative expenses.

We may raise additional funds in equity or debt financings or enter into credit facilities in order to access funds for our capital needs. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and

pursue business opportunities. In addition, due to our current level of debt, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. If we raise additional funds through further issuances of equity or convertible debt securities, and/or if we convert all or a portion of our existing debt to equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products, and significantly scale back our operations, or we may become insolvent. If this were to occur, our ability to continue to grow and support our business and to respond to business challenges could be significantly limited.

We have a significant amount of debt, which may adversely affect our ability to operate our business and our financial position and our ability to secure additional financing in the future.

As of June 30, 2018, we had $7.8 million in principal and interest outstanding under a Term Loan Agreement, or the Loan Agreement, with CRG Partners III L.P. and certain of its affiliated funds (collectively CRG). This amount reflects the completion of the Series B Offering and CRG s conversion of $38 million in outstanding principal and interest into Series A preferred stock (the CRG Conversion). Our significant amount of debt may:

- make it more difficult for us to satisfy our obligations with respect to the Loan Agreement;

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

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

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

- restrict us from exploiting business opportunities;

Table of Contents

- make it more difficult to satisfy our financial obligations, including payments on the Loan Agreement

- place us at a competitive disadvantage compared to our competitors that have less debt obligations; and

- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes on satisfactory terms or at all.

The existence of a substantial amount of debt may make it difficult for us to run our business effectively or raise the capital we need to continue our operations.

Covenants under the Loan Agreement will restrict our business in many ways.

The Loan Agreement contains various covenants that limit, subject to certain exceptions, our ability to, among other things:

- incur or assume liens;

- incur additional debt or provide guarantees in respect of obligations of other persons;

- issue redeemable stock and preferred stock;

- pay dividends or make distributions on capital stock, repurchase, redeem or make payments on capital stock or repay, repurchase, redeem, retire, defease, acquire or cancel debt prior to the stated maturity thereof;

- make loans, investments or acquisitions;

- create or permit restrictions on the ability of our subsidiaries to pay dividends or make other distributions to us or to guarantee our debt, limit our or any of our subsidiaries ability to create liens, or make or pay intercompany loans or advances;

- enter into certain transactions with affiliates;

- sell, transfer, license, lease or dispose of our or our subsidiaries assets, including the capital stock of our subsidiaries; and

- dissolve, liquidate, consolidate or merge with or into, or sell substantially all the assets of us and our subsidiaries, taken as a whole, to, another person.

In particular, the Loan Agreement, as amended, includes a covenant that we maintain a minimum of $3.5 million of cash and certain cash equivalents, and we will have to achieve minimum revenue of $15.0 million in 2020, $20.0 million in 2021 and $25.0 million in 2022. 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. There can be no assurance as to our future compliance with the covenants under the Loan Agreement, as amended.

The covenants contained in the Loan Agreement could adversely affect our ability to:

- finance our operations;

- make needed capital expenditures;

- make strategic acquisitions or investments or enter into alliances;

- withstand a future downturn in our business or the economy in general;

- refinance our outstanding indebtedness prior to maturity;

- engage in business activities, including future opportunities, that may be in our interest; and

- plan for or react to market conditions or otherwise execute our business strategies.

Table of Contents

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. The existing collateral pledged under the Loan Agreement 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. If we default under any of these debt covenants and are unable to cure the default within the relevant cure period, we would need relief from default or else our creditors could exercise their remedies. There can be no assurance that our debtholders would accord any relief from default. In addition, potential sources of equity financing may decline to invest in our company given the amount of debt and the rights that debt holders have to get paid before equity holders. In order to facilitate equity investments, future equity investors may require that we convert all or a portion of our debt to equity, and our debtholders may not agree to such terms. The amount of debt could therefore affect our ability to finance our company and prevent us from obtaining necessary operating capital as a result.

We may not be able to generate sufficient cash to service our credit facility with CRG. If we fail to comply with the obligations under our credit facility, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.

Borrowings under our credit facility are secured by substantially all of our personal property, including our intellectual property. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to numerous risks, including the risks in this section, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated. If we fail to comply with our obligations under the Loan Agreement, the lender would be able to accelerate the required repayment of amounts due and, if they are not repaid, could foreclose upon our assets securing our obligations under the Loan Agreement.

CRG has the right to acquire a significant percentage of our stock upon conversion of its Series A preferred stock and has the ability to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement.

Even though Series A preferred stock is non-voting stock, and has beneficial ownership restrictions, the Series A Certificate of Designations has protective provisions that will require CRG to consent to certain significant Company events. For example, CRG s consent would be necessary to create additional shares of Series A preferred stock, amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire, and may adversely affect the market price of our common stock.

The Series A preferred stock has a liquidation preference senior to our common stock and the Series B preferred stock.

Series A preferred stock has a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of the Series 1 or Series 2 warrants) and Series B preferred stock. As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series A preferred stock would have the right to receive up to approximately $41,800,000 from any such transaction before any amount is paid to the holders of our Series B preferred stock or common stock or pursuant to the redemption rights in the warrants for fundamental transactions. The payment of the liquidation preferences could result in common stockholders, Series B preferred stockholders and warrantholders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. Furthermore, any conversion of Series A preferred stock into common stock will cause substantial dilution to our common stock holders.

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

We were incorporated in 2007, began commercializing our initial non-Lumivascular platform products in 2009 and introduced our first Lumivascular platform products in the United States in late 2012. We received 510(k) clearance from the FDA, for

Table of Contents

commercialization of Pantheris in October 2015, an additional 510(k) clearance for an enhanced version of Pantheris in March 2016 and commenced sales of Pantheris in the United States and select international markets promptly thereafter. Our current version of Pantheris, Pantheris 3.0, received FDA clearance in May 2018. Our limited commercialization experience and number of approved products make it difficult to evaluate our current business and predict our future prospects. We have encountered and will continue to encounter risks and difficulties frequently experienced by companies in rapidly-changing industries. These risks and uncertainties include the risks inherent in clinical trials, market acceptance of our products, and increasing and unforeseen expenses as we continue to attempt to grow our business.

In addition, we have in the past, and may in the future, become aware of performance issues with our products. For example, prior to becoming commercially available on March 1, 2016, Pantheris had been used in clinical trials mainly in controlled situations. Since its commercialization and as more physicians have used Pantheris, we have received additional feedback on its performance, both positive and negative. We have attempted to address certain of these concerns with Pantheris 3.0. However, there can be no assurance that the changes and improvements will fully address the performance issues that have been raised by earlier versions of Pantheris. 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. Our revenue has been and continues to be adversely impacted by these product performance issues. We also had to incur additional expenses to make 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. If we are unable to improve the performance of our products to meet the concerns of physicians our revenue may decline further or fail to increase.

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

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

Ocelot, Ocelot PIXL, Ocelot MVRX, Lightbox, Wildcat, Kittycat 2 and Pantheris are our only products currently cleared for sale, and our current revenues are wholly dependent on them. Sales of Wildcat and Kittycat 2 have declined and are continuing to decline as we focus on the promotion of our Lumivascular platform products. In addition, the long-term viability of our company is largely dependent on the successful commercialization and continued development of Pantheris and we expect that sales of Pantheris 3.0 and our other current and future Lumivascular platform products in the United States will account for substantially all of our revenues for the foreseeable future. Accordingly, our success depends on the continued and growing acceptance and use of Pantheris and our other Lumivascular platform products by the medical community. All of our products have a limited commercial history. For example, we received 510(k) clearance from the FDA to commercialize Pantheris in October 2015 as well as a separate FDA clearance to market enhanced versions of Pantheris in March 2016 and May 2018, and those versions of Pantheris became commercially available in the United States and select international markets promptly thereafter. As such acceptance among physicians of these products may not increase or may decline.

Our ability to successfully market Pantheris will also be limited due to a number of factors including regulatory restrictions in our labeling. We cannot assure you that demand for Pantheris and our other Lumivascular platform products will continue to grow and our products may not significantly penetrate current or new markets. Market demand for Pantheris and physician adoption of this product also may be negatively impacted by product performance issues that we have experienced and the need to replace certain products in accordance with our warranty policy. Utilization of our products has been less than we anticipated historically. If demand for Pantheris and our other Lumivascular platform products does not increase and we cannot sell our products as planned, our financial results will be harmed. In addition, market acceptance may be hindered if physicians are not presented with compelling data from long-term studies of the safety and efficacy of our Lumivascular platform products compared to alternative procedures, such as angioplasty, stenting, bypass surgery or other atherectomy procedures. For example, if patients undergoing treatment with our Lumivascular platform products have retreatment rates higher than or comparable with the retreatment rates of alternative procedures, it will be difficult to demonstrate the value of our Lumivascular platform products. Any studies we may conduct comparing our Lumivascular platform with alternative procedures will be expensive, time consuming and may not yield positive results. Physicians will also need to appreciate the value of real-time imaging in improving patient outcomes in order to change current methods for treating PAD patients. In addition, demand for our Lumivascular platform products may decline or may not increase as quickly as we expect. Failure of our Lumivascular platform products to significantly penetrate current or new markets, or our failure to successfully commercialize Pantheris, would harm our business, financial condition and results of operations.

Table of Contents

We are also aware of certain characteristics and features of our Lumivascular platform that may prevent widespread market adoption. For example, in procedures using the current model of Pantheris, some physicians may prefer to have a technician or second physician assisting with the operation of the catheter as well as a separate technician to operate the Lightbox, potentially making it less financially attractive for physicians and their hospitals and medical facilities. It may take significant time and expense to modify our products to allow a single physician to operate the entire system and we can provide no guarantee that we will be able to make such modifications, or obtain any additional and necessary regulatory clearances for such modifications. 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. As a result, risks of complications from radiation and contrast dye are still present and may limit the commercial success of our products. Finally, it will require training for technicians and physicians to effectively operate our Lumivascular platform products, including interpreting the OCT images created by our Lightbox, which may affect adoption of our products by physicians. These or other characteristics and features of our Lumivascular platform may cause our products not to be widely adopted and harm our business, financial condition and results of operation.

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

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

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

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

Our gross margin was (5%) for the three months ended June 30, 2018 compared to (59%) for the three months ended June 30, 2017. Our gross margin was 7% for the six months ended June 30, 2018 compared to (34%) for the six months ended June 30, 2017. Gross margin for the three and six month periods ended June 30, 2017 was negatively impacted by increases in charges related to excess and obsolete Lightbox and Pantheris inventories.

Our gross margin is impacted by the revenue that we generate and the costs incurred to generate the revenue. To the extent that our revenue does not grow or declines, it is difficult to improve our gross margins as our fixed costs must be spread over a lower revenue base. Our future revenue

may be adversely affected by a number of factors including the competitive market environment in which we operate, which may result in a decrease in the number of products sold or a decrease in the average selling prices achieved for our product sales. If our revenue does not improve, or if our cost of revenue increases by a greater percentage than our revenue, or if we are not able to reduce expenses in the event of a decline in revenue, we may continue to generate losses from operations and use cash, which could reduce our cash faster than budgeted, cause us to need to obtain additional financing and have a material adverse effect on our operations and stock price.

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

In order to generate sales, we must be able to clearly demonstrate that our Lumivascular platform is both a more effective treatment system and more cost-effective than the alternatives offered by our competitors. If we are unable to convince physicians that our Lumivascular platform leads to significantly lower rates of restenosis, or narrowing of the artery, and leads to fewer adverse

Table of Contents

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

Our products compete with a variety of products and devices for the treatment of PAD, including other CTO crossing devices, stents, balloons and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the CTO crossing, stent and balloon markets include Abbott Laboratories, Boston Scientific, Cardinal Health, Cook Medical, CR Bard and Medtronic. Competitors in the atherectomy market include Boston Scientific, Cardiovascular Systems, Medtronic and Philips. 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

Table of Contents

well-established reputations, as well as broader product offerings and worldwide distribution channels that are significantly larger and more effective than ours. Competition with these companies could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

- trouble in managing multiple clinical sites;

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

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

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

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

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

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

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

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

Table of Contents

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 warnings or enforcement action by the FDA and other government agencies. In the future, if we want to market a variation of Ocelot or Pantheris in the United States for use in other applications for which we do not currently have clearance, such as the coronary arteries, we will need to make modifications to these products, conduct further clinical trials and obtain new clearances or approvals from the FDA. There can be no assurance that we will successfully develop these modifications, that future clinical studies will be successful or that the expense of these activities will be offset by additional revenues.

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

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

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

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

- any expansion in our manufacturing capacity, could require changes to our production processes;

- key components and sub-assemblies of our Lumivascular platform products are currently provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components and

sub-assemblies; if we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;

- we may experience a delay in completing validation and verification testing for new controlled-environment rooms at our manufacturing facilities; and

- we have limited experience in complying with the FDA s quality system regulation (QSR), also referred to as good manufacturing practices (GMPs), which applies to the manufacture of our Lumivascular platform products.

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

Table of Contents

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

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

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

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

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

- interruption of supply resulting from modifications to, or discontinuation of, a supplier s operations;

- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier s failure to consistently produce quality components;

- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;

- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;

- difficulty identifying and qualifying alternative suppliers for components in a timely manner;

- inability of the manufacturer or supplier to comply with QSR as enforced by the FDA and state regulatory authorities;

- inability to control the quality of products manufactured by third parties;

- production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications; and

- delays in delivery by our suppliers due to changes in demand from us or their other customers.

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

Table of Contents

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

We rely on single and limited source suppliers for several of our components and sub-assemblies. For example, we rely on single vendors for our optical fiber and drive cables that are key components of our catheters, and we rely on single vendors for our laser and data acquisition card that are key components of our Lightbox. These components are critical to our products and there are relatively few alternative sources of supply. We do not carry a significant inventory of these components. Identifying and qualifying additional or replacement suppliers for any of the components or sub-assemblies used in our products could involve significant time and cost. Any supply interruption from our vendors or failure to obtain additional vendors for any of the components or sub-assemblies incorporated into our products would limit our ability to manufacture our products and could therefore harm our business, financial condition and results of operations.

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

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

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

Our success largely depends upon the continued services of our executive management team and key employees and the loss of one or more of our executive officers or key employees could harm us and directly impact our financial results. Our employees may terminate their employment with us at any time. Changes in our executive management team resulting from the hiring or departure of executives could disrupt our business.

We must attract and retain highly qualified personnel. Competition for skilled personnel is intense, especially for engineers with high levels of experience in designing and developing medical devices and for sales professionals. We have, from time to time, experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources

and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. In addition, we invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business would be harmed.